Upgrading NIPERs to meet evolving needs of pharmaceutical business in India & bring NIPERs in top 50 in world ranking

Study conducted by Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India
SEPTEMBER, 2023

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1. INTRODUCTION

1.1. Background

Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers is nodal agency for the scheme “Strengthening of Pharmaceutical Industry (SPI)", with a total financial outlay of Rs.500 Cr for the period from FY 21-22 to FY 25-26. The scheme aims to address the rising demand in terms of support required to existing Pharma clusters and MSMEs across the country to improve their productivity, quality and sustainability.

The objectives of the Scheme “Strengthening of Pharmaceutical Industry (SPI)” are to strengthen the existing infrastructure facilities in order to make India a global leader in the Pharmaceutical Sector. Under the Scheme, there is a provision for the financial assistance to pharma clusters for creation of Common Facilities.

Further, in order to upgrade the production facilities of SMEs and MSMEs so as to meet the national and international regulatory standards (WHO-GMP or Schedule-M), the incentives like interest subvention or capital subsidy on their capital loans is being provided to facilitate the growth in volumes as well as in quality of drugs in India.

The SPI Scheme of Department of Pharmaceutical has broadly 3 components / sub-schemes:

Assistance to Pharmaceutical Industry for Common Facilities (APICF): To strengthen the existing pharmaceutical clusters’ capacity for their sustained growth by creating common facilities. Under the API-CF sub-scheme, support for clusters for creation of common facilities with the focus on R&D Labs, Testing Laboratories, Effluent Treatment Plants, Logistic Centres and Training Centres in this order of priority with an outlay of 178 Cr for the scheme period of five years is proposed.

Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS): To facilitate Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards. Under the PTUAS sub-scheme, support for about SME Industries is proposed, either through up to maximum of 5% per annum (6% in case of units owned and managed by SC/STs) of interest subvention or through Credit linked Capital subsidy of 10%. In both the cases, the loan supported under this is to a limit of 10 Crores and the eligible components of the loan has been listed out in the scheme guidelines. An outlay of 300 Cr has been earmarked for sub scheme for the scheme period of five years.

Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS): To facilitate growth and development of Pharmaceutical and Medical Devices Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry. Under the PMPDS sub-scheme, knowledge and awareness about the Pharmaceutical and MedTech Industry will be promoted. This will be done by undertaking studies, building databases and bringing industry leaders, academia and policy makers together to share their knowledge and experience for overall development of the Pharma and Medical Devices sector. An outlay of 21.5 Cr has been earmarked for the sub scheme for the scheme period of five years. It is expected that the units supported under this scheme will act as Demonstration

Firms for the pharma clusters and MSE Pharma Industries, to develop on quality and technology upgradation fronts.

Under the same PMPDS Scheme, the department took an initiative to conduct a challenging and interesting landscaping and market intelligence study on upgrading the NIPERS to meet evolving needs of Pharmaceutical Business and ensure positions for all NIPERs in top 50 institutes in world ranking.

1.2. Overview of NIPERs

National Institute of Pharmaceutical Education and Research (NIPERs) are a group of seven national level institutes of pharmaceutical sciences in India. NIPERs have been established by Government of India under the NIPER Parliament Act 1998 and subsequent NIPER Amendment bill 2021 to promote pharmaceutical research and bring it to small Indian pharmaceutical companies and have been declared as Institutes of National Importance. NIPERs operate as autonomous bodies under the aegis of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India.

SI No	Location	Name of institutions incorporated under this Act institute and the State	Date of establishment of Institution
1	Mohali, Punjab	The National Institute of Pharmaceutical Education and Research Society, Mohali	8th July, 1998
2	Ahmedabad, Gujarat	The National Institute of Pharmaceutical Education and Research, Ahmedabad	6th September, 2007
3	Hajipur, Bihar	The National Institute of Pharmaceutical Education and Research, Hajipur	6th September, 2007
4	Hyderabad, Telangana	The National Institute of Pharmaceutical Education and Research, Telangana	6th September, 2007
5	Kolkata, West Bengal	The National Institute of Pharmaceutical Education and Research, Kolkata	6th September, 2007
6	Guwahati, Assam	The National Institute of Pharmaceutical Education and Research, Guwahati	5th August, 2008
7	Raebareli, Uttar Pradesh	The National Institute of Pharmaceutical Education and Research, Raebareli	26th September, 2008

The main objectives of establishing the NIPERs are as under: -

- Nurture and promote quality and excellence in pharmaceutical education and research.
- Run Master's, Doctoral and post-Doctoral courses and research in pharmaceutical education.
- Develop a multi-disciplinary approach for research and training of pharmaceutical manpower.
- Act as a nucleus for academia-industry interaction by undertaking sponsored research.

Currently, the NIPERs offer only Post-graduate and PhD degrees in pharmaceutical research and management related fields. NIPERs carry out a lot of interdisciplinary research and therefore has candidates with backgrounds and qualifications not only from Pharmaceuticals but also in the filed like Chemistry, Life Sciences, Biotechnology, Genetics and Biochemistry who compete at a national level entrance test to qualify for the admissions to respective postgraduate courses. Few NIPERS also offers M. Tech and MBA degrees in pharmaceutical management to cater to the technical and management requirements of pharmaceutical companies.

The NIPERs are governed by the respective Institute's Board of Governors of which consist of the following persons, namely:

(a) A chairperson (an eminent academician or scientist or technologist or professional nominated by the Visitor.

(b) the Director of the institute, ex officio.

(c) the Joint Secretary to the Government of India in Department of Pharmaceuticals dealing with the national institutes of pharmaceutical education and research, ex officio.

(d) the Secretary, dealing with medical or technical education in the State Government concerned, ex officio.

(e) the representative of Drug Controller General of India, Ministry of Health and Family Welfare of the Government of India, ex officio.

(f) three eminent pharmaceutical experts, at least one of whom is a woman, having special knowledge or practical experience in education, research and biotechnology, to be nominated by the Council.

(g) two pharmaceutical industrialists to be nominated by the Council.

(h) two professors at the institute, to be nominated by the Senate.

Further a provision has been made to create an Apex Council of NIPERs to deal with the policy and coordination issues of NIPERs. This council consists of a chairperson (the Secretary of Department of Pharmaceuticals), the chairpersons of all of Board of Governors of NIPERs, the directors of all NIPERs, AS & FA Department of Pharmaceuticals and Joint secretary – NIPERs, Department of Pharmaceuticals.

1.3 Study Assumptions and Study Definition

Study Assumptions:

- The study assumed that the information available on various secondary data sources like different Ranking Systems and NIPERs like their respective annual reports, their websites and Department of Pharmaceutical's reports is accurate and reliable.
- The study assumed that inspite of having a strong foundation in pharmaceutical education and research, the current ranking of most of NIPERs are outside the top 50 pharmaceutical institutes as per the QS World Ranking system. Further, there is a willingness among Department of Pharmaceutical (DoP) Government of India, NIPERs' management, faculty, students, and stakeholders to work towards upgrading the institutes to meet emerging industry needs and achieve a top 50 global ranking in QS world ranking.
- The study assumed that access to sufficient and relevant data related to NIPERs' current state, industry demands, and global rankings was available for analysis and the recommendations made on the basis of analysis of the data will be realistic, feasible, and aligned with the capabilities and resources of NIPERs. Further the effective implementation of the proposed upgrades and initiatives will happen over the time, will be sustainable in long term and will depend on support from relevant authorities, including funding agencies, pharmaceutical industry and the Government of India
- The study assumed that the pharmaceutical industry in India has an intent for collaboration with NIPERs and is willing to engage in joint research and partnerships with NIPERs in

interdisciplinary areas of pharmaceutical research. It is also assumed that the NIPERs will actively involve industry experts, alumni, and other stakeholders in the upgrading process to gain valuable insights and support from the mentioned stakeholders.

Study Definition: The assessment study entitled **" Upgrading NIPERs to meet evolving needs of pharmaceutical business in India & bring NIPERs in top 50 in world ranking** " encompassed the following key components:

- Assessment of current research and development trends in pharmaceutical industry with disease/ area and forecast for 2030.
- Assessment of strategies, infrastructure (accreditation labs, etc.), manpower and logistics framework in pharmaceutical companies and pharma research institutes for executing research and development.
- Evaluation of global best practices should cover at least top pharmaceutical companies pharmaceutical research institutes.
- Evaluation of major ranking parameters of at least 3 top globally recognized agencies such as QS, Times Higher Education World University Rankings etc.
- Gap analysis for NIPERs
- Recommendations for upgrading NIPERs to meet the evolving needs of pharmaceutical business and for achieving top 20-50 rank in world rankings.

1.4. Base Estimates and Working Approach

Base Estimate:

- **Duration:** The study was estimated to be conducted over a period of 6 months.
- **Resources:** The study required a team of researchers, analysts, and subject matter experts with expertise in the pharmaceutical industry, Biomedical research, pharmaceutical education, market research and analysis. The team allocated by BHPL included experienced individuals in the above-mentioned areas along with skills in data analysis, research methodology, and report writing in Pharmaceutical Sector. In addition, BHPL already had experience of working with NIPERs in recent past on a study entitled “Assessment of Skill Requirements of Indian Pharmaceutical Industry”.
- **Data Sources:** The study primarily relied on publicly available data sources such as websites of NIPERs, various Ranking organisations, top pharmaceutical institutes, pharmaceutical companies, industry reports, and scholarly articles. Additionally, the primary data was collected using the questionnaires and semi structured interviews with industry experts and above-mentioned key stakeholders to gather insights and opinions.

- **Target Respondents** and **Sample Size:** Purposive sampling was employed to ensure representation of key stakeholders during the primary data collection. The primary data of more than 50 faculty and scientific staff members of NIPERs, 50 students perusing Masters and PhD programs and 4 Directors of NIPERs and 25 pharmaceutical, biotech and CRO companies was collected using the questionnaires, face to face interviews and focussed group discussions using ICTs. In addition, the secondary data of 7 NIPERS, 50 top pharmaceutical institutes as per QS ranking system was collected and analysed. No financial incentives were provided to the respondents during the study.

Working Approach: The study employed a combination of quantitative and qualitative research methods, including, literature review, online questionnaires, stakeholder's interviews and expert opinions. Before distributing the online questionaries to the target respondents, a pilot test was conducted within the BHPL team and a small group of respondents to identify the potential issues with the survey design, question clarity and other technical problems. After the data collection was completed, the data was cleaned and analysed to summarize the responses and examine key patterns and trends. Further the survey findings were interpreted in the context of the given research objectives and existing literature and industry reports to provide a comprehensive understanding of the project.

2. RESEARCH FRAMEWORK

2.1. Primary Research

Robust and comprehensive questionnaires were used for the primary data collection of pharmaceutical and research & development companies during the study. The Semi-Structured and In-Depth Interviews with Pharmaceutical & CRO industry experts, education experts, policymakers, and key stakeholders like students, faculty, scientists were conducted to gather qualitative insights and opinions during the onsite visits of institutions.

2.2. Secondary Research

Reputable and reliable sources of information relevant to the research objectives were identified and utilized in secondary data collection. Systematic literature review was conducted to gather relevant academic articles, research studies, case studies related to the education policies, industry trends and ranking parameters. These sources included were not limited to:

- **Academic databases:** Databases like PubMed, Scopus, or Google Scholar to access scholarly articles and research studies related to the pharmaceutical education and industry dynamics.

- **Industry reports:** Reports published by market research firms, industry associations, or consulting agencies that provide insights on the pharmaceutical industry, latest market trends, education policy, research and development funding etc.
- **Government publications:** Reports and publications from governmental bodies such as Department of Pharmaceutical, Government of India, NIPERs, Pharmacy council of India to provide insights into pharmacy education policy interventions and their implications.

2.3. Data Triangulation

The data was validated by cross-referencing the information obtained from different sources. The quantitative and qualitative data gathered from various sources, including primary and secondary sources was combined to enhance the robustness of the analysis. Data was checked for consistency and coherence in the findings across the sources and converging evidence for consistent overarching trends, themes and patterns in the data. As a result of this holistic understanding of the data, the key insights were derived from the triangulation process.

2.4. Insight Generation

The key findings were interpreted within the broader context of the pharmaceutical industry, market dynamics, pharmaceutical education streams, strengths and weaknesses of NIPERs, regulatory environment, and relevant socio-economic factors to synthesize insights. The generated insights were validated by checking their alignment with the data, analysis, and research objectives. It was ensured that the generated insights were logical, supported by evidence, and consistent across different sources and methods used in the study.

3. EXECUTIVE SUMMARY

3.1. Current Landscape of Pharmaceutical Education in India

The pharmaceutical education sector is one of the most important sectors in India which offers various levels of professional courses based on the skill sets required in the industry and market. These courses are as following:

- Diploma in pharmacy
- Bachelor in Pharmacy
- Master in Pharmacy (with various technical and management specializations)
- PhD in Pharmacy / Pharm D (with various specializations)

The colleges and institutes affiliated to and approved by Pharmacy Council of India (PCI) can offer the diploma, undergraduate, post-graduate and PhD degrees depending upon their approval status for particular course/s with PCI. As per the annual report of PCI for the year 2020-2021, there were 3150 institutes with annual intake capacity of 1,90,000 approved by them in India for offering the Diploma in Pharmacy course. During the same period, for offering the undergraduate and post graduate degrees, there were 2243 institutes approved by PCI with annual intake capacity of 166841.

The pharmacy diplomas ad degrees are tailored to meet various skill set requirements of the pharmaceutical sector at various levels and across core and allied pharmaceutical industries. Irrespective of the criterion of diploma or degree, every pharmacy student who passes any of the pharmacy courses mentioned above is a registered pharmacist and has the option of working at or running a pharmacy retail store. Various kinds of skill set levels (in ascending complexity order) and the corresponding courses required for the pharmaceutical industry can be listed as following:

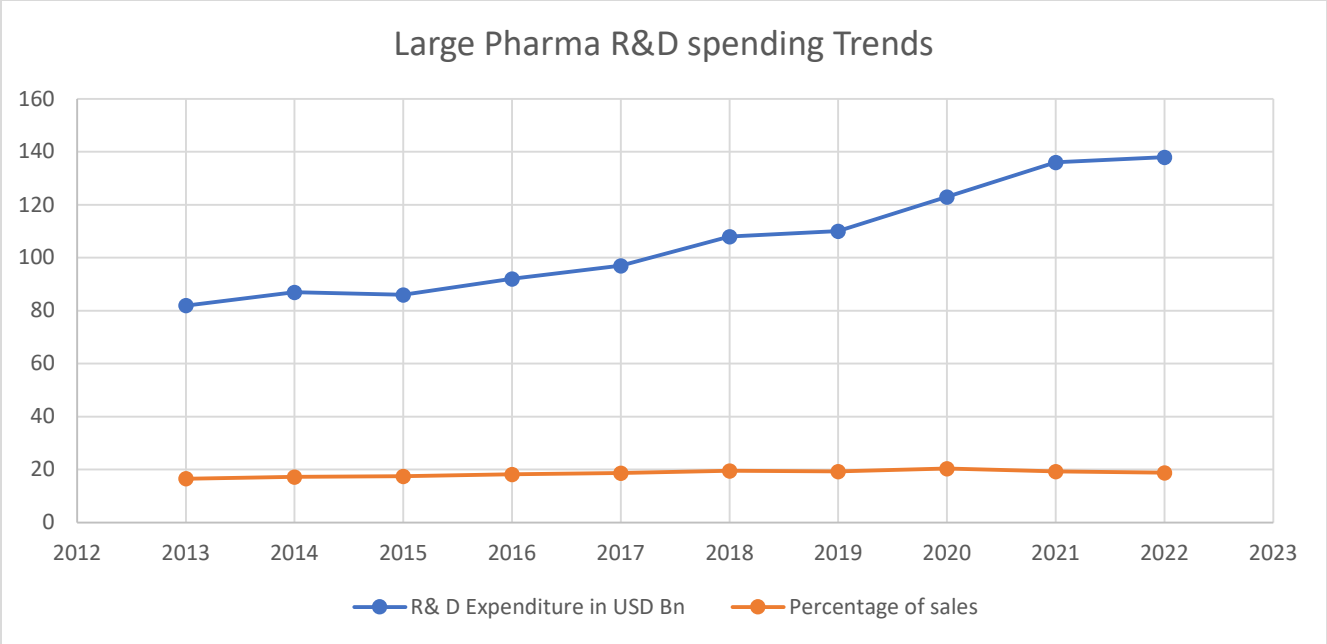
Skill Set Level	Course	Potential Career Opportunities
Level-1	Diploma in Pharmacy	Hospital Pharmacist Retail Store Pharmacist Retail Store Owner
Level-2	Bachelor in Pharmacy	Hospital Pharmacist Retail Store Pharmacist Retail Store Owner API Manufacturing- Executive Formulation Manufacturing-Executive Regulatory Affairs Executive Pharma Sales Representative
Level-3	Masters in Pharmacy/ M.S in Pharmacy/ M. Tech	Hospital Pharmacist Retail Store Pharmacist Pharmacy Retail Store Owner API Manufacturing- Supervisor Formulation Manufacturing- Supervisor Formulation and Development Scientist Regulatory & Scientific Affairs – Executive/Manager Research and Development Associate/Scientist Pharmacovigilance Associate /Manager Pharma Sales Management- Supervisory Role
Level-4	PhD in Pharmacy/ D. Pharm	Clinical Pharmacist Pharmacy Retail Store Owner API Manufacturing- Supervisory Role Formulation Manufacturing- Supervisor Role Formulation and Development Scientist Regulatory & Scientific Affairs – Executive/Manager Research and Development Associate/Scientist Pharmacovigilance Associate /Manager

3.2. Current R&D trends in Pharmaceutical Industry

3.2.1 Increasing R&D expenditure worldwide

The worldwide increase in research and development (R&D) expenditure is a significant market driver for the pharmaceutical industry. The largest pharmaceutical companies together spent more than USD 138 Billion on research and development in 2022, up 1.7% from 2021. Since 2017, R&D spending for large companies has increased by 43% with a five-year CAGR of 7.4%. (Refer to Exhibit 2)

Exhibit 1: Large pharma R&D spending and spending as a percentage of sales 2013–2022*, USD Billion



Source: Financial statements of companies; IQVIA Institute, Jan 2023.

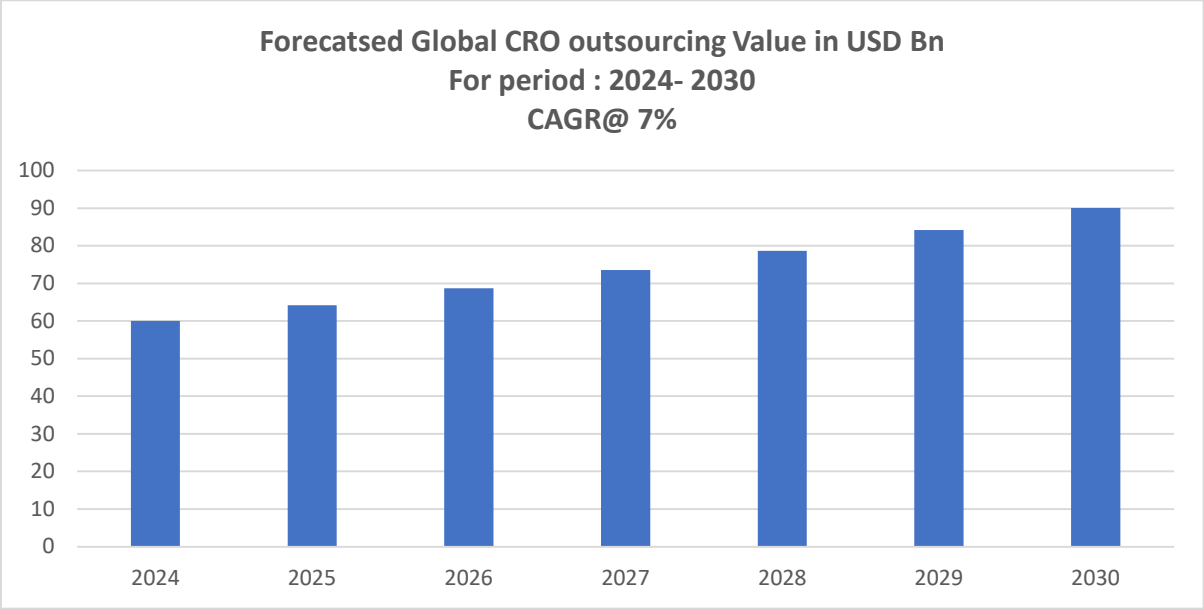
The increase in R&D expenditure by pharmaceutical companies globally signifies a higher investment in the development of new drugs, therapies, and healthcare solutions. As pharmaceutical companies allocate more resources to R&D, there is a greater need for specialized support and expertise in various stages of the drug development process.

3.2.2. Growing outsourcing of R&D activities.

Outsourcing has become an integral part of how research and early development (R&D) is executed in biotech companies and large pharmaceutical organizations. During the years between 2022-30, the global contract research outsourcing market is expected to grow @ CAGR of 7 % and reach USD 90.4 Billion by 2030 (Exhibit 2).CROs offer specialized expertise across various stages of the drug development process, including preclinical research, clinical trials, data management, regulatory support, and post-marketing surveillance. Pharmaceutical companies can leverage the knowledge and experience of CROs to enhance their research capabilities and overcome challenges in specific therapeutic areas or research domains. The availability of specialized expertise, accelerated timelines and cost efficiencies are the compelling reason for global pharmaceutical companies to outsource their R&D activities to CROs, driving the overall demand for CRO services. The Pharmaceutical companies can choose from several operational models when partnering with a contract research service provider, ranging from short-term, fee-for-service (FFS)-based arrangements to more strategic

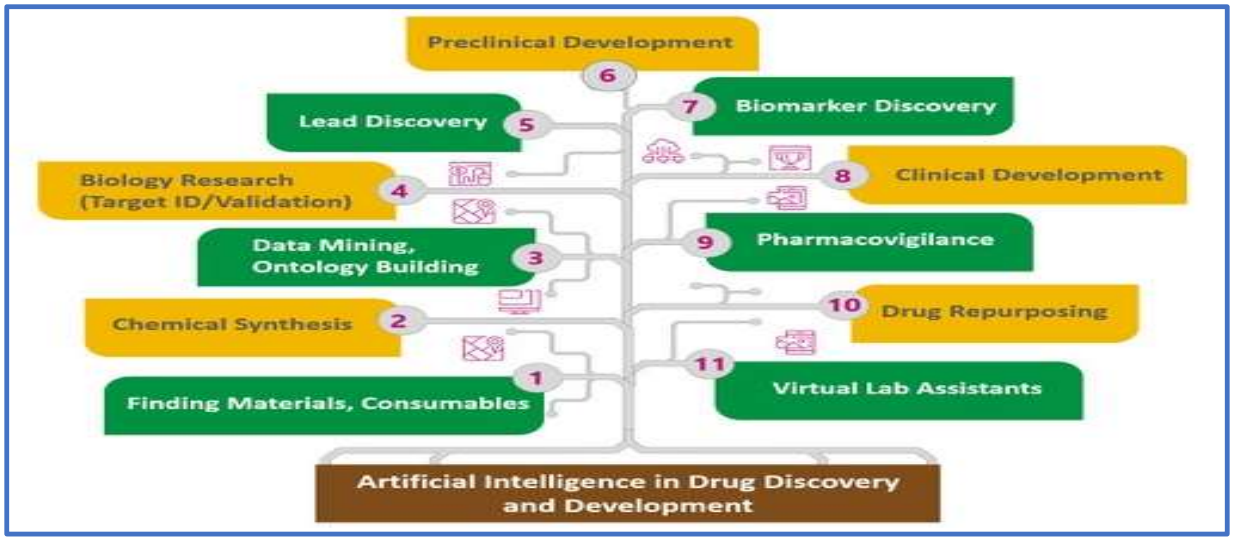
full-time-equivalent (FTE)-based collaborations and even risk-sharing relationships thereby making outsourcing a value-based proposition.

Exhibit 2: Forecasted Global Contract research outsourcing Market for the period 2022-2030



3.2.3. Rising technological advancements. Pharmaceutical companies are going to invest heavily on advanced research tools like high-throughput screening, molecular profiling, next-generation sequencing, bioinformatics analysis, and advanced imaging technologies. Advances in genomics, proteomics, and other molecular profiling techniques have paved the way for personalized medicine approaches in drug development. Pharmaceutical and Biopharmaceutical companies will focus on harnessing the futuristic Artificial Intelligence (AI) along with supercomputing to improve understanding of more efficient and effective drug development processes. The 2022 thematic research report titled 'Artificial Intelligence (AI) in Drug Discovery' from GlobalData predicts that the total expenditure on AI by the pharmaceutical sector is projected to escalate to more than $3 billion by the year 2025. Some of the applications of Artificial Intelligence on overall pharmaceutical sector are mentioned in Exhibit 3

Exhibit 3: Artificial Intelligence in Drug Discovery and Development



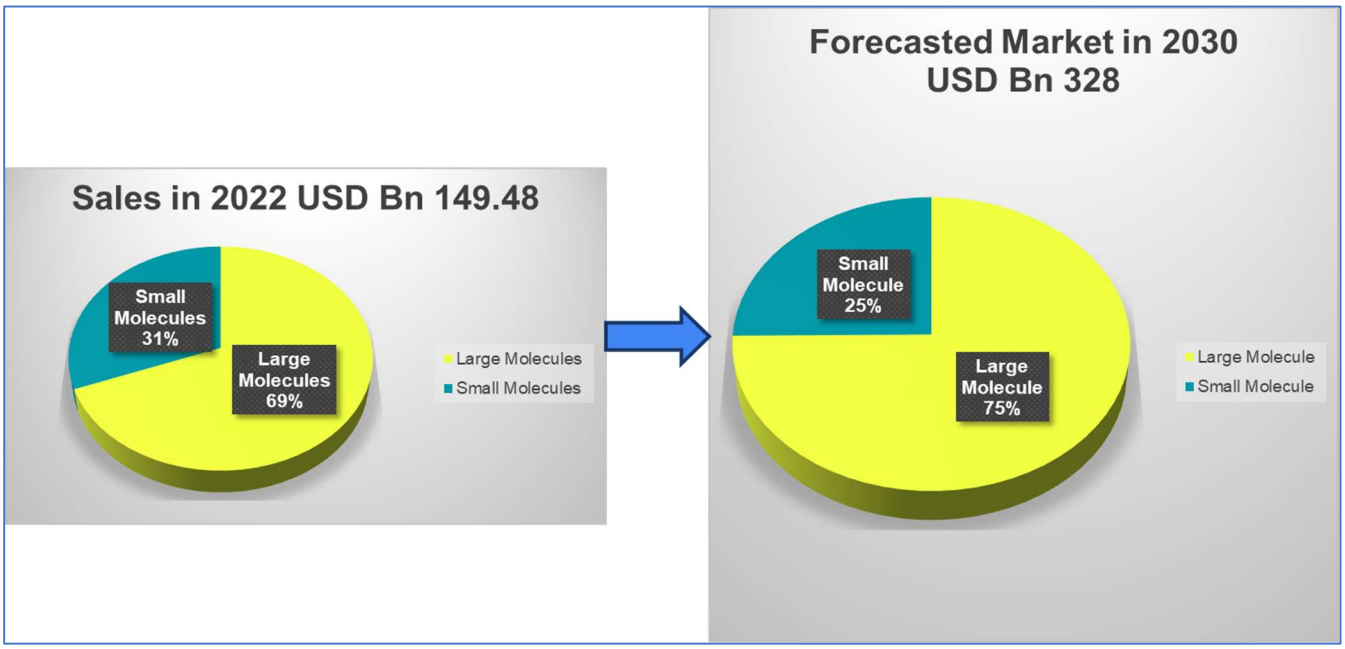
Artificial and Machine learning have been integrated into the drug discovery process by many pharmaceutical companies and research organisations which have the capabilities to leverage these tools to assist in virtual screening, lead optimization, prediction of drug-target interactions, and identification of novel drug candidates helping them to spearhead the drug discovery area in terms of efficiency and productivity. In addition, the use of robotics, automation, miniaturization, and innovative assay formats by such pharmaceutical companies to screen large compound libraries more quickly and cost-effectively is going to provide a competitive edge to such companies.

3.2.4. Surge in Demand for Discovery Services: The global drug discovery outsourcing market which was valued at USD 3.8 Billion in the year 2022 is increasing @ CAGR of 7.3% and is expected to reach USD 6.2 Billion by the year 2031. On the basis of service type, the market is segmented into biology services and chemical services. Gene editing, stem cells, immunotherapies and new types of biologics are now mega-trends in the pharmaceutical industry, however, there are several hot areas in small molecule drug discovery, suggesting a lot of untapped potential and investment prospects in this more "traditional" pharmaceutical research space. The Discovery Chemical Segment, focussed on small molecules has accounted for largest market share in year 2022. This trend is expected to continue till the year 2030. Biology services is expected to witness the fastest growth of 7.5% from 2023 to 2030. The growing demand for technical experts to conduct drug discovery services while abiding by regulatory requirements is one of the key factors promoting segment growth

3.2.5 Shift from Chemical generics to Biosimilars by 2030:

As per the data analysis conducted for the sales of 24 blockbuster drugs by BHPL for another DoP study, biologics like biosimilars, immunomodulators and monoclonal antibodies are going to further dominate the pharmaceutical industry between 2022-2030 (Exhibit 4). The biosimilar revenues which comprised 69 % of overall revenues of these 24 blockbuster drugs in 2022 is going to increase to 75% by 2030 (Exhibit:5) New pharmaceutical technological advancements like high-throughput screening, molecular profiling, next-generation sequencing, bioinformatics analysis, proteomics, and other molecular profiling techniques have paved the way for personalized medicine approaches in drug development which has led to more biologics reaching the market.

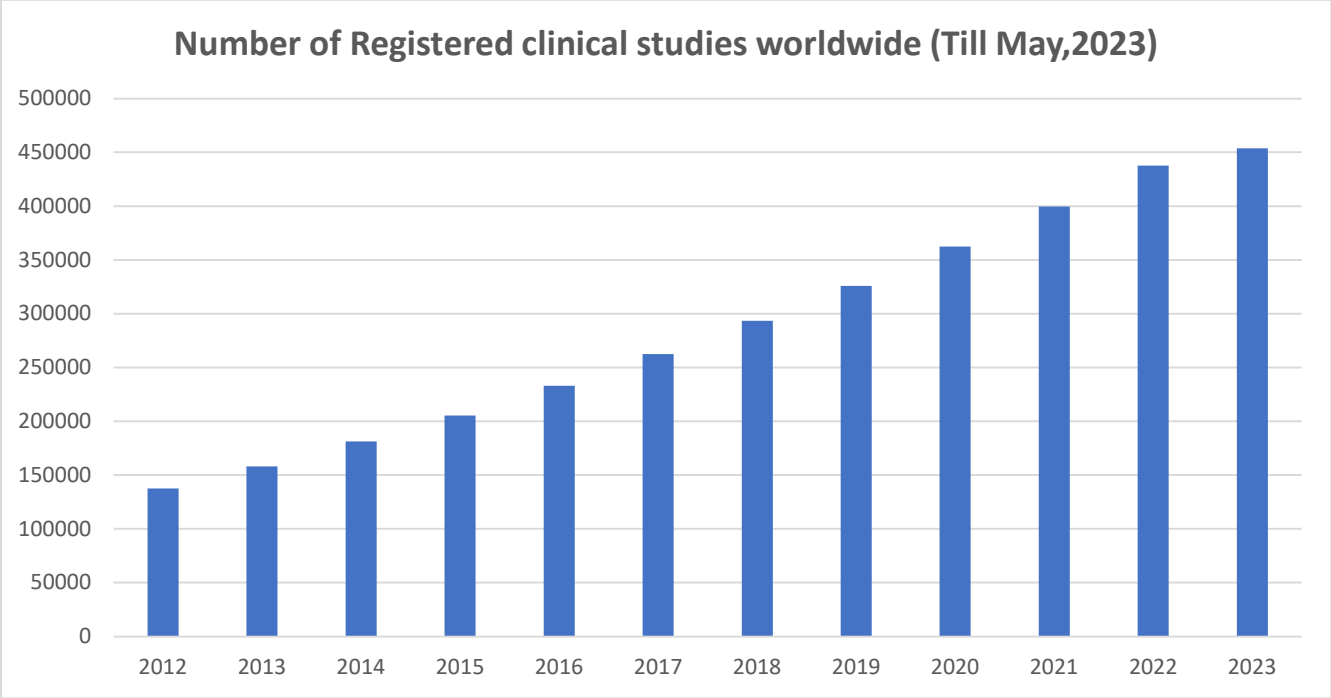
Exhibit 4



3.2.5. Growing number of clinical trials worldwide

The growing number of clinical trials is a major indicator of pharmaceutical research and development market. As per the latest Statista report there were 4,53,803 clinical studies registered worldwide as on May,2023. The exhibit 5 demonstrates the increase in the number of registered clinical studies since 2012

Exhibit 5: Registered Clinical Studies worldwide till May,2023

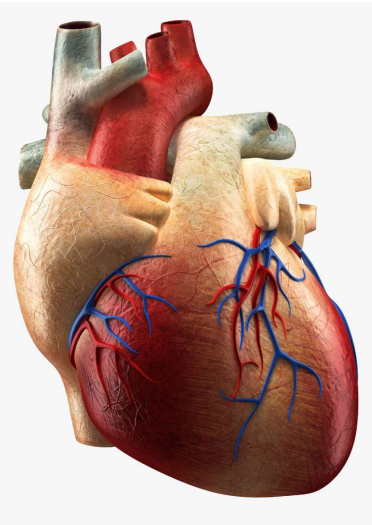


3.2.6. Ever increasing Regulatory Complexity:

The regulatory landscape in the pharmaceutical industry is complex and constantly continuously evolving. Pharmaceutical companies need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. Pharmaceutical companies operating globally must navigate these regional variations and adapt their strategies according. The pharmaceutical companies need to ensure that the research and development activities carried out meet each region's unique documentation requirements, local safety reporting obligations, and specific regulatory approvals.

3.3. Current Disease Area trends in Pharmaceutical Industry

3.3.1. Cardiovascular diseases:



Global Market Size in 2020: USD 82 Billion

Expected Global Market Size in 2026: USD 110 Billion

Expected CAGR: 5%

Types of Conditions that come under the therapeutic area:

- Hypertension
- Dyslipidaemia Heart failure
- Ischemic heart disease

Key Drivers of the Global Cardiovascular Market:

Several factors contribute to the growth of the cardiovascular therapeutic area. These include the rising prevalence of cardiovascular diseases globally

- An ageing population,
- unhealthy lifestyles,
- increasing awareness about early diagnosis and treatment.

Additionally, advancements in drug therapies and innovations in medical devices for cardiovascular interventions drive market growth.

Key Drug Classes in Cardiovascular Area: The global cardiovascular therapeutic area encompasses various drug classes. Some of the key drug classes include:

- Antihypertensive agents (such as ACE inhibitors, beta-blockers, and calcium channel blockers),
- Lipid-lowering agents (such as statins and PCSK9 inhibitors),
- Antiplatelet agents, anticoagulants, and heart failure medications (such as beta-blockers and angiotensin receptor blockers)

Prominent Markets for Cardiovascular Drugs:

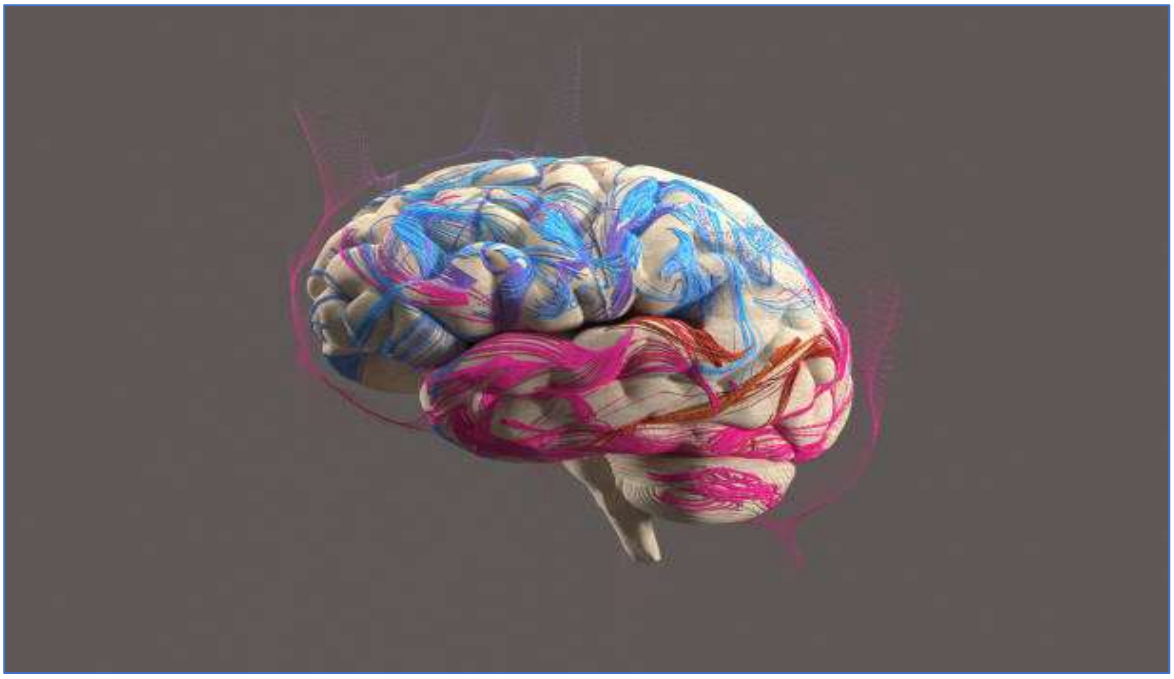
The global cardiovascular market is geographically diverse. North America, including the United States, holds a significant market share, driven by a high prevalence of cardiovascular diseases and robust healthcare infrastructure. Europe also accounts for a considerable portion of the market, primarily due to the ageing population. The Asia-Pacific region, particularly countries like China and India, is expected to witness substantial growth due to increasing awareness, rising healthcare spending, and a growing patient population.

Competitive Landscape: The global cardiovascular market is highly competitive, with both multinational pharmaceutical companies and generic drug manufacturers competing in this space. Major pharmaceutical companies such as Pfizer, Novartis, AstraZeneca, Merck & Co., and Bristol Myers Squibb

have a strong presence in the cardiovascular therapeutic area. However, generic manufacturers, including Indian companies like Sun Pharma, Dr Reddy's, and Lupin, also play a significant role in providing affordable cardiovascular medications.

Emerging Therapies in Cardiovascular Area: The cardiovascular therapeutic area is witnessing advancements in treatment approaches. There is an increasing focus on precision medicine, targeted therapies, and innovative drug delivery systems. Additionally, research and development efforts are underway to explore new therapeutic modalities like gene therapies and regenerative medicine for cardiovascular conditions.

3.3.2 Central Nervous System Disorders:



Global Market Size in 2020: USD 83 Billion (Source: Statista)

Expected Global Market Size in 2026: USD 105 Billion. Expected CAGR: 4%

Types of Conditions that come under the therapeutic area:

- Alzheimer's disease
- Parkinson's disease
- Epilepsy
- Depression
- Anxiety disorder
- Schizophrenia, and
- Multiple sclerosis

Key Drivers of Global CNS Market: Overall, the global CNS therapeutic area presents significant opportunities for pharmaceutical companies, including generic manufacturers. The market growth is

driven by the increasing prevalence of CNS disorders, advances in neuroscience research, and the need for improved treatments.

Key Drug Classes in CNS area:

- Antidepressants
- Antipsychotics
- Anxiolytics
- Mood stabilizers
- Antiepileptic drugs
- Cognitive enhancers
- Neurodegenerative diseases

Competitive Landscape: The CNS therapeutic area is highly competitive, with both multinational pharmaceutical companies and generic manufacturers competing in this space. Major pharmaceutical companies such as Johnson & Johnson, Pfizer, Novartis, Eli Lilly, and AstraZeneca have a strong presence in the CNS market. Additionally, there are several specialized biopharmaceutical companies and generic manufacturers that focus on CNS disorders.

3.3.3. Oncology

Global Market Size in 2020: USD 150 Billion (Source: Statista)

Expected Global Market Size in 2026: USD 250 Billion

Expected CAGR: 8%

Types of Conditions that come under the therapeutic area:

The oncology therapeutic area encompasses various cancer types, including

- Breast cancer
- Lung cancer
- Colorectal cancer
- Prostate cancer
- Leukaemia
- Lymphoma
- Melanoma

Each cancer type requires different treatment approaches and has specific market dynamics.

Key Drivers of the Oncology Market: Several factors contribute to the growth of the oncology therapeutic area. These include the increasing prevalence of cancer worldwide, advancements in cancer research and treatment, a growing ageing population, and the introduction of innovative therapies such as targeted therapies, immunotherapies, and precision medicine approaches. Additionally, rising awareness, early detection, and improving access to healthcare services drive market growth.

Major Treatment Therapies:

- Chemotherapy
- Radiation therapy
- Surgery
- Targeted therapies
- Immunotherapies
- Hormonal therapies

Competitive Landscape: The global oncology market is highly competitive, with major pharmaceutical companies actively involved in the development and commercialization of oncology drugs. Key players in the industry include Roche, Novartis, Pfizer, Merck & Co., Bristol Myers Squibb, AstraZeneca, and Johnson & Johnson, among others. Additionally, smaller biopharmaceutical companies and generic manufacturers play a role in providing cost-effective oncology therapies.

In terms of Emerging Therapies, the oncology therapeutic area is witnessing rapid advancements, particularly in the field of targeted therapies and immunotherapies. Precision medicine approaches, such as genomic profiling and liquid biopsies, are gaining prominence, allowing for personalized treatment decisions.

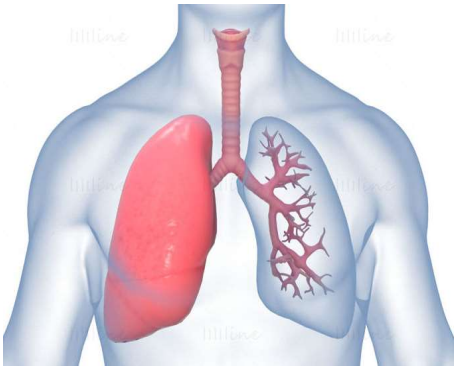
Additionally, cell-based therapies like CAR-T cell therapy and gene therapies are emerging as potential game-changers in certain cancer types.

3.3.4. Respiratory Disorders:

Global Market Size in 2020: USD 40 Billion (Source: Statista)

Expected Global Market Size in 2026: USD 55 Billion

Expected CAGR: 5%



Types of Conditions that come under the therapeutic area:

The respiratory therapeutic area covers various respiratory conditions. Asthma and COPD are the most prevalent respiratory diseases, affecting a large population globally. Other respiratory conditions include

- Respiratory tract infections,
- Pulmonary arterial hypertension,
- Idiopathic pulmonary fibrosis, and
- Sleep apnea

Major Treatment Modalities in Respiratory Area:

- Corticosteroids

- Bronchodilators
- Combination therapies
- Immunomodulators
- Antibiotics
- Mucolytics
- Inhalers and Nebulizers

Prominent Markets for Respiratory Drugs: North America, particularly the United States, accounts for a significant share of the global respiratory market due to a high prevalence of respiratory conditions and a well-established healthcare system. Europe also holds a considerable market share, driven by an aging population and environmental factors.

The Asia-Pacific region, including countries like China and India, is witnessing significant growth due to improving healthcare infrastructure, rising pollution levels, and increasing awareness of respiratory diseases.

Competitive Landscape: The global respiratory market is competitive, with both multinational pharmaceutical companies and generic manufacturers operating in this space. Key players in the market include GlaxoSmithKline, AstraZeneca, Boehringer Ingelheim, Novartis, and Teva Pharmaceuticals. Generic manufacturers also play a role in providing affordable respiratory medications.

Emerging Therapies in Respiratory Area: The respiratory therapeutic area is witnessing advancements in treatment approaches. There is ongoing research and development to explore innovative therapies, including biologics, gene therapies, and targeted therapies, for respiratory conditions like severe asthma and cystic fibrosis. The COVID-19 pandemic has significantly impacted the respiratory therapeutic area. The demand for respiratory medications and devices surged due to the respiratory complications associated with COVID-19. The development of vaccines and antiviral therapies targeting respiratory infections has also gained prominence. Additionally, digital health solutions, such as telemedicine and remote patient monitoring, are being integrated into respiratory care.

3.3.5 Diabetes:

Global Market Size in 2020: USD 26.5 Billion (Source: Statista)

Expected Global Market Size in 2026: USD 42.4 Billion

Expected CAGR: 8.1%

Types of Conditions that come under the therapeutic area:

The diabetes therapeutic area covers conditions like Type-1 Diabetes and Type-2 Diabetes.

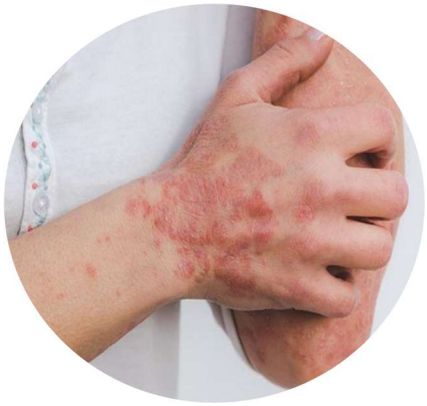
With the expiration of patents for various antidiabetic drugs, Indian generic companies can play a significant role in providing affordable options for patients with diabetes. This includes generic versions of oral antidiabetic agents, insulin, and other related medications.

3.3.6 Autoimmune Disorders:

Global Market Size in 2020: USD 62 Billion

Expected Global Market Size in 2026: USD 100 Billion

Expected CAGR: 8%



Types of Conditions that come under the therapeutic area:

The autoimmune diseases therapeutic area encompasses a wide range of disorders, including

- Rheumatoid arthritis,
- Psoriasis,
- Systemic lupus erythematosus (SLE),
- Multiple sclerosis (MS),
- Inflammatory bowel disease (IBD),
- Type 1 diabetes, and others.

Treatment Modalities in Autoimmune Therapeutic Area: Various treatment modalities are used in the autoimmune diseases therapeutic area. These include immunosuppressants, disease-modifying anti-rheumatic drugs (DMARDs), biological therapies, corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), and targeted therapies. The use of biologics and targeted therapies has been transformative in managing certain autoimmune disorders.

Prominent Markets of Autoimmune Therapeutic Area: North America, particularly the United States, holds a significant share of the global autoimmune diseases market due to a high prevalence of autoimmune disorders, advanced healthcare infrastructure, and favourable reimbursement policies. Europe is also a prominent market, driven by increasing disease prevalence and investments in research and development. The Asia-Pacific region, including countries like China and India, is witnessing significant growth due to improving healthcare infrastructure, increasing awareness, and rising disease burden.

Competitive Landscape: The global autoimmune diseases market is highly competitive, with major pharmaceutical companies actively involved in the development and commercialization of therapies. Key players include AbbVie, Johnson & Johnson, Pfizer, Novartis, Bristol Myers Squibb, and Roche. Additionally, specialized biopharmaceutical companies and generic manufacturers also play a role in providing affordable therapies for autoimmune diseases.

Emerging Therapies in Autoimmune Disorders Area: The autoimmune diseases therapeutic area is witnessing advancements in treatment options. There is ongoing research and development to explore novel drug targets, develop more specific and effective therapies, and harness immunomodulatory approaches. Additionally, personalized medicine and precision therapies are gaining attention in certain autoimmune disorders.

3.4. Current Ranking Systems of Pharmaceutical Institutions

University rankings have gained significant attention from experts, academics, and researchers affiliated with educational or scientific institutions. The topic is also a subject of discussion among students pursuing master's and doctoral degrees. Various ranking bodies evaluate institutes and universities based on different criteria, standards, and parameters and these rankings are helpful for the involved stakeholders in the following ways:

- **Provide a platform for universities to monitor their work:** Universities worldwide value rankings to attract faculty and students. Departments use reward and punishment policies for ranking progress. Rankings carry immense importance for intellectual, marketing, scientific, and financial aspects. Institutions anticipate results and create divisions to improve quality and ranking. This positively reflects on their work.

- **Provide a platform for students to choose the optimal university:** It's evident to both internal and external observers that a university's ranking is one of the main questions that any student contemplating enrolling in the university considers. Other important questions include accreditation, quality policies, employment rates, library access, and faculty qualifications. Ranking act as an Independent and autonomous reference for updated information. Ranking may not be directly related to the student or teaching process, but it's still a significant criterion that affects a student's decision to choose a university. Universities must maintain absolute neutrality and provide all relevant information to students to help them make informed decisions. This highlights the importance of ranking for both the student and higher education institution.

- **Encourage institute to compete with other similar or close institutes in the ranking:** Higher education is not exempt from competition, and institutes compete in various aspects, such as research, academic rankings, faculty qualifications, student resources, and more. Ranking is one of the most crucial opportunities for universities to showcase their strengths and achievements and compete on a global scale. It's an effective and optimal portal for universities to improve their ranking and achieve higher rankings than other universities.

- **Encouraging institution to establish partnerships with universities of common interest:** The significance of rankings cannot be overstated, as they have the power to facilitate global and regional partnerships and networking. These rankings are instrumental in boosting university performance and instilling confidence in management's decision-making abilities. By leveraging rankings, universities can forge new partnerships, sign agreements, and create opportunities for student exchange programs, educational process development, and curriculum enhancement.

- **Supports decision-making policy, promotes courage and encourage educational institutions to make courageous steps for the best of their students:** Institution rankings drive decisions to support and develop university structures, increase scientific research, allocate financial resources towards teaching staff development and curriculum improvement, and encourage communication with new universities. Progress in the rankings can also promote concrete steps to support the institution's quality policy.

- **Development of the Institution in specific areas:** University rankings help measure performance in related areas, leading to the overall development of the educational process. Even if some aspects aren't covered, other areas bound by the criteria will benefit from the ranking's influence. Therefore, the ranking can contribute to the institution's development beyond what is directly covered by the ranking.

- **Encourage the institution to do scientific research:** Ranking bodies encourage scientific research and support universities in their research and academic studies. Some people misunderstand the ranking process and believe it is just a technical process without academic value. However, ranking is a scientific academic research process that utilizes modern technology. About 40-50% of the ranking criteria are based on scientific and academic factors, such as research publications, academic publications, and other scientific standards. Therefore, the scientific factor of the ranking is clear.

- **Encouraging the institution to develop action plans:** Plausible plans and consistent hard work facilitate an institution's success. Tangible progress in the ranking over several years motivates it to improve and change its structure to enhance quality assurance. However, it's important to remember that ranking should reflect the actual reality of the institution. Therefore, institutions should approach ranking realistically and logically.

- **Act as a motivation for positive change:** Ranking is a major motivation for educational institutions to make positive changes in their work. Whether there is progress or a downturn, the institution will take real steps to achieve as much progress as possible. If there is a downturn, the institution will identify weaknesses and find solutions to improve the ranking. If there is progress, meetings will be held to identify factors that contributed to it and work to develop and strengthen them. This helps to improve the ranking and support the institution's scientific processes.

Rankings systems have some ambiguity as well. Although ranking bodies are impartial and independent in their standards, criteria, factors, and results, there is relative chaos that cannot be altered or delayed, the same institute can have different rankings and categories in different rankings. Furthermore, the number of universities targeted in each ranking is different, leading to an increase in the abnormality factor and error rate in the results presented. Further, students can lose concentration and feel disappointed when continuously comparing academic rankings. At the same time, some higher education institutions neglect the educational process and focus on ranking, leading to non-transparency and manipulation of results to obtain a higher ranking.

The most popular international ranking systems for Pharmacy and life sciences are

1. QS World University Ranking,
2. THE (Times Higher Education) World Ranking
3. Shanghai ranking’s Academic Ranking of World Universities (ARWU).

In India, NIRF ranking is the leading benchmark of the academic and research institutions including the institutions offering courses in pharmacy/pharmacology.

The QS World University Rankings 2023 featured over 1,400 universities worldwide, making it the biggest ranking yet. Institutions are evaluated across six categories or indicators to effectively capture university performance, namely academic reputation, employer reputation, Faculty/student ratio, Research citations, and international faculty/student ratio.

QS World University Ranking		
S.No.	Criteria	Percentage
1	Academic Reputation	40%
2	Employer Reputation	10%
3	Faculty Student Ratio	20%
4	Citation per faculty	20%
5	International Faculty Ratio	5%
6	International Student Ratio	5%

***QS World University Ranking excludes joint or double degree programs and programs run on overseas cases.**

S. No.	Ranking Parameters	Performance Indicators
1	Teaching - 30%	• Reputation survey - 15% • Staff-to-student ratio - 4.5% • Doctorate-to-bachelor's ratio - 2.25% • Doctorates-awarded-to-academic-staff ratio - 6% • Institutional income - 2.25%
2	Research - 30%	• Reputation survey 18% • Research income - 6% • Research productivity - 6%
3	Citations - 30%	• Field Weighted Citation Impact - 30%
4	International Outlook - 7.5%	• Proportion of international students - 2.5% • Proportion of international staff - 2.5% • International collaboration - 2.5%
5	Industry Income - 2.5%	• Research income from industry & commerce / Academic Staff - 2.5%

Other Major Criteria for Institutions to be included in the List

- Over 1,000 relevant publications should have been published by them over the last five years and over 150 relevant publications in any one year.
- Undergraduate-level teaching should be provided. More than 0 UG degrees should have been awarded. Therefore, institutions offering only post-graduate programs are not considered.
- Focus should not be on a particular narrow subject area.
- 'Overall' numbers for the ranking year should have been provided.
- More than two critical values should not exist as null (either withheld or unavailable). These include - undergraduate degrees awarded, students, international academic staff, research staff, research

income from industry and commerce, doctorates awarded, academic staff, research income, institutional income, and international students.

- Atleast one subject should have been marked applicable by the universities. The institution will be excluded if no applicable subjects are reported
- The customer exclusions list should not have included their names.

Shanghai Ranking's Academic Ranking of World Universities (ARWU) considers several indicators of academic and research performance, including the number of Nobel Laureates, Fields Medallists, Highly Cited Researchers, or papers published by an institution. Additionally, a significant number of papers indexed by Science Citation Index-Expanded (SCIE) also included. This ranking system evaluates more than 2000 universities worldwide.

For each indicator, the highest-scoring institution is assigned a score of 100, and other institutions are calculated as a percentage of the top score. The scores for each indicator are weighted to arrive at a final overall score for an institution. An institution's rank reflects the number of institutions that sit above it. Moreover, the distribution of data for each indicator is examined for any significant distorting effect, and standard statistical techniques are used to adjust the indicator if necessary.

Criteria	Indicator	Code	Weightage
Quality of Education	Alumni of an institution winning Nobel Prizes & Fields Medals	Alumni	10%
Quality of Faculty	The staff of an institution winning Nobel Prizes & Field Medals	Award	20%
Quality of Faculty	Highly Cited Researchers	HiCi	20%
Research Output	Papers published in Nature and Science*	N&C	20%
Research Output	Papers indexed in Science Citation Index-Expanded and Social Science Citation Index	PUB	20%
Per Capita Performance	Per Capita academic performance of an institution	PCP	10%
Total			100%

NIRF is India's own ranking system, which ranks universities and institutes at the national level. It is a methodology adopted by the Ministry of Education, Government of India, to rank higher education institutions in India. NIRF was launched by the Minister on 29 September 2015.

The approved set of parameter groups and the weightages assigned in respect of overall rating and for colleges are as below

Parameters	**Overall**
Teaching, learning and resources (TLR)	30%
Research, productivity, impact and IPR (RPII)	30 %
Graduation outcome (GO)	30%
Outreach and inclusivity (OI)	10%
Perception (PR)	10%

Further sub-criteria for the ranking framework as per NIRF system is mentioned below in the table:

S NO.	Parameter	Weightage/Marks
1)	Teaching Learning and Resources (TLR)	Ranking Weight age 0.30
	A. Teacher Student Ratio with emphasis on Permanent Faculty	25 Marks
	B. Combined Metric for Faculty with Ph.D. and Experience	25 Marks
	C. Metric for Library and Laboratory Facilities	40 Marks
	Metric for Sports and Extra Curricular Facilities	10 Marks
2)	**Research Productivity, Impact and IPR (RPII)**	**(Ranking Weightage =0.40)**
	A. Combined Metric for Publications	45 Marks
	B. Combined Metric for Citations	45 Marks
	C. Intellectual Property Right	10 Marks
3)	**Graduation Outcome (GO)** A. Combined Performance in University Examinations	**(Ranking Weightage =0.05)** 50 Marks
	B. Combined Performance in Public Examinations	50 Marks
4)	**Outreach and Inclusivity (OI)**	**(Ranking Weightage =0.15)**
	A. Outreach Footprint(Continuing Education, Services)	25 Marks
	B. Percentage of Students from Other States/Countries	25 Marks
	C. Percentage of Women Students and Faculty	20 Marks
	D. Percentage of Economically and Socially Disadvantaged Students	20 Marks
	E. Facilities for Differently Abled Persons	10 Marks
	Perception (PR)	**(Ranking Weight age =0.10)**
	Process for Peer Rating in Category	50 Marks
	Application to Seat Ratio	50 Marks

4. GLOBAL BEST PRACTICES IN PHARMACEUTICAL INDUSTRY

4.1. Quality Management System (QMS)

Establishing implementing and maintaining a comprehensive Quality Management System is vital for pharmaceutical companies with global aspirations. A well-designed QMS encompasses procedures, policies, and processes that ensure consistent quality throughout the entire product lifecycle, from product development to manufacturing, distribution, and post-marketing surveillance. This includes documentation control, change management, internal audits, and continuous improvement initiatives. Implementing a culture of continuous improvement is crucial for generic companies to stay competitive and maintain high-quality standards. This involves monitoring key performance indicators, conducting regular quality reviews, and implementing corrective and preventive actions to address any deviations or non-conformities. Learning from quality incidents, customer feedback, and emerging industry trends helps the pharmaceutical companies drive continuous improvement initiatives. The Pharmaceutical companies normally opt for and ensure overall compliance to ISO 9001:2015 Quality Management System standard.

4.2. Regulatory Compliance:

Pharmaceutical companies need to adhere to stringent regulations and guidelines set by regulatory bodies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) or the national regulatory bodies. Further, regulatory policies and requirements can change over time, potentially affecting the drug approval processes. Changes in regulations, guidelines, or interpretation of regulatory standards can create uncertainties and impact timelines for approval for pharmaceutical companies. The regulatory compliant companies perform the proper assessment of the regulatory risks, develop systems and resources to ensure the compliance, develop the expertise to navigate the regulatory requirements and address the deficiencies or inquiries from the regulatory authorities.

4.3. Good Laboratory Practices

It is necessary for manufacturers of pharmaceutical products to submit all relevant data and information related to their development, including the facilities used, the experimental designs employed in the validation of manufacturing processes, and quality control procedures employed during the R&D to the regulators for review before getting the market approval. With an ever-increasing awareness of the risks in pharmaceutical production and control and the life cycle approaches being followed, the pharmaceutical companies emphasise on ensuring that the research and development of pharmaceutical products are appropriately controlled and documented. The main objective of following the GLPs are to:

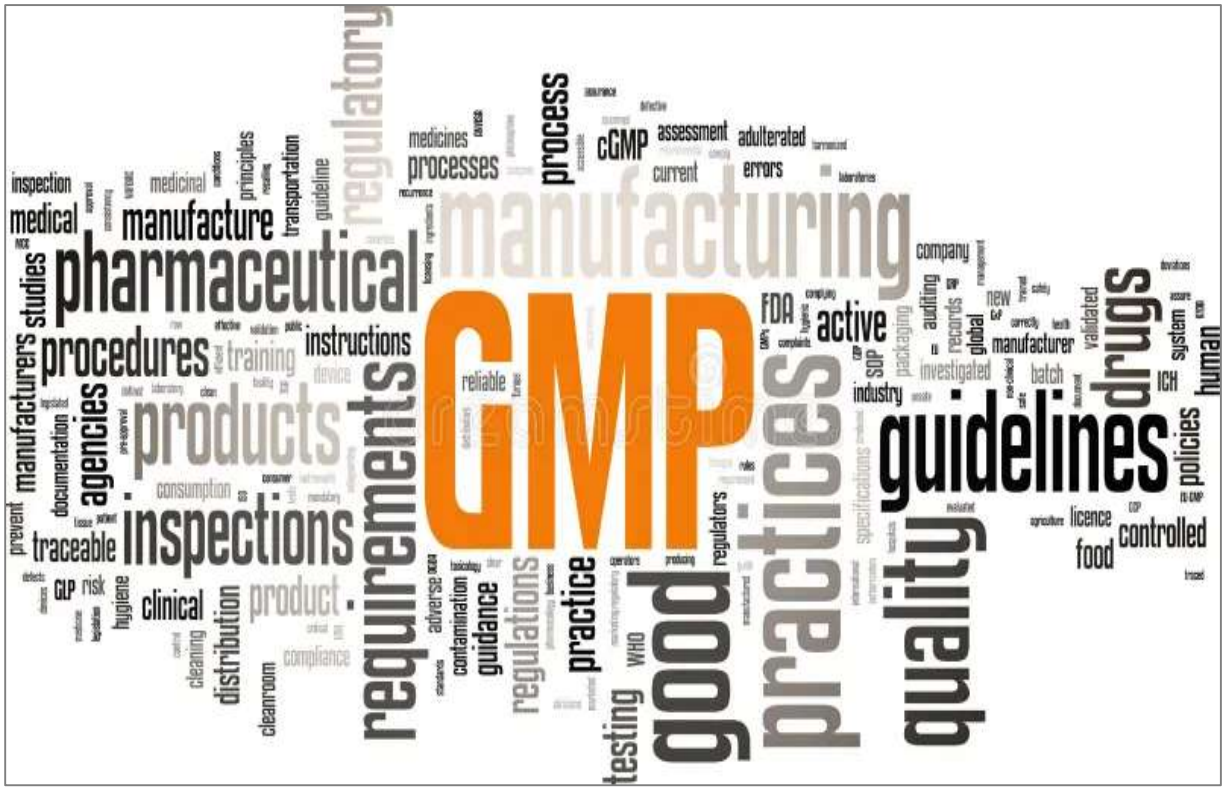
- Ensure that the facilities, quality systems, data and information meet the appropriate regulatory standards and applicable Good Laboratory Practices.
- Ensure that the correct systems are followed, ensuring appropriateness, reliability and the quality of pharmaceutical products, processes, procedures and data.
- Ensure that pharmaceutical products meet the requirements for safety, efficacy and quality that they purport to possess.

The Good Laboratory Practices particularly address the requirements related to Premises, Equipment, Facilities, Sanitation and Hygiene, personnel, Maintenance of buildings and equipment, Storage of starting materials and finished products, production and in-process control, documentation, data integrity, qualification and validation of processes, calibration of instruments or measurement systems and records of previous self-inspections and any corrective steps taken to address them. The GLP compliant companies also have validated Laboratory information management system(s) (LIMS) in place which can be used for the collection, processing, reporting, storage and retrieval of data. OECD GLP certification is normally taken by pharmaceutical companies to ensure the compliance to GLPs. In India, NGMCA is the authorised to provide this certification to pharmaceutical companies with research and development centres. The scope of the certification may vary from company to company depending on the activities carried out by R&D centres of pharmaceutical companies. In addition, many companies also opt for the Laboratory Management System (LMS) accreditation from International Organisation for Standardisation as per the ISO 17025:2016 standard. The certification and accreditation from reputed bodies develop confidence about the products and services of pharmaceutical companies among the customers and consumers

4.4. Good Clinical Practices

The pharmaceutical companies working on new and innovative products need to go through entire clinical development cycle of Phase I to Phase IV clinical studies whereby the medicinal products are tested in human subjects to test their safety and efficacy. For the newly developed generic versions of the pharmaceutical products also the pharmaceutical companies need to demonstrate bioequivalence to the Reference Listed Drug (RLD) in terms of pharmaceutical equivalence and bioavailability. To meet the regulatory and marketing licence requirements, pharmaceutical companies conduct robust clinical studies to ensure the safety and efficacy of the drugs and submit the clinical data as a part of the regulatory dossiers submitted to various regulatory agencies to obtain marketing authorisation in respective countries. Most of the pharmaceutical companies outsource the clinical studies/ trials to the specialized Contract Research Organisations. The Pharmaceutical companies need to be very careful and conduct proper due diligence while selecting the CROs for conducting the clinical trials/ studies because the ultimate responsibility of the clinical data and regulatory compliance always stays with the pharmaceutical company. For conducting the clinical trials, in addition to applicable local regulations, it is important for pharmaceutical companies to adhere to ICH-GCP norms. Any compromise on the safety, rights and well-being of clinical trial participants or data integrity issues with the clinical trial data can lead to jeopardizing the entire regulatory submission of a pharmaceutical company ultimately resulting in rejection of application for marketing approval.

4.5. Good Manufacturing Practices:



Pharmaceutical companies need to adhere to Good Manufacturing Practices (GMP) to maintain quality standards throughout the manufacturing process. GMP regulations cover various aspects, including facility design, equipment qualification, raw material sourcing, process controls, packaging, labelling, and quality control testing. Compliance with GMP as per US & EU standards ensures consistent quality and safety of the pharmaceutical products. Rigorous quality control testing is conducted by GMP compliant pharmaceutical companies throughout the manufacturing process to ensure that the pharmaceutical product meets the required specifications for identity, strength, purity, and quality. These tests include assays, dissolution testing, impurity analysis, stability testing, and other quality parameters to confirm product quality and safety. In addition, the GMP compliant companies establish comprehensive batch release procedures to ensure that each batch of the product meets the required specifications before being released for distribution. Batch release typically includes a thorough review of manufacturing records, quality control test results, and compliance with applicable regulatory requirements. The documentation associated with batch release is maintained as part of the company's quality records by GMP compliant companies for the prescribed retention period.

4.6. Supply Chain Resilience

Over the past several decades, pharmaceutical manufacturing has become increasingly global and supply chains have become longer, more complex, and fragmented. While pharmaceutical products available to patients and customers typically conform with appropriate standards, supply chains are often affected by disruptive events and shocks that impact public health. One of the best practices followed by pharmaceutical manufacturers is to invest in resilient supply chain so that the interests of patients are served by risk-based drug shortage prevention and employing mitigation strategies to proactively manage supply chain complexities and ensure availability of drugs to the needy patients at all times.

4.7. Good Data & Records Management Practices:

Good documentation practices are critical elements of the quality system which when implemented, provide a high level of assurance that throughout the product life cycle, all GLP, GMP and GCP records and other relevant data are complete, reliable and reproducible. Activities

such as equipment qualification, analytical method validation, cleaning validation, stability studies, analytical method process development & validation, manufacturing process validation, or manufacturing technology transfers etc. are executed on the basis of predefined, preapproved protocols and results of these activities are documented by pharmaceutical companies in a final report with conclusions. All batch records, staff records and copies of CoA are retained for a defined period are stored by pharmaceutical companies compliant to good documentation practices. In addition; the GDP compliant companies ensure that amendments to technical records and documents are traceable to previous versions, handwritten records are signed and dated at the time the information is entered and all Standard Operating Procedures or Work Instruction documents have the effective date printed or stamped on them. In case, date and time is automatically printed by computer software, the date and time format of the instrument/machine are followed and reviewed periodically for any discrepancy.

4.8. Intellectual Property Protection

Developing drug involves navigating complex intellectual property landscapes. Pharmaceutical companies try to create legal barriers in the form of patents and trademarks so that the competitors cannot develop and market the protected products. The patent holders pharmaceutical companies have a very strong multilayer patent network to extend their exclusivity rights or sue the generic companies for patent infringement. Most of the originator companies have well established systems and teams in place to initiate patent litigation against the generic manufacturers. Further, the patent landscape is dynamic, and new patents or changes to existing patents norms can impact the development of drugs. Pharmaceutical companies closely monitor patent expiration dates, patent challenges, and legal developments to identify

opportunities for generic drug development. The innovator companies also try evergreening the patents by extending the exclusivity period of the drugs by obtaining additional patents or regulatory exclusivities. This can delay the entry of Indian generic competitors into the market.

4.9. Ethical Marketing Practices:

Governments and regulatory bodies worldwide have come up with strict regulations and laws in place to prevent bribery and unethical practices in healthcare sector. The global and reputed pharmaceutical companies also take a range of efforts to ensure ethical communication and interaction with healthcare professionals and patients. The ethical practices are designed to ensure that the information, where permitted, is balanced, accurate and cantered on what is best for the patient. The pharmaceutical companies are expected to self- regulate, develop antibribery policies and follow a code of ethical marketing supported with clinical evidence while approaching the healthcare professionals. These practices prohibit the pharmaceutical companies from any form of inducement or incentives such as financial incentives, sponsored trips or gifts to physicians for favouring and prescribing their drugs.

4.10. Post Marketing Surveillance and Adverse Event Reporting:

Continuous monitoring of the drug's safety and effectiveness after it enters the market is essential. Post-marketing surveillance programs help the pharmaceutical companies detect and assess any potential safety issues that may not have been apparent during clinical trials. Timely reporting and response to safety concerns are crucial to ensure patient well-being. Implementing a robust pharmacovigilance system is crucial for monitoring and reporting adverse events associated with drugs. Indian Global pharmaceutical have companies establish processes to capture, evaluate, and report any safety concerns promptly. The companies have provision on

their websites to contact them directly in case of any adverse events. Global Pharmaceutical companies have dedicated safety reporting centres where the adverse events related to drugs can be reported by patients or healthcare care professionals.

4.11. Occupational Health and Safety Practices:

Occupational Health and Safety Practices implementation by pharmaceutical companies aims to prevent work-related injury and ill-health and to provide safe and healthy workplaces. As an international standard, ISO 45001 is a benchmark and is often implemented by pharmaceutical companies to increase organisational resilience through proactive risk prevention, innovation and continual improvement. It not only strengthens the legal and regulatory compliance whilst reducing business losses but also demonstrate the pharmaceutical company's responsibility by committing to decent work conditions safe, healthy and sustainable work for its employees.

4.12. Environment Management Practices:

One indicator of the pharmaceutical industry's commitment to reducing the negative environmental impacts of its operations is the progress leading companies are making toward adopting environmental management systems (EMSs) that meet internationally accepted standards, such as the International Organization for Standardization's (ISO 14000) guidelines. Pharmaceutical companies have to adopt environment management standards not only to comply with government's environmental regulations, but also to move beyond compliance by proactively managing environmental aspects of their products and operations in order to eliminate waste and prevent pollution and environmental degradation.

4.13. Commitment to UN's Sustainable Development Goals (SDGs):

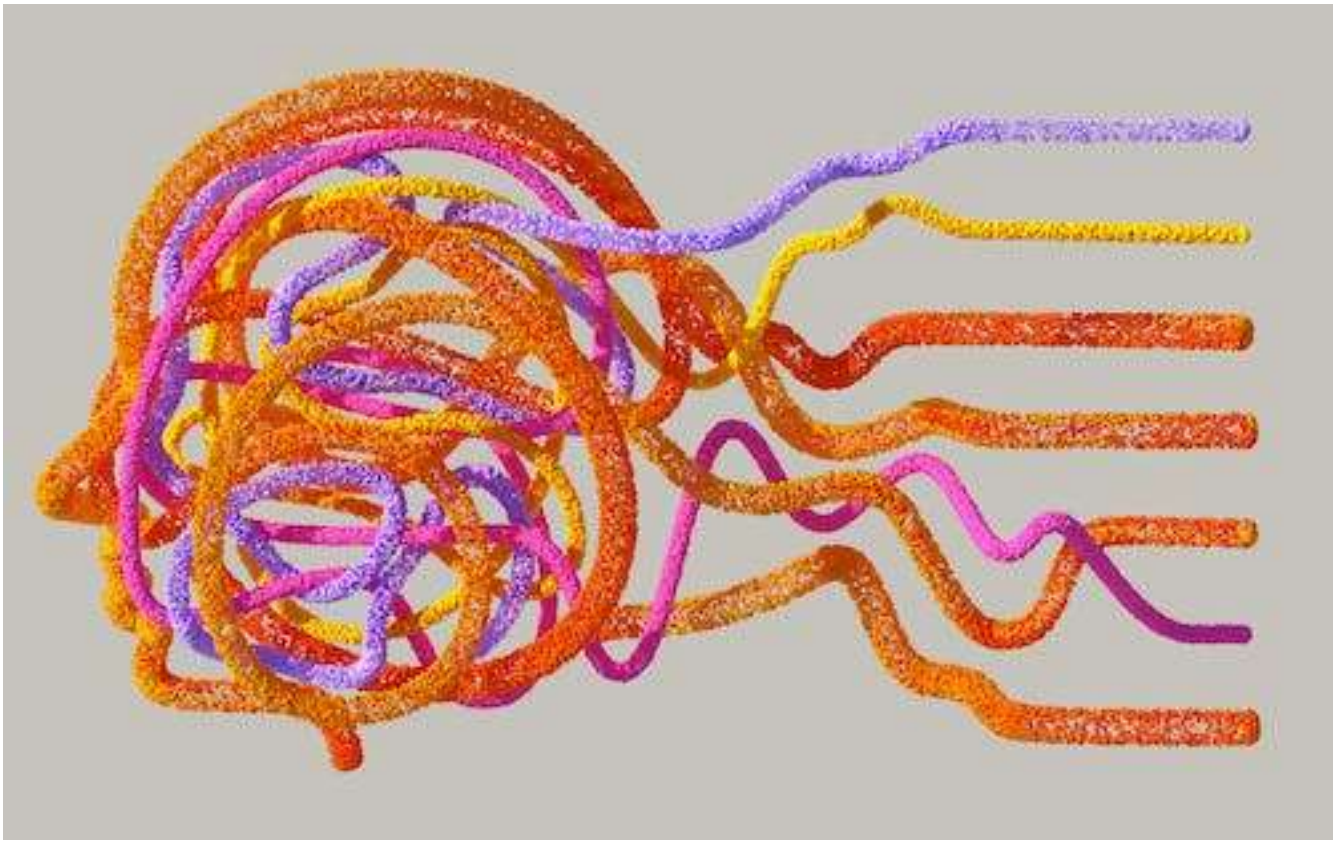
Pharmaceutical companies that are committed to sustainability are increasingly aligning their corporate strategies to the United Nation's Sustainable Development Goals (SDGs). The pharmaceutical companies seeking to enhance their ESG (Environmental, Social and Governance) profile, implementation of standards like ISO 45001 and ISO 14000 and their alignment to the SDGs sends a powerful message to shareholders and stakeholders including employees, that they truly care for their people and environment.

5. Global best practice followed by Top Pharmaceutical Institutes

5.1. Robust and Diverse Funding Sources:

Among the myriad components that elevate the world's top pharmaceutical education and research institutes, research funding stands out as a linchpin for catalyzing progress, fostering innovation and shaping the future of pharmaceutical science. The top pharmaceutical research organizations recognize this importance and tap into all possible channels, including government grants, private foundations, philanthropic and alumni donations, corporate partnerships and collaborations with industry players. This approach minimizes dependence on a single source and ensures a steady influx of funds. Funding agencies are often drawn to innovative, high-risk, high-reward projects that have the potential to disrupt the status quo in pharmaceutical and healthcare industry. The top pharmaceutical institutes develop expertise in preparing competitive grant applications that capture the interest of funders, resonate with mission and priorities of funding agencies. The top pharmaceutical institutes maintain strong networks within the scientific community by engaging with potential funders in conferences, workshops, and networking events. For example, as per website of University of Oxford, in the financial year 2021/22, its total research income, including the QR funding, totaled £856.1 million. Of this sum, £711.4 million was from externally funded grants and contracts.

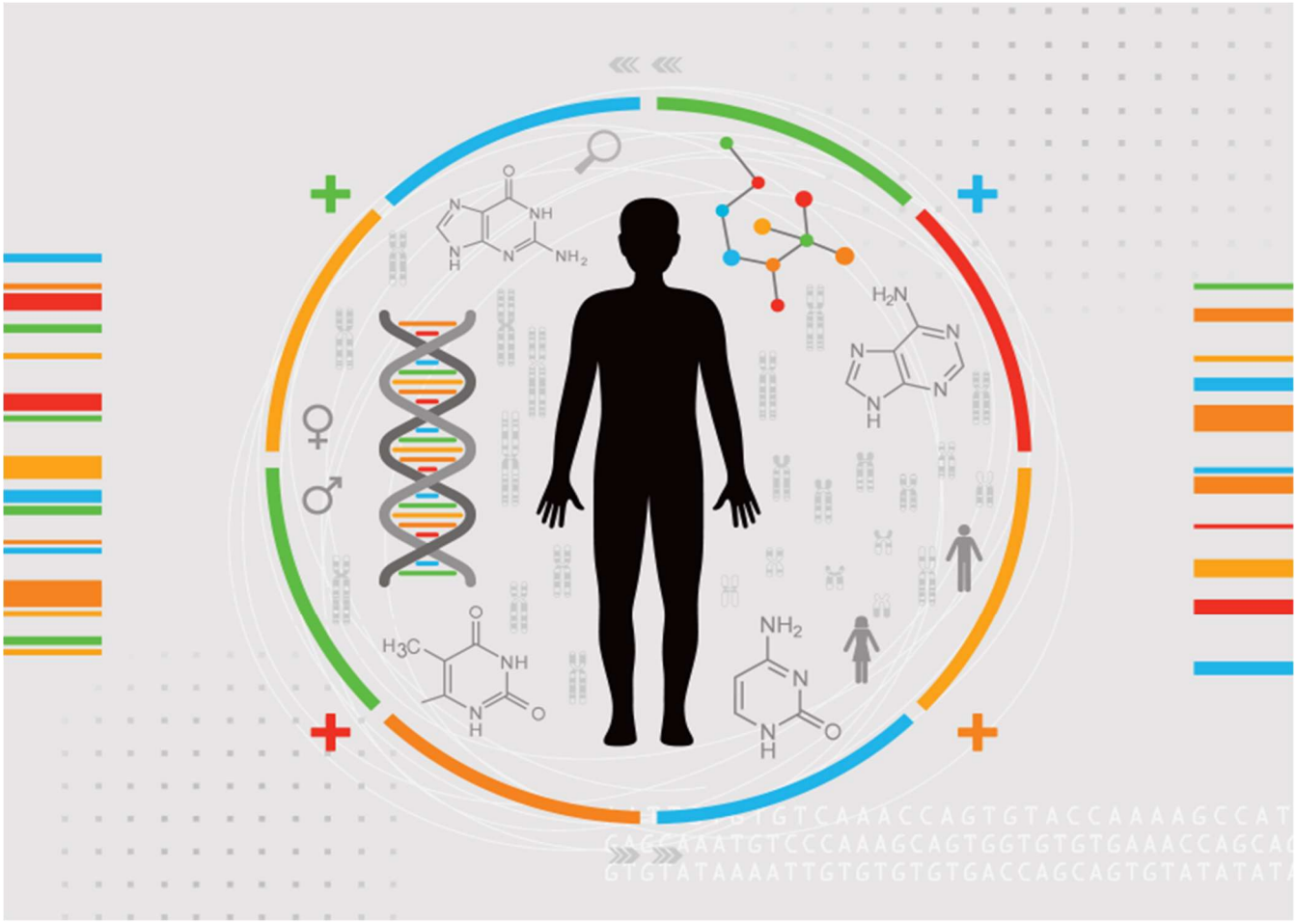
5.2. Focus on Interdisciplinary Research



Traditionally, scientific disciplines have operated within their own silos, with limited interaction between fields such as chemistry, biology, medicine, engineering and computer science. In the fast-paced world of pharmaceutical research, the complexities of disease mechanisms, drug development and patient care demand to break down the silos for progress and work on a multidimensional approach. Top pharmaceutical research institutions have recognized that embracing interdisciplinary collaboration across different disciplines such as chemistry, biology, medicine, engineering, and data science is not just a strategy but a necessity for fueling and driving innovation and tackling healthcare challenges that affect millions of lives worldwide. Top pharmaceutical research institutions offer interdisciplinary training to their students exposing them to a broader spectrum of knowledge and skills which make them better equipped to tackle real-world challenges and drive innovation. Top pharmaceutical research institutions believe in holistic problem-solving approach by creating collaborative spaces for creating interdisciplinary collaboration bridges where researchers from diverse backgrounds can interact, share ideas, and collaborate on projects to amplify their collective knowledge and accelerate drug discovery. It has been observed that when individuals from different disciplines collaborate, they bring their unique methodologies, skillset, tools, and viewpoints to the table. This cross-pollination sparks innovation, often leading to breakthroughs that wouldn't

have been possible otherwise. For instance, integrating computer science with pharmaceutical research has opened doors to advanced simulations, data analysis, and artificial intelligence-driven drug design.

5.3. Bench to Bedside approach- Translating Research to Practice



The world's top pharmaceutical education and research institutions and universities distinguish themselves from the normal pharmaceutical institutes through their steadfast commitment to bridging the gap between benchside innovation and bedside application through the dynamic process of translational research. Over the time, these institutions develop the capabilities and expertise to fundamental discoveries into tangible solutions for the needy patients and healthcare professionals. Their projects often begin with a deep understanding of the clinical context, ensuring that research efforts align with unmet medical needs and have the potential to improve patient well-being. Translational pharmaceutical research institutes foster bi-directional learning using clinical insights to develop basic research framework and vice versa.

A continuous feedback mechanism between researchers and clinicians enhances the relevance of research projects and ensure they remain closely aligned with real-world healthcare needs. Top-ranking pharmaceutical

institutions also boast unparalleled expertise in designing and conducting clinical trials and have capabilities to navigate the complex landscape of regulatory approvals, ethical considerations, patient recruitment, and data collection to ensure the highest standards of research integrity.

5.4. State of Art Infrastructure and Cutting-Edge Facilities

Access to advanced tools, technologies and facilities is crucial for conducting innovative pharmaceutical research and development. In the dynamic realm of pharmaceutical education and research, staying at the forefront demands not only original thinking minds but also state-of-the-art facilities that facilitate groundbreaking discoveries. The world's top-ranking pharmaceutical institutes understand that cutting-edge facilities are the bedrock of innovation, enabling researchers and students to push the boundaries of scientific understanding and therapeutic advancements. Therefore; these institutes invest heavily in state-of-the-art laboratories, equipment and technology to facilitate advanced drug development processes. Many of the laboratories of such institutes are accredited and certified by reputed accreditation and certification bodies. With the evolving technology landscape, these institutes keep investing in adopting emerging technologies, updating equipment, and renovating laboratories to ensure that researchers have access to the latest tools and environments conducive to innovation. These institutions either have all facilities under one roof or have strong collaborations with various industry partners to not only screen the drug candidates but also take the identified drug candidates through preclinical testing, early-phase clinical trials and if successful, the larger-scale clinical trials required for regulatory approval

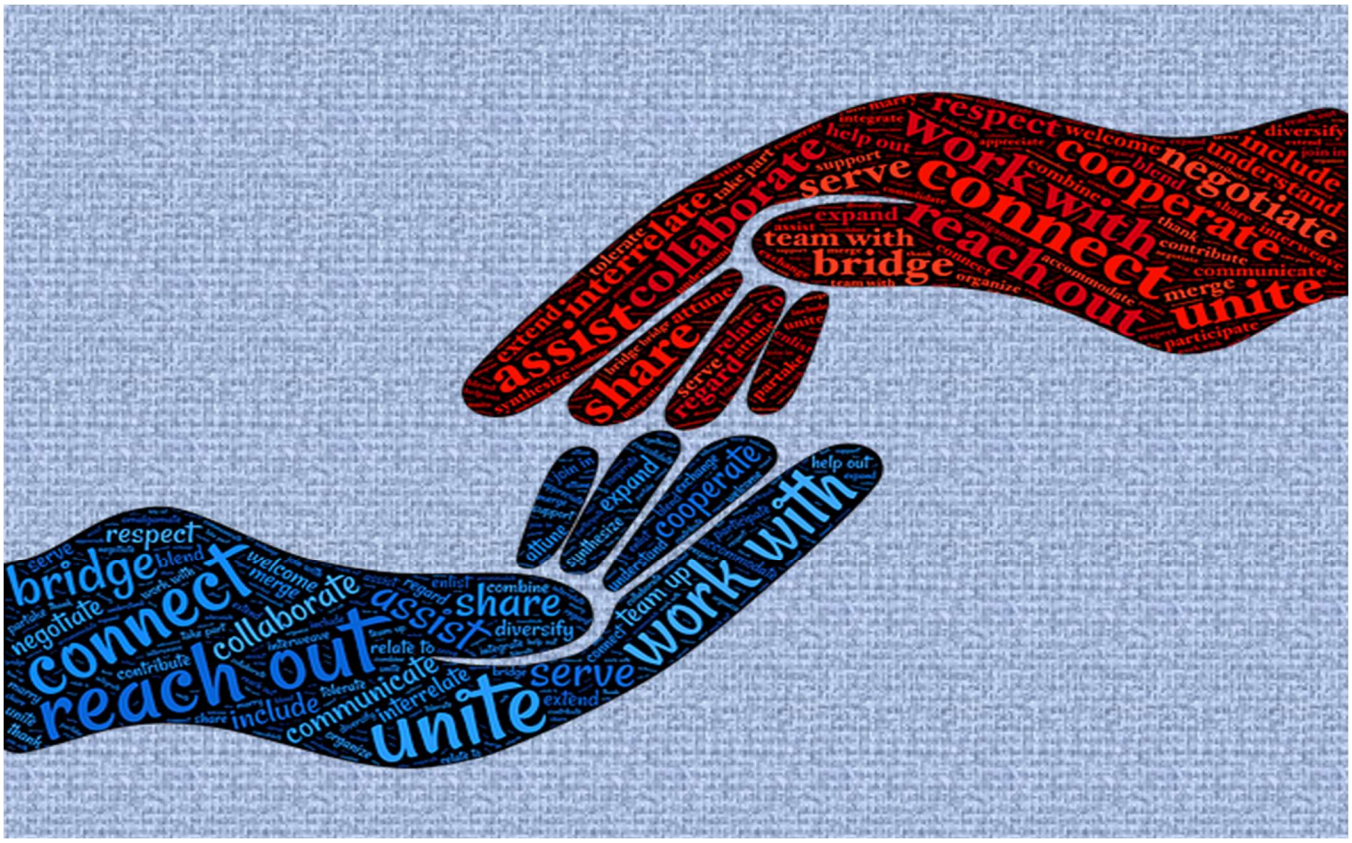
of drugs. Institutes that engage in nanotechnology, drug delivery research, and biopharmaceutical production require specialized cleanroom facilities All top-ranking pharmaceutical institute are advanced laboratories equipped with cutting-edge latest instruments which cater to various disciplines, from chemistry and biology to pharmacology and biotechnology. Modern spectrometers (LCMS- MS and HPLCs), imaging equipment (electron microscopy, confocal microscopy, and cryo-electron microscopy), High-throughput screening systems, and Next-Generation Sequencers are indispensable tools that empower researchers to conduct intricate experiments and collect high-quality data in pharmaceutical research. The top pharmaceutical research institutes also have been increasingly using computational methods for drug design, molecular modeling, and data analysis. For preclinical studies and drug testing, GLP compliant animal facilities equipped with appropriate housing, veterinary care, and research support are available in the top pharmaceutical research institutes for enabling the researchers to evaluate the safety and efficacy of potential therapies before advancing to clinical trials. Many top pharmaceutical institutes focusing on vaccines, biosimilars, therapeutic proteins and monoclonal antibodies, gene therapies also maintain very high-end bioprocessing laboratories.

5.5. Top-Notch and Distinguished Faculty

Top pharmaceutical institutions are distinguished by the expertise and accomplishments of their faculty members in terms of their knowledge, research publications, and participation in cutting-edge projects. In the pursuit of groundbreaking discoveries, transformative advancements and the nurturing of future pharmaceutical leaders, the strength of faculty in pharmaceutical education and research institutions is a paramount factor. The top pharmaceutical research and education institutions understand that their faculty members are not only educators but also catalysts for innovation, shaping the course of pharmaceutical scientific progress and influencing the next generation of pharmaceutical professionals. The impact of strong faculty in these institutes extends far beyond their tenure. The faculty members of the institutions are not only the knowledge pioneers in their field of respective pharmaceutical research but also the inspirational mentors who pass on their practical wisdom and

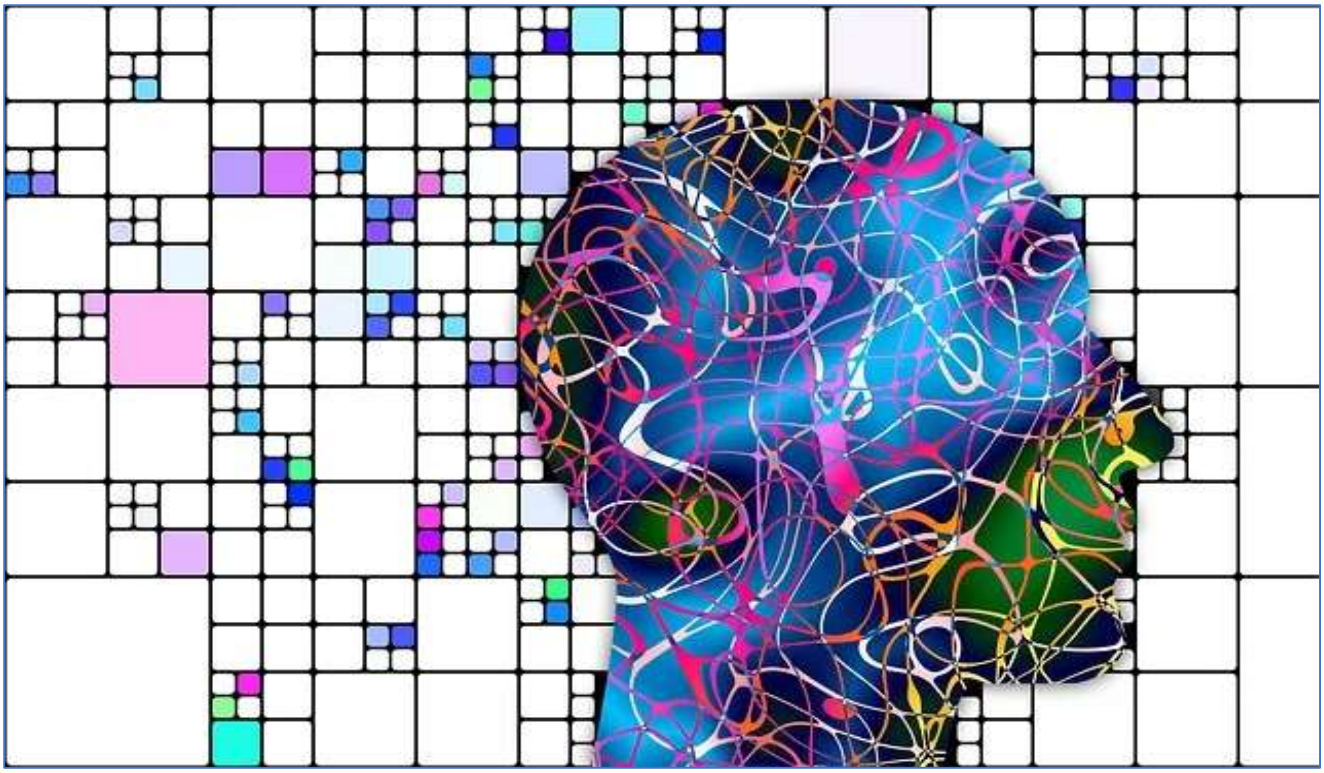
values like critical thinking, ethical conduct and perseverance to the next generation of pharmaceutical professionals. The credibility and influence of these faculty members attract top-tier students, research funding, and strategic partnerships, solidifying the position of such institution as a leader in pharmaceutical education and research.

5.6. Industry Collaboration:



Industry partnerships create avenues for students of top pharmaceutical institutes to engage in internships, job shadow programs and collaborative projects. This exposure allows students to gain practical experience, understand industry workflows, and build networks that can open doors to future career opportunities. Collaborations with pharmaceutical, biotechnology and medical device manufacturers provide access to funding, resources, and expertise necessary for taking research findings from concept to commercialization. In an era marked by rapid scientific advancements and a global drive for healthcare innovation, the symbiotic relationship between academia and industry has become more vital than ever. This alignment with industry priorities encourages researchers of top pharmaceutical institutions to pursue projects with a clear path to commercialization, ensuring that research outcomes have a tangible impact on patient care and healthcare systems. It also works as an external validation of the research conducted in academic settings and the adoption of research outcomes by pharmaceutical companies underscores the quality and relevance of the institute's work, bolstering its reputation within the scientific and industrial communities.

5.7 High Quality Research Output



Top pharmaceutical education and research institutions consistently produce high-quality research output to demonstrate their commitment to pushing the boundaries of scientific understanding. Each publication becomes a building block in the edifice of knowledge, contributing to a collective effort to unravel the complexities of diseases, drug mechanisms, and medical interventions. Top pharmaceutical educational and research institutes prioritize the dissemination of their findings through patents, presentations and publications in reputable scientific journals. The journals further undergo rigorous peer review processes, ensuring that published research meets high standards of accuracy, validity, and significance. Publishing in such journals not only validates the quality of the research but also provides a platform for reaching a wider audience of experts and peers through citations. The interplay between reputable scientific journals, citations, and the quality of research not only shapes the pharmaceutical institute's reputation but also influences the trajectory of pharmaceutical science, driving it forward toward transformative discoveries and innovations that have far-reaching implications for pharmaceutical and healthcare sector. For example, John Hopkin University has nearly 3,700 patented inventions and ideas ready to go. University is dedicated to using best ideas to improve the lives of people around the world. From potable water in the 1920s to 21st-century prosthetic limbs, their innovations contribute to the common good. Their discoveries also generate funding to pay for even more research. John Hopkin's had 3,692 active patents in fiscal year 2022, when the university's inventions generated $32.1 million in licensing revenue with the guidance of Johns Hopkins Technology Ventures. These active patents held by Johns Hopkins today could become lifesaving medical devices and therapeutic treatments tomorrow. As new technologies, new companies, and new alumni launch from Homewood and East Baltimore campuses, Baltimore continue to become a growing hub for innovation, a community working to support and fuel entrepreneurial growth. They have more than 43,000 square feet of incubation space in out two Baltimore innovation hubs, providing co-working options, private offices, and shared lab spaces that enable students, startups, and entrepreneurs to take their ideas to the next level.

5.8. Research Ethics

Top Pharmaceutical research institutes follow Ethical research practices to essentially maintain the integrity of scientific research. Ethical research ensures the reliability and accuracy of data collected during the scientific experiments. This reliability is critical for assessing the safety and efficacy of drugs and making informed decisions about their approval and use. Falsifying data or manipulating results can have severe consequences including harm to patients and undermining public trust in the pharmaceutical industry. Ethical conduct in research helps the top pharma institutes in build trust among research community, international journal publishers, healthcare providers, regulatory agencies, and the general public.

5.9. Global Collaborations in Pharmaceutical Research

- Global collaborations instill a global mindset among researchers, fostering an awareness of the interconnectedness of scientific endeavors and the potential for collective impact on a global scale. The top pharmaceutical research and education institutes have the capacity to transcend geographical, cultural, and disciplinary boundaries harness the power of collective knowledge, diverse perspectives, and shared resources to advance the frontiers of pharmaceutical science. These institutions forge partnerships with research institutions around the world ensuring exchange of knowledge, insights and methodologies. Global collaborations also facilitate the pooling of resources, talents, and expertise to help in leveraging

each other's expertise in different phases of drug development, from target identification and optimization to preclinical testing and clinical trials. For example, Monash University and Moderna have recently formed a partnership to advance homegrown mRNA medicines.

5.10. International Students and Faculty

International faculty and students contribute significantly to an institution's quality, diversity, research output, global reputation, and overall competitiveness. They are often considered important factors in world university ranking systems, which seek to assess and recognize universities' global impact and contributions to higher education on a global scale. A diverse student body and faculty contribute to a rich and dynamic learning environment that prepares graduates to work in diverse and multicultural settings. For example, in University College London (UCL) about 53% of the students come from countries outside the UK.

Similarly, the international faculty's exposure to different teaching styles and academic traditions can broaden students' horizons. Collaboration among international faculty and students can lead to research partnerships, joint projects, and publications that have a global impact. Pharmaceutical Research institutes benefit from a diverse pool of talent and ideas, which can lead to breakthroughs in pharmaceutical field. International students of the top pharmaceutical institutes become alumni who maintain connections with the institutes and contribute towards fundraising and future networking efforts

6. CURRENT STATUS OF NIPERs ON MAJOR BENCHMARK PARMETERS

6.1. Infrastructure:

S. No	Name of Institute	Establishment Year	Status of Campus/ Area	Research Focus
01	NIPER, Mohali	1998	Own Campus spread over 130 Acres in Mohali, Punjab.	• Neglected Diseases • Infectious diseases • AMR • Anti-Cancer • Lifestyle disease
02	NIPER, Hyderabad	2007	Currently operating from old IDPL campus. Another 50-acre land allocated for new campus construction	• Drug Discovery & Product Development Programmes • Cancer, Inflammation & related proliferative diseases • Anti - Diabetes & metabolic disorders • Infectious diseases • Autoimmune disorders • In vitro and in vivo screening • Development of novel Process for NCEs, Bulk Drugs and Intermediates • Development of Analytical Methods, Impurity Profiling and Stability studies • Solid state characterization • Targeted drug delivery systems
03	NIPER, Kolkata	2007	20.55 acres of land of BCPL's allocated for new campus. About 10 acres of land in, Distt. Nadia offered by Govt. of WB.	• Drug development and delivery system • Biomaterial optimization for Medical Devices • Biosensor development • Advanced dosage forms manufacturing of dosage forms • Neglected Diseases • Infectious -diseases • AMR • Anti-Cancer • Lifestyle disease
04	NIPER, Guwahati	2008	Own campus spread over 51.42 acres of land.	• Target-based and Phenotype drug delivery • Anti-cancer, Inflammatory, respiratory, Neurological, Fibrotic, cardio-renal, infectious and Anti - Diabetes • Toxicological Studies • Design, development, optimization, and evaluations • API/KSM/intermediate Synthesis etc. • AM-driven next generation personalized medicines

				• Nanomedicines, nano/microemulsions & targeted drug delivery systems • Pharmacological & Toxicological Studies • AI/ML modelling • API/Key-intermediate Synthesis, Phytopharmaceuticals, etc. • Impurity profiling, proteomics, metabolomics, stability testing, etc. • Pharmacovigilance, Tribal health, etc. • Medical devices, biosensors & actuators
05	NIPER, Ahmedabad	2007	Own Campus Spread over 60 Acre of land in Gandhinagar. Currently Operating from transient campus in same area.	• Medical Devices • API/ Excipient compatibility studies • Analytical Studies • Pharmacological and toxicological Studies • Anti-cancer, neuro-diabetic • Medicinal Chemistry
06	NIPER, Raebareli	2008	Rented Campus in outskirts of Lucknow 49 acres of land allocated in Raebareli for new campus	• Neurodegenerative diseases • Heavy Metal Toxicity • Japanese Encephalitis • Tuberculosis • Development and evaluation of drugs using Nano formulations. • Development of green & eco-friendly synthetic methods
07	NIPER, Hajipur	2007	Rented Campus 12.5 Acre land allocated in Hajipur for new campus.	• Infectious disease & AMR • Nanotechnology • Pharmacovigilance & Materiovigilance • Anti-Cancer & neurological disorders • Herbal, synthetic and biological products • In-vivo/ex-vivo & In-vitro characterization • Targeted drug delivery system • Pharmaceutical Analysis

6.2 Main Equipment & status of LIMS:

S. No	Name of Institute	Main Equipment	Status of LIMS
01	NIPER, Mohali	600 MHz NMR, 500 MHz-LCNMR, HR-TEM ESI/APCI-UHPLC-HRMS, VARIABLE PRESSURE SCANNING, CONFOCAL, ATOMIC SPACE MICROSCOPES, X RAY DIFFRACTION (XRD), REAL TIME IN VIVO OPTICAL IMAGING, GCMS, HEAD SPACE GC CAPILLARY ELECTROPHORESIS MALDI TOF – TOF FREEZE DRYER/SPRAY DRYER LC-MS, SUPERCRITICAL FLUID EXTRACTOR, UPLC, MPLC, HPTLC THERMAL GRAVIMETRIC ANALYSIS (TGA), HYDROGENATION REACTORDIFFERENTIAL SCANNING CALORIMETRY MULTIPLE ORGANIC SYNTHESIZER FLOW CYTOMETER , PEPTIDE SYNTHESIZER, BIOCHEMISTRY ANALYZER	No online LIMS Only log books are maintained.
02	NIPER, Hyderabad	NMR, LC-MS QTOF, UPLC, HPLC, ATR-FTIR, GC-MS, ICP-MS, PREP LC, Benchtop mass spectrometer, UV NIR, Particle Size Analyser, Freeze Dryer, High Pressure Homogenizer, Rheometer, Spray Dryer, SEM Facility, Hot Melt Extruder, Texture Analyzer, Tablet Coating Machine, TGA, DSC, PXRD, Fluorescence Microscope, Whole Body Plethysmography, Chemdoc, Fully Automated Rotary Microtome, Micro Ultracentrifuge, Confocal Microscope, Extracellular flux Analyzer, Parafin tissue Embedding system, RT -PCR, Bead beating Grinder and Lysis system MP Biomedicals fastprep-24, Stereo Microscope, IR Actimeter	No online LIMS Only log books are maintained.
03	NIPER, Kolkata	Q-Tof LC-HRMS, Q-Tof LC-MS , HPLC (Shimadzu and Agilent), FACS , NMR (400 MHz), 400 MHz NMR, CD Spectrophotometer, Auto Analyzer Automatic Tissue Processor, ITC, Flash Chromatography, Electrochemical Workstation, Inverted Fluorescence Microscope, Centrifuge, Ultra-Weighing Balance, CO2 Incubator, UV-Visible Spectrophotometer, FACS, Rotary Evaporator, Lyophilizer, Chemi Doc Probe Sonicator, QPCR, Electroporator, Thermocycler, BOD Incubator, Plethysmometer	No online LIMS Only log books are maintained.

04	NIPER, Guwahati	3D Printers, UHPLC, DSC, TGA, XRD, SEM, NMR, UV-VIS, FTIR, Dissolution & diffusion test apparatus, Mastersizer, Zetasizer, Spray dryer, HME, Inverted Fluorescence Microscope, Confocal Microscope, Animal Imaging, micro-CT, GCMS, UPLC/ESI/MS/MS, HPLC, tablet compression machines, etc.	No online LIMS Only log books are maintained.
05	NIPER, Ahmedabad	Chromatographies, Ultracentrifuge Thermogravimetric Analyzer, UV Plate Reader, Microscopes, CO2 Incubator, RT-PCR, Blot unit, Centrifuge, Synthesizer, Deep freezer, Melting Point Apparatus, Fumehood, Sonicator, Hypoxia Chamber, Passive avoidance apparatus, Refrigerated Centrifuge, Rotarod Apparatus, Vibratoem Paraffin Embedder, Microtome, Granulator, Auto-coater, Hot stage Microscope, Rheometerm Magneto Meter, Stroke apparatus.	No online LIMS Only log books are maintained.
06	NIPER, Rae Barelli	NMR, Zetasizer, HPLC, Bio analyzer, DSC, LC-MS, Hot Stage Microscope, Flow-cytometrym Animal Imaging System, Lyophilizer, Calorimeter, CD Spectrometer, Probe Sonicator Confocal System, FT-IR Spectrometer, Cary Eclipse, 12-cell cary 100UV, Multi-mode Plate reader.	No online LIMS Only log books are maintained.
07	NIPER, Hajipur	Multimode reader, HPLC (3 units)– 5 detectors (UV, PDA, FL, RI, ELSD) Preparative HPLC (CAD detector) Fluorescence spectrophotometer 3D Cell culture with clean room, DSC, ITC, Nanoparticle Tracking analyzer, Disc Centrifuge based particle analyzer, Texture analyzer, GC-MS QQQ, 3D Cell culture with clean room facilities, Stereotaxic Instrument, Biochemistry analyzer Inverted Fluorescence microscope (with 3 FL filters, 2 units), Rheometer, DLS	No online LIMS Only log books are maintained.

Source: Websites of NIPERs and Annual Reports

6.3. Accreditations of Laboratories:

S. No	Name of Institute	Accreditations/Certifications of Laboratories	Scope of Certification
01	NIPER, Mohali	GLP certification Issued by: NGMCA No: GLP/C120/2018	Toxicity studies in rodent species only • Acute Toxicity Studies • Sub-acute Toxicity Studies • Chronic Toxicity Studies.
02	NIPER, Hyderabad	ISO 17025:2017 Issued by: NABL No: TC-9777	Analytical Testing • Folic Acid • Paracetamol (API) • Paracetamol (Tablets)
03	NIPER, Kolkata	None	Not Applicable
04	NIPER, Guwahati	None	Not Applicable
05	NIPER, Ahmedabad	QMS (ISO 9001:2015) Issued by: BSCIC No:BN21670/20994 MDQMS (IS0 13485) Issued by: BSCIC No:BN21671/20990	Testing of trace impurities in Pharmaceutical KSM/Intermediates/API, Excipients, Formulations, Medical Devices, Testing of Implants and accessories (IAF scope:34 &38) Testing of Raw Material and Finished orthopaedic implants i.e., Bone plates, Bone Nails, Bone Screws, Spinal implants and Hip systems. TA: A.1.1.12
06	NIPER, Raebareli	None	Not Applicable
07	NIPER, Hajipur	None	Not Applicable

Source: Websites of NIPERs and Annual Reports

6.4 Manpower

S. No	Name of Institute	Number of Faculty/ Teaching Resources	Student to Faculty ratio
01	NIPER, Mohali	28	30:1
02	NIPER, Hyderabad	10	20:1
03	NIPER, Kolkata	14	15:1
04	NIPER, Guwahati	27	14:1
05	NIPER, Ahmedabad	19	23:1
06	NIPER, Rae Barelli	18	16:1
07	NIPER, Hajipur	13	16:1

Source: Websites of NIPERs and Annual Reports

6.5. Annual Funding (From Department of Pharmaceuticals)

Year	Mohali	Ahmedabad	Guwahati	Hajipur	Hyderabad	Kolkata	Raebareli	Total
2018-19	29.00	12.00	33.50	9.50	24.00	12.00	15.00	**135.00**
2019-20	30.60	18.50	43.90	5.00	27.00	18.00	17.01	**160.01**
2020-21	60.55	60.50	79.45	26.00	44.50	34.82	28.00	**333.82**
2021-22	51.00	54.00	59.45	41.00	72.91	47.64	46.00	**372.00**
2022-23*	43.05	28.00	32.00	15.00	29.00	15.75	14.50	**177.30**
Total	**214.20**	**173.00**	**248.30**	**96.50**	**197.41**	**128.21**	**120.51**	**1178.13**

*Till Dec,2022 Source: DoP Annual Report 2022-2023

6.6. Courses Offered

NIPERs offer a wide range of academic programs, including Master of Pharmacy (M. Pharm), Master of Science (MS), Master of Technology (M. Tech), M.B.A, Integrated PhD and Doctor of Philosophy (Ph.D.). These programs cover various specializations such as pharmaceutical chemistry, pharmacology and toxicology, pharmaceutics, regulatory affairs, biotechnology, Natural Products, Pharmacoinformatics, Medicinal Chemistry, Medical Devices and Pharmaceutical Management.

6.7. Admission Eligibility Criteria:

The admissions to various branches in MS/PhD in all the seven NIPERs are made through a common Joint Entrance Examination (JEE) held every year in the month of June/July. The applicants, who qualify the Graduate Pharmacy Aptitude Test (GPAT), are eligible to appear in the common JEE examination. Successful candidates of JEE get admission in NIPERs through Counselling. Admission Procedure for M.B.A. (Pharm.) is slightly different. Based on the performance in the written test, list of candidates are called for GD/interview. Combining 85% of written and 7.5% of GD and 7.5% % of interviews candidates are finally called for Counselling. From this year onwards, for the Masters courses in Medical Devices it has been proposed to conduct a separate entrance test which will allow the students with engineering background also to appear for the entrance test. All Master degree students (except for MBA Pharmaceutical management) students receive fellowship of INR 12,400/- per month.

The PhD students get a fellowship of INR 31,000- 35,000/ - per month. The NIPERs also have the provision to take the PhD students whose fellowship is sponsored by other government agencies like Department of Biotechnology, Department of Science and Technology, ICMR and CSIRs.

6.8. Annual Student Intake Capacity

S. No	Name of Institute	For PG courses	For PhD.
01	NIPER, Mohali	283	63
02	NIPER, Hyderabad	229	62
03	NIPER, Kolkata	88	26+2
04	NIPER, Guwahati	379	103
05	NIPER, Ahmedabad	162+26	44
06	NIPER, Raebareli	110	28
07	NIPER, Hajipur	91	40

6.9. International Faculty & Students

S. No	Name of Institute	Number of current international faculty	Number of current international students	Nationalities of International students
01	NIPER, Mohali	0	0	Till 2009 students were there mainly from African regions
02	NIPER, Hyderabad	0	0	No International students from any countries till now.
03	NIPER, Kolkata	0	0	No International students from any countries till now.
04	NIPER, Guwahati	0	0	No International students from any countries till now.
05	NIPER, Ahmedabad	0	0	No International students from any countries till now.
06	NIPER, Raebareli	0	0	No International students from any countries till now.
07	NIPER, Hajipur	0	0	No International students from any countries till now.

6.10. Examination System of NIPERS:

The Masters courses namely M.S. (Pharm.), M.Pharm., M.Tech. (Pharm.) and MBA (Pharm.) are of 4 semesters. 1st and 2nd semesters are devoted to course work to give appropriate thrust to the areas under study. Semester 3rd and 4th are prepared in such a manner to give optimal exposure to theoretical and practical experience. The course of study culminates in practical aspects followed by dissertation and consummates in defence of thesis. This kind of potential framework seeks to equip the students with updated knowledge and emerging trends in epistemology. NIPERs also runs MBA(Pharm.) comprising of 4 semesters are succinctly dedicated to theoretical parameters alongside practical exposure through training. This course caries 100 credits with focus on placement of the students. The Ph. D courses at NIPER comprises two categories i.e. Pre-NIPERIAN and others. The Pre-NIPERIAN scholars are mandated to obtain 12 credits while others are required to earn 28 credits out of which 12 credit shall be in the doctoral programme. The doctoral programme spans 5 years initially and detoured through expert reviews in the form of SRC etc. and finally the research work permeates in the form of thesis which is evaluated by two examiners, one Indian and other foreigner. On the basis of composite report, open defence is conducted as per the norms in force.

6.11. Placement Records (Master's Degree)

S. No	Name of Institute	Average CTC M. Pharm/ M.S Pharm/ M. Tech (INR)	Major Recruiters
01	NIPER, Mohali	7.25 LPA	ZS Associates Pvt. Ltd., Dr. Reddy's Laboratories, Bain Capability Network, Accenture, GDS-EY Global Service, Aspect Ratio, IQVIA, Merck (MSD), Baxter, Alkem Laboratories, Axteria, Evalueserve, Xogene, Sentiss Pharma Pvt. Ltd., Novartis, Neuland Laboratories, Lupin, Solutionec Pvt. Ltd., BIOCON, WNS Global Services (P) Ltd., Infosys, UPL Limited, Sun Pharma ,Indegene, Sanofi, Aragen Life Sciences, MU-Sigma, Macloeds, Granules India, Zydus Lifesciences Limited, Meril Life Sciences, Maven Profcon Services LLP, Serum Institute of India, Phyto Life Sciences, Georgia Institute of Technology, UCONN the Graduate School, University of the Pacific Parul University, Vadodara, Gujarat, India, Texas A&M University Kashiv Biosciences Pvt. Ltd., LSC Lifesciences Consultants,Parexel, Boehringer Ingelheim, Syneos Health, Sravathi Advance Process Technologies Pvt. Ltd.
02	NIPER, Hyderabad	8.5 LPA	Johnson & Johnson, Novartis, Dr Reddy's Laboratories Ltd., Genpact, Hetero, Tech Mahindra, Granules India, Syngene, Springers Nature Publishing, Eli Lilly, Cipla, Sai life Sciences, AMRI, ViVo Biotech, Credo Life Sciences, Cognizant Healthcare, Mylan, Gentech, Shasun, Lupin, Aurobindo, Biological E, Aizant, Cognizant Health care, Core Diagnostics, Aurobindo, Macleods Pharmaceuticals, Roche etc.
03	NIPER, Kolkata	5 LPA	Intas, Schrodinger, WNS Global Services, Aragen Life Sciences, Jubilant Pharmova, Sravathi Advance Process Technologies Pvt. Ltd Vivo Biotech Ltd
04	NIPER, Guwahati	4.5 LPA	Viatris, Dr. Reddy's, Gland Pharma, MacLeod's, GVK-Bioscience, Syngene, Novartis, Aragen, Novo Nordisk, Indegene, Sai Lifesciences, AMTZ, Cognizant, Macleods, etc.
05	NIPER, Ahmedabad	5.59 LPA	Audree, Bharat serum, Xogene, Evalueserve, Aragen, Eli Lily, Freyrs Solutions, Genpact, WNS, Tech Mahindra, Granules, J&J, IQVIA, Keva, Mylan, Novartis, PharmaAce, Hetero, Syngene, ZS associates, Peter Surgical.
06	NIPER, Raebareli	4.04 LPA	Genesis, Aurigene, ToxIndia, Intox, Mu Sigma, JODAS, Torrent Pharma, Sun Pharma, Aten Porus, Eugia, GSK, Sai, Novo Nordisk
07	NIPER, Hajipur	5 LPA	Novartis, Aurobindo, Fryer solutions, IQVIA, Indigene, Taj Pharma, Johnsons & Johnsons, ICMR-RMRIMS (JRF), AIIMS (JRF), Panacea Biotech, Mankind Pharma, TCS, GeneSys, Cognizant, Delveinsight, Cadila, APCER, Parexel, etc

6.12. Research Publications & Citations:

S. No	Name of Institute	Number of Research Publications in last year	Areas of research
01	NIPER, Mohali	134	Leishmaniosis, tuberculosis, and malaria; Metabolic pathways in diseases like inflammation, infection, cancer, diabetes, obesity, Parkinson's disease, neurodegeneration; API, KSM, Intermediates, Herbal Drug formulation; Toxicological Studies, Chemo-enzyme synthesis; Epigenetic; HEOR and Pharmacovigilance etc.
02	NIPER, Hyderabad	158	Application of Nano technology as biosensor, Micro and Nano scale technology, Pharmacovigilance and Materiovigilance, Medication safety and drug utilization, Infectious disease & AMR, clinical efficacy and safety studies, pharmacogenetic and biomarker studies, Development of pharmacologic, genetic, and stem cell-based interventions, identification of simple, cost-effective and easy to use biomarkers for detection, prognosis, and therapeutic assessment of various disorders, pharmacokinetic based and toxicological studies on herbal, synthetic and biological product; in vitro & ex–vivo/ in-vivo characterization of API & formulation, LC-HRMS based proteomic profiling, Natural Product profiling/ identification etc.
03	NIPER, Kolkata	81	Drug Delivery system and 3D Printing, Biomaterial Optimization, Biosensor development, Advanced Manufacturing, Sphingosine inhibitor development, API Synthesis, Structural Bioinformatics, anti-microbial agent designing, small molecule bioengineering, phytopharmaceutical and herbal formulation, Genome editing, Phytochemistry, etc.
04	NIPER, Guwahati	145	Target-based and phenotype-based drug discovery, Genetically modified bacteria, pharmacogenetics and personalized medicine, Disease mechanism, various Cancer based studies, basic biology, Biopharmaceutical Technology, screening of small molecules ; physiological, pharmacological, toxicological, and nutritional basis of disease and therapeutics; Clinical and Translational, Biomarkers Discovery, Pharmacogenomics, Clinical Studies to Diseases Management Programs, Medication Utilization & Medication Safety Evaluation, Tribal

			Population Health, Health Economics and Outcomes, Evidence Synthesis, Dosage form design, development, optimization, and evaluations, Biosensor, Nano biotechnology, cold plasma technology; drug delivery system; herbal product development; etc
05	NIPER, Ahmedabad	108	Genetic profile and Biomarker identification, Molecular mechanism dissection , Cancerous cell studies, Hippocampal sAHP modulation in temporal lobe epilepsy, Ischemic brain Injury, novel polymeric nanomaterial development, Formulation development, NIR laser activatable Nanoplates/Nanoseeds, Neuropathic / inflammatory pain and spinal cord injury studies, neurological studies, Excipient/API/ NCEs related studies, Complex injectable Ophthalmic formulation and characterization, Spinal cord regeneration, Peptide and peptidomimetics based soft material, construction of drug candidates, Targeted Therapy, Etc.
06	NIPER, Raebareli	81	Neurodegenerative diseases, Heavy Metal Toxicity, Japanese Encephalitis, Tuberculosis, Development and evaluation of drugs using Nano formulations, Development of green and eco-friendly synthetic methods
07	NIPER, Hajipur	43	Infectious disease, AMR, Nanotechnology as a biosensor, Micro and nano scale technologies, Pharmacovigilance and Materiovigilance, safety and drug utilisation, pharmacologic, genetic, and stem cell-based interventions, simple, cost-effective, and easy-to-use biomarkers for detection, prognosis, and therapeutic assessment of neurological disorders, cancer, diabetes, and infectious diseases, In-vitro & ex-vivo / in-vivo characterisation of API & formulations, LC-HRMS-based proteomics profiling of microbial, animal tissue, and human serum, Natural product profiling/identification secondary metabolite, Industry-relevant analytical method development etc.

6.13. Patents and Technology Transfers & Products commercialized

S. No	Name of Institute	Number of granted Patents in last year	Number of Technology transfers done in last year	Number of commercialized products in last year
01	NIPER, Mohali	8	0	0
02	NIPER, Hyderabad	6	0	0
03	NIPER, Kolkata	1	0	0
04	NIPER, Guwahati	6	0	0
05	NIPER, Ahmedabad	0	0	0
06	NIPER, Rae Barelli	4	0	0
07	NIPER, Hajipur	3	0	0

(According to compendium report for year 2022)

7. BENCHMARKING OF NIPERS WITH TOP PHARMA INSTITUTES

7.1 Comparative Analysis of NIPERs with Top Ranked Institutions:

- NIPER Mohali is the only institute among all NIPERs which has secured a rank among top 50 pharmaceutical institute in pharmacy/pharmacology category as per QS ranking of year 2022. Below is the comparative table of its relative ranking with top 5 institutes as per QS rankings in the year 2022 and 2023:

Rank in 2023	Rank in 2022	Institution	Location	Academic Reputation	Employer Reputation	Citations per Paper	H Index	International Research Network	Score
1	2	Harvard University	United States	93	100	93.2	100	96.2	95.5
2	1	Monash University	Australia	100	82.2	93	95.7	69.6	92.9
3	3	University of Oxford	United Kingdom	89.4	98.1	95.6	99.2	81.3	92.7
4	4	UCL	United Kingdom	85.1	84.9	94.6	99.9	89.3	90.4
5	8	Johns Hopkins University	United States	82.9	90.4	91.9	95.3	85	88.1
54	44	NIPER, Mohali	India	75.7	68.7	94.8	89.8	24.9	76.6
101-150	101-150	BITS, Pilani	India	67.5	70.8	86.8	83.4	28	<72.8
101-150	101-150	Jamia Hamdard, New Delhi	India	66.5	41.9	92	86.9	26.2	<72.8
101-150	101-150	JSS Academy Bangalore	India	73.2	75	77.6	77.8	24.2	<72.8
101-150	101-150	MAHE, Manipal	India	67.9	67.5	79.4	81.1	31.8	<72.8

Source: QS Ranking 2023 (Field: Pharmacy)

Following inference can be drawn from the above table:

- NIPER Mohali is nearly at par with worlds top 5 institutes on the parameters like Citations per paper and H index.
- NIPER Mohali has fairly performed on the parameters of academic reputation.
- The criterion of Employer reputation is the area of improvement for NIPER Mohali.
- The IRN criterion is an area of concern for NIPER Mohali as the absence of international students, international faculty and international collaborations is a barrier in further improvement of its ranking in the QS Ranking system.

The other 6 NIPERs need consider themselves as new entrants and start working on the below mentioned eligibility criteria for consideration in the QS ranking system:

1	Regional Bar	NIPERs need to demonstrate performance in the Top 50% of regional ranking before being considered for the World University Ranking.
2	New Entrants	The respective NIPER should be in the global Top 30% in academic reputation.
3	Paper Threshold	For the QS World University Rankings, each NIPER should have at least 100 papers indexed by Scopus and published over a 5-year window. Only papers of relevant paper types and after the affiliation cap is applied are considered.
4	Small Size	All NIPERs are small size institutions (fewer than 5,000 students). Therefore, QS ranking system looks at the performance in Academic Reputation, Employer reputation and Citations per Faculty. More specifically, it needs at least one of the following conditions to be met for the last few editions: ● to be in the top 1,000 by all the indicators in the triple ● to be in the top 900 by all indicator pairs in the triple ● to be in the top 800 by any indicator in the triple

- There is no separate category for Pharmacy, Pharmaceutical science or Pharmacology in Times Higher Education (THE) ranking system. Considering NIPERs to be focussed on interdisciplinary research, the closest subject category in which NIPERs can apply is the biological sciences. None of the 7 NIPERs are listed among the top institutes as per latest THE rankings list.

- In the Shanghai Ranking's Academic Ranking of World Universities (ARWU), there is a subject category of Pharmacy and Pharmaceutical sciences. None of the 7 NIPERs appear among the top pharma institutes. However Indian Pharmaceutical institutions like University of Delhi, Academy of Scientific and Innovative Research (AcSIR) and Jamia Hamdard University are listed in the ranks ranging 301-500 in ARWU ranking system.

7.2 Comparative Analysis of NIPERs as per NIRF:

Ranking Parameters and Weightages as per NIRF Ranking (Pharmacy)

	Parameter	Marks	Weightage
1	Teaching, Learning & Resources (TLR)	100	0.30
2	Research and Professional Practice (RP)	100	0.30
3	Graduation Outcomes (GO)	100	0.20
4	Outreach and Inclusivity (OI)	100	0.10
5	Perception	100	0.10

The relative ranks of NIPERs in NIRF ranking for the last three years have been as per table mentioned below:

Institution	Rank (2021)	Rank (2022)	Rank (2023)	Variation
NIPER Mohali	**4**	**4**	**6**	**-2**
NIPER Hyderabad	**6**	**2**	**1**	**5**
NIPER Ahmadabad	**10**	**10**	**13**	**-3**
NIPER Raebareli	**13**	**27**	**14**	**-1**
NIPER Guwahati	**19**	**13**	**12**	**7**
NIPER Kolkata	**33**	**NA**	**32**	**1**
NIPER Hajipur	**NA**	**75**	**44**	**31**

On the basis of the above table, following inferences have been drawn:

- NIPER Hyderabad showed a considerable improvement in its rank from 2021-2023. From rank 6 it has jumped to rank 1.
- NIPER Mohali had a dip of 2 ranks from 4th position to 6th position.
- NIPER Ahmedabad and NIPER Raebareli have been in the rank range of 10-14.
- NIPER Guwahati showed a considerable improvement in its rank by 7 positions over the last three years.
- NIPER Kolkata showed a minor improvement of one rank from 33 to 32.
- NIPER Hajipur showed a considerable improvement of 31 ranks from rank 75 to rank 44.

Comparison among all NIPERs on various parameters of NIRF between 2021- 2023

Institute	TLR (100)	RP (100)	GO (100)	OI (100)	PERCEPTION (100)	Score	Rank
Year-2021							
NIPER Mohali	77.38	61.47	81.56	65.54	100	74.52	4th
NIPER Hyderabad	79.55	58.81	89.96	71.06	74.72	74.08	6th
NIPER Ahmadabad	73.19	51.4	73.85	65.4	46.25	63.3	10th
NIPER Raebareli	86.8	36.86	63.82	63	41.71	60.33	13th
NIPER Guwahati	67.16	31.6	74.59	57.7	54.07	55.73	19th
NIPER Kolkata	80.13	13.74	57.25	63.71	39.24	49.9	33th
Year-2022							
NIPER Mohali	81.42	61.57	83.59	65.51	96.08	75.78	4th
NIPER Hyderabad	91.13	57.88	95.5	72.57	83.91	79.46	2nd
NIPER Ahmadabad	86.28	49.57	62.91	67.81	47.35	67.83	10th
NIPER Raebareli	67.88	31.94	69.65	59.9	45.42	54.41	27th
NIPER Guwahati	81.49	34.58	79.62	57.04	49.2	61.36	13th
NIPER Hajipur	54.85	7.13	62.58	53.19	43.4	40.77	75th
Year-2023							
NIPER SAS Mohali	77.1	58.84	82.76	65.49	97.02	73.58	6th
NIPER Hyderabad	91.87	59.68	95.58	73.22	69.58	78.86	1st
NIPER Ahmadabad	82.79	42.94	77.45	64.06	46.17	64.24	13th
NIPER Raebareli	88.49	37.71	70.58	63.35	52.62	63.58	14th
NIPER Guwahati	85.27	45.15	81.07	57.2	52.62	66.32	12th
NIPER Kolkata	89.52	13.87	68.21	62.16	40.57	54.94	32th
NIPER Hajipur	78.49	22.55	63.42	55.75	26.46	51.22	44th

	Area of Improvement
	Performance improved as compared to earlier year's score

Following inference can be drawn from the above table:

- The considerable improvement of 5 ranks in NIPER Hyderabad to attain number 1 position in NIRF ranking can be attributed to improvement in the four out five parameters including TLR, RP, GO and OI. The improvement in TLR and GO is by a considerable margin. However, on the parameter of perception, the score of NIPER Hyderabad has decreased over the last three and also is much lower than NIPER Mohali in current year.

- The dip in ranking for NIPER Mohali's can be attributed to no major improvement in four out of the five parameters including TLR, RP, GO and OI scores as compared to NIPER Hyderabad. The perception score has been more or less excellent for NIPER Mohali as compared to other NIPERs.

- The dip in ranking for NIPER Ahmedabad can be attributed to no major improvement in two out of the five parameters including TLR and OI and perception scores as compared. The OI score OF NIPER Ahmedabad has improved over the last two years but still it is far much behind the current OI scores of NIPER Mohali and NIPER Ahmedabad.

- NIPER Raebareli more or less maintained its rank with fall of just 1 rank. The dip in ranking for NIPER Raebareli can be attributed to considerably lower score for RP and OI.

- NIPER Guwahati showed a good improvement of 7 ranks from 19th to 12th during the last three years. This was due to improvement in TLR, RP and GO by approximately 17, 14 and 7 points respectively. The OI and perception score have been more or less same.

- NIPER Kolkata showed an improvement of 1 rank which was mainly due to improvement in TLR by approximately 9 points. The RP, GO, OI and perception scores as compared to NIPER Hyderabad and NIPER Mohali.

- NIPER Hajipur showed a significant improvement of 31 ranks from 75 to 44 in the last three years. This was due to improvement in four out of five major the parameters including TLR, RP, GO and OI scores. Perception scores for NIPER Hajipur has decreased as compare to the year 2023.

7.3 Identified Best Practices & Areas for Improvement for NIPERs:

7.3.1 For improving Teaching, Learning & Resources (TLR)

- NIPERs should create provision for admitting more PhD students, especially students with their own fellowships (CSIR, ICMR, DBT etc) and should appropriate changes in ordinances to attract these students.
- NIPERS should also frame new admission policy to attract industry employees for PhD program.
- NIPERs should fill in all the allocated faculty positions as soon as possible.
- NIPERs should try to main a Ratio of Assistant Professor: Associate Professor: Professor as 1:1:1. Future recruitment should be planned with focused to achieve this ratio

- NIPERs need to increase the funding resources and work on getting the extramural research funding.

7.2.1 For improving Research and Professional Practice (RP)

- NIPERs should increase the number of patent Filings
- Increase in Annual research funding earnings by technology transfers, offering testing and knowledge consulting services to industry

7.2.3 For Improving Graduation Outcomes (GO)

• NIPERs need to strengthen its placement cell and should target 100 % placement of the students.

• NIPERs should maintain the information pertaining to the students getting off-campus placements and students pursuing the higher studies after completion of their degree.

7.2.4 For improving Outreach and Inclusivity

- NIPERs should focus on getting the international students, research scholars and faculty in their campus.
- Provision for adequate gender ratio in the campus.
- NIPERs should have a mechanism of collecting information about economically challenged and physically handicapped students.

7.2.5 For improving the Perception

Perception is a subjective assessment of NIPERs reputation and improving this parameter can be challenging because it is relies on all stakeholders including students, faculty, academic community, research circles, peer groups, employers and international collaborators. Improving perception for new NIPERs will take takes time and therefore it is essential to focus on long-term strategies. New NIPERs need to consistently demonstrate excellence in education and research while maintaining transparency and highest ethical research standards.

8. KEY GAP ASSESSMENT FINDINGS

- Except for NIPER Mohali and Guwahati, the other NIPERs are either operating from their transit campuses or the rented buildings. The construction of new NIPERs is in full swing and all permanent campuses are expected to be ready by 2025. Currently, the institutes like NIPER Kolkata which are operating from a heritage building have a limitation of making any modifications in the infrastructure like changes in false ceiling or necessary electrical wiring to meet increased power load of high-end research equipment. NIPER Hajipur faces issues like overall access to the institute, lack of uninterrupted power supply and industrial area related air pollution. NIPER Raebareli which is currently operating from its transit campus in Lucknow anticipates retention of the faculty and scientific staff as a challenge once their permanent campus comes up in Raebareli. NIPER Ahmedabad by virtue of its presence in an educational hub of Gandhinagar and having close proximity to pharmaceutical industry belt in and around Ahmedabad has a strategic advantage in terms of potential industry collaboration and better placement opportunities for the students.

- NIPERs offer the technical Masters, Integrated PhD and PhD degrees in various streams of pharmaceutical sciences like Medicinal chemistry, Pharmacology and toxicology, Pharmaceutics, Natural Products, Biotechnology and medical devices. Institutions like NIPER Mohali, Ahmedabad and Hyderabad also offer the M.B.A in Pharmaceutical Management. A new master's degree course in Biopharmaceuticals has also been conceptualized by some NIPERs which are planning the student intake from this year onwards. The admissions to various branches in MS/PhD in all the seven NIPERs are made through a common Joint Entrance Examination (JEE) held every year in the month of June/July. The applicants, who qualify the Graduate Pharmacy Aptitude Test (GPAT), are eligible to appear in the common JEE examination. Successful candidates of JEE get admission in NIPERs through Counselling. From this year onwards, for the Masters courses in Medical Devices it has been proposed to conduct a separate entrance test which will allow the students with engineering background also to appear for the entrance test. The students perusing their Master's degree (except for MBA pharmaceutical management) and PhD degree are provided with a stipend by Department of Pharmaceuticals during their course.

- All NIPERs are working on one or other cutting-edge technologies and have the inhouse latest machinery and equipment for carrying out the pharmaceutical research and development. All NIPERs have dedicated Central Instrumentation Facility/Laboratory which houses very high-end capital equipment like NMR, LCMS-MS, HPLC, Confocal Microscope, Imaging Systems etc. Some NIPERs also have the High Throughput Screening (HST) platforms used in the process of drug discovery. The NIPERs also have stream specific laboratories for fields like Medicinal Chemistry, Pharmacology and Toxicology, Analytical Chemistry etc. All most all NIPERs maintain their own CPCSEA approved animal houses for conducting the preclinical studies. In addition, institutes like NIPER Mohali have niche Technology Development Centres (TDCs) for API and Formulations and National Bioequivalence centre (NBC).

- Except for NIPER Guwahati which has substantial extramural research projects from DBT, DST, SERB, BIRAC, NMHS, ICMR, DRDO (> INR 40 crores), most of the NIPERs have limited external research funding sources. The sources of the funding for most of NIPERs are grants from DoP and few Indian government funding agencies. Most of the MoUs reviewed during the assessment were of non-functional nature,

primarily executed with government and academic research institutions and had no or limited financial consideration. However, NIPER Ahmedabad and Hyderabad were found to have a good number of MoUs with industry partners in addition to international academic research organisations.

- In spite of having the best and latest high-end equipment and utilities in the laboratories, it was observed that most of the NIPERs did not have any formal Quality Management System or Laboratory Management Systems in place, making them unsuitable for future industry collaboration or industry sponsored testing services. NIPER Ahmedabad was an exception to it as they maintained ISO 9001:2015 (QMS certification) and ISO 13485:2016 (MD-QMS certification) and were in the process of getting NABL (ISO 17025:2017) certification for an upcoming laboratory. NIPER Hyderabad had the NABL accreditation for ISO 17025:2017 for analytical testing laboratory but the scope of the testing was miniscule. Similarly, NIPER Mohali had the NGMCA GLP certification for its preclinical centre (Animal house) but the scope was limited to only toxicity studies in spite of having gone through multiple certification cycles.

- During the assessment it was observed that most of the sample load in the laboratories of NIPERs was inhouse and was either free of cost or highly subsidized. NIPERs need to work towards developing SOPs, implementing the QMS across institution and LMS in its laboratories, recruit the additional scientific and technical staff to ensure increase in the flow of industry samples and ensure optimum utilization of existing infrastructure and equipment.

- During the assessment it was observed that state of art facility like National Bioequivalence Centre (NBC) Mohali, was non-functional for more than fifteen years due to its inability to meet the regulatory requirements of CDSCO and additional requirements of manpower and inhouse bioanalytical equipment. Further Technology Development Centre (API) at NIPER Mohali needed a major upgradation to meet up the bare minimum GMP requirements of any industry sponsored project. However, it was observed that the upcoming Technology Development centre (Formulations) which is still under-construction at NIPER Mohali was being developed as per GMP norms, has the state of art infrastructure and can be a major service offering from NIPER Mohali to the industry.

- During the assessment, it was observed that the rates for some of testing services especially in NIPER Mohali were not at par with the current industry rates. For example, NIPER Mohali charges the industry more than INR 4500/sample for the bioanalysis of single analyte in plasma sample on LCMS. The normal market rate for same test in a CDSCO/GLP approved private laboratory is in the range of INR 800-1000. The exorbitant testing charges may be one of the non-starters for the pharmaceutical companies to approach the NIPERs for their testing requirements.

- During the assessment, it was observed that the NIPERs Kolkata, Hajipur and Raebareli had severe space constraints. Some NIPERs were running/ or planning to run the academic classes in makeshift classrooms (Prefabricated container rooms) for the new student batches. The student intake is expected to increase in NIPERs in the coming years and therefore there is need to add new classrooms with required AV tools/gadgets across all NIPERs. The other academic infrastructure like Faculty cabins, Auditorium, Seminar rooms, Hostels and Library etc also need to be adequately provisioned for in the newly built NIPER campuses.

- Considering the current available academic and research infrastructure, student intake in Masters and PhD degrees in NIPERs is on the higher side. There are currently no foreign students perusing their Masters or PhD degrees in any of the NIPERs. The absence of international students in NIPERs is one of the most important reason for NIPERs not appearing in the world's top most 50 pharmaceutical academic and research institutes as per the international QS ranking system.

- Inadequate Faculty and Scientific staff/student faculty ratio: All NIPERs have shortage of scientific and technical staff. Most of the NIPERs have 20-30% faculty positions vacant. The inadequate number of faculty members result in a higher student faculty ratio (> 12:1) which can lead to a compromised quality of education being offered at the institutes. There are no international faculty members employed in any of NIPERs. All of above reason also contribute towards NIPERs not appearing in the world's top most 50 pharmaceutical academic and research institutes as per international QS ranking system.

- It was observed during the assessment that all most all NIPERs have excellent scientific publication and citation record in the journals of international repute. The faculty members have been meeting most of the targets set by DoP for the publication numbers and publication quality parameters (like Scopus indexing, requisite impact factor and H factor etc). Faculty members of NIPER Ahmadabad like Dr. Pallab Datta, has been recognized as the Top 2% scientist according to a recent list published by Stanford University. On an average, all NIPERs have also been filing five to seven Indian patents every year. These are good key performance indicators are should be further improved.

- Most of the NIPERs have not done any substantial technology transfers to any pharmaceutical or biotechnology companies in the last three years. This should be an area of concern for all NIPERs. NIPER Mohali however is an exception to it. It has set a good example whereby it has started reaping the benefits of one of such technology transfers done several years back and has recently received a royalty amount of INR 1.63 Crores from the licensee company.

- The examination system of NIPERs to evaluate the semester wise performance of students is not impartial. As per the information shared with BHPL during the assessment, for every semester examination the questions papers are set by the respective faculty of each NIPER and the answer-sheet evaluation is also done by the same faculty. This can be viewed as an area of potential conflict of interest. There is no centralized examination system among the NIPERs which can ensure that the answer-sheets of particular stream of one NIPER are evaluated by corresponding faculty of same stream in other NIPER (if available).

- Most of the faculty members teaching in the NIPERs had wide research acumen and have a normal expected scientific career progression before they came into the academics. Some of the faculty members also had wide industry experience. It was however observed that except for a few faculty members, most of the faculty had no hard-core formal training in education. The KPIs for the faculty members were also primarily linked to their scientific research contributions rather than their academic performance.

- During the assessment, face to face interactions with 50 plus students of NIPERs were done. It was observed that most of the students had limited spoken English

skills. The students were staying in the campus or nearby hostels and were satisfied with the available facilities. The students in NIPER Hajipur however reported the issues related to frequent power cuts and high air-pollution levels in and around the existing campus. As far as the fellowship amount was concerned, all students confirmed that they receive their fellowships on time. On career aspirations front, most of the M.S. Pharma students wanted to pursue their career in industry in hard core pharmaceutical research profiles like discovery and analytical research and had neutral feedback on the campus placement activities carried out by institute. The average expected salary per month by M.S Pharma students was in the range of INR 50,000 to 70,000. Most of the students perusing their PhD in NIPERs wanted to continue their academic and research careers in government research/educational institutions with few wanting to pursue their careers outside India. Very few students showed interest in perusing the entrepreneurship as career.

- As per the requirement of the course curriculum, the M.S. Pharma students need to attend the classes in first two semesters and conduct a research project in the last two semesters of their 2-year master degree program. This research project is generally inhouse and is carried out under the supervision of a faculty member with a mandatory requirement of few publications coming out of the project. This leaves a little time for the students to pursue any industry internships and have an on-job industry experience during the course curriculum. The MBA Pharmaceutical Management students of NIPERs on the other hand utilize the last two semesters in the industry internships, are much ready for the industry and command far much better pay-packages than their M.S/MTech Pharma counterparts.

9. RECOMMENDATIONS

Established under the aegis of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, NIPERs were conceptualized to bridge the gap between academia and industry, foster innovation, and contribute to the development of the pharmaceutical industry in India. While NIPERs play a crucial role in developing skilled professionals and promoting research in the pharmaceutical sector, they are facing several challenges which hamper their ability in meeting the evolving requirements of the pharmaceutical industry. On the basis of the onsite and virtual assessments of all NIPERs, interviews of the stakeholders BHPL would like to make the following recommendations for upgrading the NIPERs to meet the emerging industry requirements and be among the top pharmaceutical institutes in global ranking systems:

- **Need for Academic Infrastructure and Technological Upgradation**: The pharmaceutical industry is highly technology-driven, with continuous advancements in areas such as drug discovery, manufacturing processes, and quality control. Most of the NIPERs need to work quickly towards having their respective permanent campuses with provisions for future upgradation in terms of academic infrastructure, emerging research technologies, high-end equipment, accreditations and standardized systems.

- **Focus on "Industry-Relevant" Translational Research:** Pharmaceutical companies require cutting-edge research to develop new drugs and improve existing ones. The healthcare landscape is constantly changing with emerging technologies, new diseases, personalized medicine, and new gene-based treatment modalities. NIPERs need to calibrate their education degree programs and research infrastructure to educate students on the aspects of Translational research and prioritize the research that is not only scientifically rigorous but is product focussed and has a direct application for the pharmaceutical industry's needs.

- **Collaborations with Clinical Establishments:** NIPERs should be looking for futuristic collaborations with clinical trial sites and hospitals to further research opportunities and knowledge exchange. Collaborating with healthcare professionals at clinical sites and hospitals brings valuable clinical insights, expertise and guidance to research projects. Working with clinical establishments often involves working with healthcare professionals from various fields, promoting interdisciplinary research that can lead to holistic and innovative solutions. These experts can help design, implement, and oversee product development to meet the patient, ethical and regulatory requirements. In addition, working with hospitals and clinical sites will allow NIPERs to validate their research findings in real-world patient populations, enhancing the credibility and generalizability of their research results.

- **Diversify the Funding Resources:** In the absence of ample funding resources and overdependence of the grants from Department of Pharmaceuticals, securing adequate funding for research and infrastructure development will be a challenge for most of the NIPERs. NIPERs should focus on converting knowledge into wealth. NIPERs need to diversify their resources of funding and look for other government funding sources (like National Research Fund) and explore co-development drug discovery and development collaborations with international research organisations and pharmaceutical companies. In addition, to the above NIPERs need to increase its inhouse revenues by offering consulting and commercial testing services to the industry.

- **Focus on One NIPER- One Commercial Service concept:** As far as the industry testing requirements are concerned, all NIPERs need not to develop every contract

research facility in one go. BHPL recommends a phased approach for developing the commercial contract research verticals in NIPERs. To start with, each NIPER should focus on developing at least one specialized commercial service for the industry and should ensure that its respective offerings not only meet the quality and regulatory parameters but are also at par with industry rates. For example, NIPER Ahmedabad, which has upcoming large animal facility can think on the lines of developing this a CRO service offering for industry. Similarly, NIPER Kolkata can develop the capabilities for meeting pharmaceutical industry requirements of Stability testing services and NIPER Mohali can developing itself as an exclusive GMP compliant formulation research and development service provider for Indian industry.

- **Optimum utilization of existing infrastructure and equipment:** Most of NIPERs need to ensure the optimum utilization of its already built infrastructure and existing equipment. NIPERs need to opt industry's best practices into its day today's operations and ensure that the capital equipment and already built infrastructure can be adequately monetized by offering commercial research services to industry. For example, the "status quo" of some the already built unused infrastructure like National Bioequivalence Centre needs to be looked at by NIPER Mohali. It needs to be either upgraded and made regulatory complaint as per CDSCO norms or should be used for other research/ academic purpose.

- **Accreditation/ Certifications of NIPERs and their Laboratories:** The optimum utilization of the research infrastructure can be ensured by NIPERs through a relevant research collaboration on industry projects and continuous flow of samples for testing from industry. The pharmaceutical companies however have their own quality assurance systems and strict due diligence process for selecting the collaborators/vendors including the research collaborators and testing service providers like NIPERs. All NIPERs need to ensure that they have dedicated and adequately accredited laboratories for offering relevant commercial testing services to the pharmaceutical companies. As the organisation, it is suggested that each NIPER should have a Quality Management system implemented as per ISO 9001:2015 standard. Having a centralized Enterprise Resource Planning (ERP) can streamline the systems and bring much more cross-functional operational efficiencies among the purchase, finance, human resource and general

administration departments. The upcoming Preclinical facilities (specially the large animal facility at NIPER Ahmedabad) needs to be developed to meet the OECD GLP requirements as per NGMCA guidelines. NIPER Mohali, which already has the GLP certificate for its preclinical research facility and NIPER Hyderabad which has NABL certification for its analytical testing laboratory should focus increasing the respective scope activities. The upcoming new campuses of NIPERs also need to have provision for proper lay-out, infrastructure and utilities for ensuring the implementation of Laboratory Information management system (LIMS) and comply to regulatory and quality compliance requirements. All of the above-mentioned steps will create a confidence on the reliability and reproducibility of NIPER's research/ technical data among the involved stakeholders including the potential pharmaceutical clients, regulators, research collaborators and the peer research fraternity.

- **Recruitment and Retention of Faculty and Scientific/Technical Staff:** In addition to developing the required academic and research infrastructure, attracting and retaining experienced faculty members and scientists with industry experience is essential for providing industry-relevant education, research guidance to students and technical/ testing services to industry. Most of the NIPERs are currently working with fifty to sixty percent of allocated faculty strength due to the challenges related to faculty recruitment. The scientific/technical staff numbers across most of NIPERs are also minimal. During the assessment, it was also observed that the employment and monetary benefits for faculty members across all the NIPERs were not uniform. Further, absence of Career Progression Plan for scientific, technical and administrative staff across all NIPERs should be an area of concern for all NIPERs and should be looked into on priority. In addition, retention of distinguished faculty and scientists in relatively difficult geographical locations (Hajipur and Raebareli) with limited infrastructure and access is also a challenge for NIPERs. To overcome these challenges, NIPERs should invest in creating a faculty development and have a defined KPI based career progression plan for the scientific and technical staff at NIPERs. In the absence of limited suitable applications for faculty positions, NIPERs can also consider their own inhouse scientists for the new faculty positions subject to meeting the qualification and experience requirements. In addition, recruiting the pharmaceutical industry professionals for the "Professor of Practice" positions is recommended.

- **Bridge the Industry-Academia Gap:** Bridging the gap between academia and industry remains a significant challenge even for the institutes of national importance like NIPERs. The pharmaceutical companies seek graduates who are not only academically sound but also possess technical skills and soft skills like verbal and written communication, teamwork and problem-solving. Most of the reputed pharmaceutical companies operate on a global scale and therefore it is imperative for NIPERs to prepare their students to work in an international context with thorough understanding of global markets, regulatory- compliance frameworks, and cultural diversity. NIPERs need to stay updated on everchanging regulatory and compliance changes in industry and incorporate them into their teaching and research activities. Further, NIPERs need to incorporate industry-focused training and personality development programs into their curriculum specially for the technical master degree students. NIPERs need to establish strong collaborations and partnerships with pharmaceutical, biotech and medical device companies to ensure that their educational programs align with industry needs and provide students with practical skills and much needed industry exposure during the course itself.

- **Enhancing Curriculum and Course Offerings:** The addition of new Master courses related to Biopharmaceuticals and Medical Devices in some of NIPERs is worth appreciation. The NIPERs further need to be more industry focussed and constantly update their curriculum and research infrastructure in consultation with industry professionals/bodies and their own alumni to keep pace with the technological changes happening in pharmaceutical sector. The concepts related to GLP, GMP, GCP and GCP should not only be a part of the curriculum, but should be demonstrated in the respective in-house labs/facilities to the students. Students should be made aware of the emerging technologies, regulatory and compliance requirements, Intellectual property rights and correct and better rewarding career choices.

- **Implementation of bias free Examination System:** Evaluation of answer sheets by each NIPERs in-house faculty can potentially lead to conflict of interest due to several factors including familiarity with students and personal biases. Most importantly, the faculty members may have unconscious bias toward their own institution, leading them to be more lenient in grading answer sheets of their institution. For the common Master Degrees/ subjects, NIPERs can explore the

option of implementing a blinded evaluation/grading system by utilizing the faculty from other NIPERs in the answer sheet evaluation process. This can help in prioritizing fairness and ensuring the impartiality in the overall examination system of NIPERs. It may be noted that revamping an examination system is a complex process that requires careful planning, commitment and ongoing evaluation. Therefore, any step in this direction should be taken after checking the realistic feasibility of same across all NIPERs.

- **Relook at the Key Performance Indicators of Faculty**: It was observed that in many of the NIPERs, the faculty members have multifaceted roles and a substantial amount of their time is spent on the administrative activities rather than teaching and research. Further it was observed that too much focus was there on the KPIs like research output in terms of research publications and citations, which may neglect the important teaching part of the faculty's profile. NIPERs can think on the lines of relaxing the research publication targets for its faculty so that more time is available for the faculty to teach the students. Faculty with diverse roles like teaching, mentoring, conducting research, contributing in industry collaboration and student placement activities should be separately recognized and rewarded by NIPERs. NIPERs should also monitor and evaluate the teaching effectiveness of the faculty by engaging students, peers and third party evaluators through a formal feedback mechanism. Faculty development and training Initiatives related to course revamping, innovative teaching techniques and student evaluation should be made mandatory for faulty. Merit-based rewards and incentives for exceptional performance in teaching should also be provisioned in the annual appraisal process of NIPERs.

- **Strengthening of Brand NIPER:** In order to move in the higher ranks in various ranking systems, NIPERs need to work on its overall perception in the market. NIPERs need to come up with a thorough marketing, branding and a positioning plan and differentiate themselves from the other PCI affiliated colleges and universities in India. NIPER needs to fill all vacant positions in their Public Relation Offices and develop an industry outreach program. In case of some NIPERs, which are ready to commercialize their testing services or have technologies ready for transfer, dedicated business development positions need to be created for reaching the potential customers. It may be specifically noted that none of the above-

mentioned activities should be given as additional charge to any of the faculty/scientific team members.

- **Internationalization of NIPERs:** It may be noted that one of the main reasons for NIPERs not appearing among the world's top pharmaceutical education and research institutes is their lack of international exposure in the otherwise globally interconnected world. It may be noted that the diverse campuses of top pharmaceutical institutes of Monash university, University of Oxford, University of Harvard and John Hopkins university foster a vibrant international community, making these institutions more visible and attractive to prospective students, faculty, partners and pharmaceutical companies worldwide. Around two-thirds of Oxford's graduate students come from outside the UK. Such institutions with international talent are often viewed more favourably in most of global world ranking systems. NIPERs need to harness India's global diplomatic relationships and use India's current geopolitical strategic advantage to rope in international faculty and students specially from US, Europe and Asia pacific region in their campuses. This can facilitate cross-border academic partnerships, joint research projects and student exchange programs. The tuition fees paid by international students can not only help NIPERs maintain financial sustainability but the same students can bring international partnerships and collaborations contributing additional funding and resources to the NIPERs. However, it is important to note that before taking any steps in this direction, NIPERs need to have the required infrastructure like international student hostels in place. In addition, admission criteria, seat reservation for foreign students, entrance examination and study visa requirements for foreign students need to be in place to facilitate smooth admission process. Timely steps in this direction can substantially elevate the NIPER's standing in the global pharmaceutical academic and research community and international rankings.

- **Student Career Support Services:** BHPL recommends to have a dedicated position for a Placement Officer in each NIPER. It may be noted that the existing student placement committees in NIPERs which generally consist of faculty members with and some final year student volunteers may not have the necessary expertise in career counselling, industry trends, and job market dynamics. Faculty members have limited time for placement activities and student volunteers on placement

committees change every year, leading to inconsistent engagement with potential employers. Further, managing logistics, scheduling interviews, and coordinating with various stakeholders can be challenging for placement committees. Having dedicated placement officers in NIPERs can bring a level of professionalism and accountability to the overall placement process and help the students in making better career choices.

- **Focus on Pharma Entrepreneurship:** NIPERs get some of the brightest and original thinking minds of pharmaceutical field but surprisingly there are hardly any student which wants to pursue entrepreneurship as a career choice. In spite of institutions like NIPER Guwahati and NIPER Ahmedabad having well established and supported incubators (Atal Incubation Centre and BioNest respectively), the interest level of students to pursue entrepreneurship was very limited. NIPERs should create an environment that fosters innovation, critical thinking and entrepreneurial mindset among students. The steps like incorporating pharma/ bio-entrepreneurship

  courses into the Master degree curriculum, inviting successful and young pharma entrepreneurs to give lectures and organize the entrepreneurship competitions for students can be helpful in this regard. Hearing real-life success stories and availability of incentivised entrepreneurship opportunities in the campus can inspire students to consider entrepreneurship as a viable career option. NIPERs can consider a provision for flexible curriculum option that can allow the students to choose between traditional research projects and entrepreneurial projects in their second year of Master's degree. Such progressive steps by NIPER can spark entrepreneurial interest among students and encourage students to work on the real-world entrepreneurial projects.

- **Focus on the quality of research output:** NIPERs have been performing well on the metrics like publications, citations, H-Index etc and are at par with world's top 5 ranking institutes. The world rankings system like AWRU however use the parameters like research publications in journals of international repute like Nature and Science as major ranking parameters. NIPERs have the scientific capabilities and research acumen to meet these requirements and should pursue the same. In addition, the research and development with tangible and realistic translational value and potential to solve real world problems within the defined time-frame should be a priority for NIPERs. NIPERs also need to develop a strong governance

framework to build accountability through strong program management of Research and Development programs and stage gated outcome-based funding mechanism to promote the viable product development initiatives and technology transfers to the industry.

- **Focus on international patents:** Most of the NIPERs have been granted three to five Indian Patents every year. The number of international patents granted to NIPERs however is miniscule. By obtaining global patents for the most promising technologies/ products, NIPERs can protect their innovations in international markets. This is important for NIPERs as the standalone Indian patents expose their innovative product/ process/ technology in the global market but does not provide the patent protection outside the geography of India. NIPERs need to create provision of separate fund for the international patent filing fees and defending the patents in case of legal challenges by competitors.

- **Develop a mechanism to monitor and review the Functional MoUs:** Most of the NIPERs have good number of existing MoUs with various research institutions for mutual future research collaborations. It may be noted that MoUs between two government education institutions can sometimes be perceived as symbolic or for formal reasons like demonstrating cooperation between institutions, without a genuine intention to engage in substantive collaboration. To ensure that the that the signed MoUs with various institutions are meeting the deliverables within the defined timeframe, NIPERs need to establish a robust system for monitoring their progress. The MoUs with industry and global philanthropic organisations should be given more weightage during the process of review and monitoring. It is further recommended that instead of less formal collaborative MoUs, NIPERs should be more focussed on the legally enforceable Service Level Agreements (SLA) with clear and crisp financial terms, deliverables and timelines for the collaborative projects


Double-stranded DNA