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FRESH TROUBLE

FDA finds lapses at Wockhardt's US facility

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WASHINGTON: The United States regulator Food and Drug Administration (FDA) has made twelve inspectional observations at the Wockhardt's Chicago-based plant, Morton Grove Pharmaceutical, and have criticised quality control, training and staff hygiene.

The observations, issued to the company under Form 483, followed inspections of the facility between January and March this year by FDA inspectors.

They found, among other things, that "laboratory controls do not include the establishment of scientifically-sound and appropriate test procedures" and lab records were not complete. They also said that critical areas of the manufacturing process were not maintained in a "clean and sanitary condition". The personnel did not receive adequate training and did not practice "good sanitation and health habits", they added.

"I observed an employee enter the gowning area and proceed directly into the manufacturing area without washing and sanitzing his hands as is the firms procedure," an inspector noted.

The FDA has already issued warning letters to two of the Wockhardt's plants in India.

Regulatory.