Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

INSPECTION REPORT

Piramal Healthcare UK Ltd
2 Roseland Hall
Earls Gate Park
Grangemouth
FK3 8ZF

Head Office:
Inspection, Enforcement & Standards Division, MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Telephone: 020 3080 6000
Email: info@mhra.gov.uk

Section A Inspection Report Summary

Inspection requested by: MHRA

Scope of Inspection: Initial inspection of a new site

Licence or Reference Number: MIA / MIA(IMP) 29595

Licence Holder/Applicant: Piramal Healthcare UK Ltd

Details of Products/Clinical trials: Manufacture of antibody drug conjugate bulk drug substances

Activities carried out by company:	Y/N
Manufacture of Active Ingredients	N
Manufacture of Finished Medicinal Products – Non-sterile	N
Manufacture of Finished Medicinal Products - Sterile	N
Manufacture of Finished Medicinal Products - Biologicals	N
Manufacture of Intermediate or Bulk	Y
Packaging – Primary	Y
Packaging - Secondary	N
Importing	N
Laboratory Testing	Y
Batch Certification and Batch Release	Y
Sterilisation of excipient, active substance or medicinal product	N
Broker	N
Other:	N

Name and Address of sites inspected (if different to cover):

Site Contact: [redacted]

Dates of Inspection: 6-8 February 2024

Lead Inspector: [redacted]

Accompanying Inspector: [redacted]

Case Folder References: Insp IMP 29595/36189300-0001, Insp GMP 29595/36189300-0002

Section D List of Deficiencies

D1 Critical

None

D2 Major

None

D3 Others

3.1 Management of system alarms was deficient, in that:

3.1.1 There was a lack of consistency between the BMS (building management system) and EMS (environmental management system) over which alarms were categorised as critical.

3.1.2 At the time of the inspection the BMS was reporting several 'critical' alarms, of which a number remained unacknowledged. For example, but not limited to, [redacted] this location was not showing as an alarm in the EMS.

Reference: EU GMP Part II: 5.46, Annex 11 (13)

3.2 Monitoring of warehouse storage conditions was not appropriately controlled, in that:

3.2.1 Of the [redacted] temperature probes used to map the warehouse and staging area, 5 probes only had a single-point calibration and so it could not be demonstrated that they were accurate over the intended range of use.

3.2.2 There was no documented justification for the location of the routine monitoring probes.

Reference: EU GMP Part I: 3.19, 3.41

3.3 The completion of documentation was unclear, in that:

3.3.1 Three consecutive aseptic fill training exercises were documented as taking place one minute apart, for each of four operators, which was not possible. The instructions in the documentation were unclear in whether the recorded time was for the time of the filling activity, or the subsequent filling of the form after exiting the biosafety cabinet and taking finger dabs.

Reference: EU GMP Part I: 4.8

3.4 Deviation management was deficient, as evidenced by a failure to adhere to procedural timelines for the initiation of deviations and/or the completion of investigations:

3.4.1 [redacted] covered events occurring between 15-Nov-2023 and 13-Dec-2023 but was not raised within [redacted] until 20-Dec-2023 and not approved until 05-Feb-2024, in breach of both the initiation and completion targets.

3.4.2 [redacted] was noted in November 2023, but not raised within [redacted] until 19-Dec2023, in breach of the initiation target.

3.4.3 [redacted] was due 01-Dec-2023 but not completed until 02-Feb-2024, in breach of the completion target.

3.4.4 [redacted] was due 19-Jan-2024 but remained open and in progress as of 7-Feb-2024, in breach of the completion target.

Reference: EU GMP Part I: 1.4 (xiv), 1.8 (v), 2.16

D4 Comments

None