Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

INSPECTION REPORT

PCCA Ltd
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Section A Inspection Report Summary

Inspection requested by: MHRA – remote desktop.

Scope of Inspection: Variation to add importation from 3rd countries MIA.

Licence or Reference Number: MIA 17661/M-0028

Licence Holder/Applicant: PCCA Ltd

Details of Products/Clinical trials: Manufacture of various non-steriles as licensed, unlicensed and IMPs. Products included potent molecules and CDs.

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

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

Site Contact: [redacted]

Dates of Inspection: 24 April 2024

Lead Inspector: [redacted]

Accompanying Inspector: N/A

Case Folder References: Insp GMP 17661/714421-0016

Section D List of Deficiencies

D1 Critical

None

D2 Major

None

D3 Others

3.1 Supplier Approval was deficient in that:

3.1.1 There site procedures did not detail the management of 3rd party audits for example confirmation of inclusion of key items such as cross contamination control, data integrity, sampling procedures and compliance with the MA and the requirement for a documented review.

3.1.2 The audit of the drug product manufacturer [redacted] carried out by a third-party auditor was weak in detail and did not confirm compliance with EU GMP and there was no visibility of the CV of the auditor.

EU GMP A16.2.2(i), A16.2.2(ii), A16.2.2(iii)

3.2 The Technical Agreement (TA) between PCCA and [redacted] did not detail timescales within which the PQR should be provided.

EU GMP C7.15

4. COMMENT

4.1 PCCA to confirm TA in place with API manufacturer.