Medicines & Healthcare products Regulatory Agency

MHRA

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gov.uk/mhra

RESTRICTED – COMMERCIAL

[redacted]
FERRING CONTROLLED THERAPEUTICS LIMITED
1 REDWOOD PLACE
PEEL PARK CAMPUS
EAST KILBRIDE
GLASGOW
G74 5PB
UNITED KINGDOM

Date 09/09/2022

Case No: Insp GMP/IMP 8731/18177-0021

SUBJECT: THE HUMAN MEDICINES REGULATIONS 2012 (as amended) (SI 2012/1916)
THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 (SI 2004/1031)

AUTHORISATION / REGISTRATION NO. MIA 8731, MIA (IMP) 8731, API 8731

Dear [redacted]

Thank you for the courtesy and co-operation shown during the inspection of your premises at the above address on 16/08/2022.

During the inspection a number of failures to comply with the principles and guidelines of Good Manufacturing Practice and / or Good Distribution Practice were observed and these are listed in the Appendix to this letter.

Please reply within 28 days, giving your proposals for dealing with these matters, together with a timetable for their implementation. Please send your response electronically by e-mail to me at the email address below.

It would be appreciated if your response was in the following format:

1. Restate the deficiency number and the deficiency as written below.
2. State the proposed corrective action and the target date for completion of these action(s)
3. Include any comment that the company considers appropriate.
4. Please provide the response as a word document.

Further guidance on responding to inspection deficiencies can be found at the following web link https://www.gov.uk/guidance/guidance-on-responding-to-a-gmpgdp-post-inspection-letter

Yours sincerely

[redacted]
GMP/IMP Inspector

E-mail: [redacted]

FAILURES TO COMPLY WITH THE GUIDE TO GOOD MANUFACTURING / DISTRIBUTION PRACTICE

1. CRITICAL

None

2. MAJOR

None

3. OTHER

3.1	Cleaning and contamination control was deficient specifically:
3.1.1	There was no appropriate risk assessment to prevent microbial and particulate contamination in using a metal brush for routine cleaning of the pessary primary packaging line.
3.1.2	The records for cleaning the robotic pessary line were not designed in a manner to assure complete cleaning in accordance with approved procedures in that they did not contain details of all possible hot spots for product entrapment.
EU GMP	C3.2, C3.36, C5.10, C5.21 Organisational Measures
3.2	Controls over storage of product were deficient specifically:
3.2.1	The temperature probes in the warehouse were sited such that the influence of the opening and closing of the loading bay doors had not been continuously assessed for goods received into the warehouse.
3.2.2	Labels used to identify material status were affixed poorly and could easily become detached, particularly in cold storage.
3.2.3	There were two versions of the control labels in use; one contained raw data regard approval status and one did not. It was therefore difficult to trace the status of materials.
3.2.4	API in the store was labelled as both IMP development and clinical trial material.
EU GMP	C1.8(iii), C5.12, C5.13, A13.5
3.3	Training was deficient in that there was no evidence of assessment of effectiveness of ongoing training.
EU GMP	C2.11
3.4	Production was deficient in that finished product foil pouches were

found in the polymer slicing room uncontrolled with no operator present, despite the room being signposted as in use for slicing polymer material under a different batch number.

EU GMP C5.12

3.5 Product Quality Reviews (PQR) were deficient in that there was no evidence of review and approval by the MAH holder as required by guidance.

EU GMP C1.11

4. COMMENT

4.1 With regards to the future implementation of the [redacted] suite, the company is requested to provide cleaning validation report(s) when available. Please also ensure equipment and control are suitable for the intended use i.e., pressure gauges on the flexible film isolators show the appropriate requirements for production.

4.2 The site is requested to provide the inspector regular updates on the progress of the new facility to ensure an inspection is performed at a suitable point in the plans.