Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

RESTRICTED – COMMERCIAL

[redacted]

Date 13/12/2022

Case No: Insp GMP/IMP 46468/17556174-0009

SUBJECT: CONTRACT TESTING LABORATORY:
THE HUMAN MEDICINES REGULATIONS 2012 (as amended) (SI 2012/1916)
THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 (SI 2004/1031)
THE VETERINARY MEDICINES REGULATIONS 2013 (SI 2013/2033)

Dear [redacted]

Thank you for the courtesy and co-operation shown during the inspection of your premises at the above address on 30/11/2022.

During the inspection a number of failures to comply with the principles and guidelines of Good Manufacturing 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]
Senior GLP and GMP Inspector

E-mail: [redacted]

FAILURES TO COMPLY WITH THE GUIDE TO GOOD MANUFACTURING PRACTICE

1. CRITICAL

None

2. MAJOR

None

3. OTHER

3.1	The root cause analysis performed as part of investigations, did not consider all aspects which resulted in the deviation. Specifically:
3.1.1	[redacted] raised following a system suitability failure did not detail previous instances of SST failure, and assess the performance of the analytical method.
3.1.2	[redacted] raised to deviate from method [redacted] did not assess the transfer of equipment from [redacted] to [redacted] and the timing of the method production in relation to the analysis.
3.1.3	[redacted] raised as a result of an OOS for residue on ignition testing, did not consider the process of how the analyst was deemed competent to perform the analysis, and that the phase one investigation did not identify the lack of adherence to the method.
EU GMP	C1.4(xiv), C1.8(vii), C4.8
3.2	Within the chemistry laboratories there were a number of records for obsolete and disposed of reference standards, some of which dated back to 2017.
EU GMP	C4.10
3.3	The autoclave print out for [redacted] testing of sample [redacted] was incomplete and did not demonstrate the required time of 30 minutes at 121 degrees Celsius had elapsed. The incomplete record had not been identified during two independent checks.
EU GMP	C4.1, C4.8

4. COMMENT

None