Medicines & Healthcare products Regulatory Agency

MHRA

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

gov.uk/mhra

RESTRICTED – COMMERCIAL
[redacted]
Bioreliance Limited
Stirling University Innovation Park
Hillfoots Road
Stirling
FK9 4NF
United Kingdom

Date 14/07/2022

Case No: Insp GMP/IMP 22774/31007-0021

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 29/06/2022.

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	Deviations were not adequately investigated as evidenced by:
3.1.1	Deviation [redacted] raised to assess issues with traceability in LIMS did not assess any potential impact of historically inaccurate information (e.g. assessing temperature deviations).
3.1.2	Deviation [redacted] raised as a result of bacterial contamination of manufactured virus did not investigate how soil based bacteria had reached a class 2 Biological safety cabinet or the effectiveness of the control measures.
EU GMP	C1.4(xiv), C1.8(vii)
3.2	Content of SOP's was not always appropriate as evidenced by:
3.2.1	SOP [redacted] effective 30 September 2021 permitted Bioreliance to perform work without valid technical agreements in place.
3.2.2	SOP [redacted] effective 28 May 2022 did not reflect the procedures used to recalculate the acceptance criteria in asymptomes when processing the data using [redacted] software.
EU GMP	Chapter 4 Principle, C4.1
3.3	There was no justification to support the two-week period permitted to commence testing of stability samples following their pull from storage.
EU GMP	C1.1, C6.26, C6.27
3.4	The requalification records for the [redacted] performed in 2019, had not been archived to ensure the integrity of the records were

maintained. This was identified during the tour of the immunological laboratory.

EU GMP Chapter 4 Principle, C4.1

4. COMMENT

Report reviewed by: [redacted]