Medicines & Healthcare products Regulatory Agency

MHRA

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

gov.uk/mhra

RESTRICTED – COMMERCIAL

[redacted]

Date 19/11/2021

Case No: Insp IMP 41042/12696367-0004

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

AUTHORISATION / REGISTRATION NO. MIA(IMP) 41042

Dear [redacted]

Thank you for the courtesy and co-operation shown during the inspection of your premises at the above address on 19/11/2021.

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]
Lead Senior GDMP 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	The IMP oversight process for shipment from listed countries to GB was deficient as evidenced by:
3.1.1	The IMP oversight process could be delegated to other personnel in the quality department however this was not mentioned in the IMP oversight [redacted]. A formal list of delegated personnel who were authorised to perform the IMP oversight process to GB was also not required.
3.1.2	The technical agreement [redacted] did not include any detail about the handling of temperature excursions, how these were taken into consideration during the IMP oversight process and how IMP associated with excursions were prevented from being used for subjects in a clinical trial. Similarly, [redacted] did not include any detail on how temperature excursions would be handled in the oversight process.
EU GMP	C1.4(xv), C4.2, C7.14

4. COMMENT

None