Medicines & Healthcare products Regulatory Agency

MHRA

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

gov.uk/mhra

RESTRICTED – COMMERCIAL

[redacted]
BIOTEC SERVICES INTERNATIONAL LIMITED
UNITS 2100, 2110, 2120, 2130, 2010, 2430 AND 2500
PHASE 18
CENTRAL PARK
BRIDGEND INDUSTRIAL ESTATE
BRIDGEND
CF31 3TY
UNITED KINGDOM

Date 03/11/2021

Case No: Insp IMP 19819/4680309-0004

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

AUTHORISATION / REGISTRATION NO. MIA(IMP) 19819

Dear [redacted]

Thank you for the courtesy and co-operation shown during the inspection of your premises at the above address on 03/11/2021.

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 GMDP 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 draft SOP [redacted] for the IMP oversight process for import into GB did not include the following details:
3.1.1	A requirement to prepare and keep up to date, a formal list of delegated persons who were approved by the Qualified Person (QP) to perform the IMP oversight process.
3.1.2	A statement that shipment under quarantine was not normally allowed but could be permitted under a deviation if requested by the sponsor for a valid reason.
3.1.3	There was no requirement to confirm that the QP performing batch release site in the listed country was specifically named on the manufacturing authorisation in that country.
3.1.4	There was a lack of detail in the SOP and quality technical agreement (QTA) regarding the notification and handling of temperature excursions after the IMP oversight approval has been sent to the batch release site for direct shipment to clinical sites.
EU GMP	C1.4(xv), C4.2

4. COMMENT

None