Medicines & Healthcare products Regulatory Agency

MHRA

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RESTRICTED – COMMERCIAL
[redacted]
ALMAC CLINICAL SERVICES LIMITED
SEAGOE INDUSTRIAL ESTATE
9 CHARLESTOWN ROAD
CRAIGAVON
NORTHERN IRELAND
BT63 5PW
UNITED KINGDOM

Date 15/09/2021

Case No: Insp GMP/GDP/IMP 20377/13423-0027

SUBJECT: 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)

AUTHORISATION / REGISTRATION NO. MIA(IMP)20377

Dear [redacted]

Thank you for the courtesy and co-operation shown during the inspection of your premises at the above address on 01/09/2021.

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]
GMP/GDP/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	Warehousing and Facility controls were lacking in that:
3.1.1	Warehousing racking consistently used non-heat-treated wood within shelving systems
3.1.2	There were no pest control units to each outer side of the Goods Inwards roller shutter doors in [redacted]
3.1.3	Pipework for the cold store next to the Goods Inwards area of [redacted] showed historic evidence of damage or corrosion, which resulted in degraded and contaminated boarding next to storage racking shelving.
3.1.4	Despatch area controls were lacking in that:
3.1.4.1	There were no logbooks to confirmation activities undertaken in despatch areas.
3.1.4.2	Despatch Label printing did not ensure that the correct printers were selectable, such that each computer could only print to the local printer/s.
3.1.4.3	2 labels had been printed on the printer in the [redacted] despatch area, these had not been removed from the area following a print order to the incorrect printer (print run originated in [redacted]
3.1.5	Material Transfer Cards were not controlled or completed correctly, as evidenced by:
3.1.5.1	Multiple examples were seen whereby details; including item and lot numbers; were not completed.
3.1.5.2	Examples were noted where a photocopy of a card had been used, with the name and date copied from the original.
3.1.5.3	Quantifies were not consistently completed to reflect the units of each items, where examples were noted to show the number of shippers rather than number of items.
3.1.6	There was nothing to prevent access from a general Almac archiving area into the control access label store within [redacted].
3.1.7	Reject material controls were lacking in that:
3.1.7.1	Rejected materials and components were not stored separately in restricted areas as these were stored in general locations within Warehouse [redacted]
3.1.7.2	Access to the physical key to [redacted] the rejected materials unit;

	was not restricted or controlled such that only required personnel could access the key and hence the building.
3.1.8	The 'Controlled Drug Vault' warehouse in the [redacted] was not maintained in a clean condition.
3.1.9	The material blisters in transparent plastic bag stored in the CD warehouse, batch [redacted] were not appropriately managed within the [redacted] inventory system and there was no record of the material usage.
EU GMP	C1.4(xvi), C1.8(ix), C3.2, C3.4, C3.19, C3.23, C5.2, C5.66
3.2	Secondary packaging controls and documentation was lacking in that:
3.2.1	The [redacted] template for work order [redacted] had not been countersigned as checked prior to the start of the job, where this was only 2nd signed 3 working days later.
3.2.2	The Station Completion table for work order [redacted] had not been completed with the operator details for 1st September at the start of the day's operations.
3.2.3	Quality Control In-Process destructive samples were not identified with date, time or signature.
3.2.4	The packaging instruction for [redacted] included an example drawing/photograph where the packaging carton had a padlock symbol in a different colour than the one on the material used during the packaging process; this had not been identified or raised as an issue during production.
EU GMP	C4.8, C4.19(e), C5.52, A13.15, A13.24
3.3	Label printing controls were lacking in that:
3.3.1	There was no detail on the Label print record or checklists to confirm if checks were manual or performed via camera visual inspection.
3.3.2	It was not possible to directly connect paperwork from Reprint records to the original print run documentation set.
3.3.3	Challenges of the [redacted] camera system were not consistently completed on the 6 monthly cycle as procedurally required.
EU GMP	C1.8(v), C3.41, C4.10, C4.26
3.4	Training was deficient as evidenced by:
3.4.1	The records for Third Party contract distribution operator [redacted] were lacking in that:
3.4.1.1	The training was incomplete, as the operator had not been trained in the revised procedures
3.4.1.2	The training file had not been closed despite [redacted] leaving during 2020, and the training plan was continuously updated with new tasks added against the curriculum. New tasks were in the status 'Opened'

	which was not addressed by the responsible manager.
3.4.1.3	There were no recorded of the individual attending any of the GMP refresher training since 2018.
EU GMP	C1.8(iii), C2.10, C2.11
3.5	Unlicenced medicine controls were lacking in that:
3.5.1	There was no reference to the MHRA Q&A guidance within the relevant SOPs.
3.5.2	Instructions relating to Notification for import controls did not correctly reflect the requirement for 25 doses or courses of treatments per application.
3.5.3	The SOP did not include appropriate detail on the requirements to name and assess Quality Releasing Officers. The Supply of Unlicensed Medicinal Products 'Specials', MHRA Guidance Note 14, https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials; MHRA Guidance for 'Specials' Manufacturers https://www.gov.uk/government/publications/guidance-for-specials-manufacturers;

4. COMMENT

None