Medicines & Healthcare products
Regulatory Agency

GDP INSPECTION REPORT

WDA(H) 14172/ 31373408

[redacted] UK LIMITED

ISSUED BY:

[redacted]
GDP Inspector

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Medicines & Healthcare products Regulatory Agency

File Ref: **Insp GDP 14172/ 31373408-0001**
Inspection Date: **11/01/2023**
Company: [redacted]**UK Limited**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 14172/ 31373408-0001
2. Inspected site(s) and contact details:	
[redacted]	
3. Authorised operations:	

☐ Procurement
☒ Holding
☒ Supply
☐ Export
☐ Products imported from countries on a list
  ☐ Products certified under Article 51 of Directive 2001/83/EC
  ☐ Products not certified under Article 51 of Directive 2001/83/EC
☒ Other activities: (please specify)

Labelling of a medicinal product [redacted] *to take account of a change to the shelf life of the product because of the thawing when used for* [redacted] *under Regulation 3A(3) of Human Medicines.*

4. Inspection date(s):	11/01/2023
5. Inspector(s):	

Name(s) of the Inspector(s).

[redacted]

MHRA

6. References:	WDA(H) 14172

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Company: [redacted]

7. Introduction:

Business Background

[redacted] had applied for a variation to add a new site to their existing licence. The site was located at Unit 1 Bedford Link [redacted]

The site at Bedford link would operate under the exact same model as site [redacted] being the national distribution centre in the South but with a warehouse of ~33,000m^2, more energy efficient and with improved automation capabilities. Transportation would be performed using their own vehicles, with a small percentage of validated subcontractors (2.5%).

Review of WDA(H)

MEDICINAL PRODUCTS

☒ With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

☒ Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market

☐ Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in the UK and not intended for the UK market

☐ With a Marketing Authorisation in EEA member state(s) and intended for the GB parallel import market

Medicinal products with additional requirements

☒ Narcotic or psychotropic products

☒ Medicinal products derived from blood

☒ Immunological medicinal products

☐ Radiopharmaceuticals (including radionuclide kits)

☒ Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

☐ Medicinal gases

☒ Cold chain products (requiring low temperature handling)

☒ Other products: Biological Products requiring independent batch release

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Date of previous inspection:

Name(s) of Inspector(s) involved in previous inspection: [redacted].

Date of last inspection: 24 Mar 2022 for site [redacted] Two more sites were added as part of the same variation; [redacted] and these were assessed remotely.

Overview of inspection findings from last inspection and the corrective action taken:

No findings from previous inspection for the 3 sites listed above.

Major changes since the previous inspection:

Addition of a new site in Bedford Link which was the subject of this inspection.

8. Scope of Inspection:
Initial inspection of a new site to assess compliance with the Good Distribution Practice guidelines and the Human Medicines Regulations 2012.
9. Inspected activities:
GDP Inspection of activities, operations, records and documentation under the licence pertaining to this site; Holding and Supply.
10. Activities not inspected:
None.
11. Personnel met during the inspection:
[redacted]

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12. Inspectors findings and observations relevant to the inspection and deficiencies:

- **Quality Management**

  A quality management system (QMS) was in place and included procedures for the management of deviations, change control, CAPAs and risk management. Within the last 12 months, 75 Deviations (760 in total), 152 CAPAs (544 in total) and 21 Change controls (21 in total) were raised for the Bedford Warehouse and transport operations. An Index of procedures was requested and provided by [redacted] on 11Jan 2023. These were managed by [redacted] the e-QMS software used for the management of standard operating procedures, forms, and work instructions. The following items were reviewed during the inspection:

  [redacted] change control for the addition of the new site. [redacted]

  Risk assessment for the above change; Reviewed by [redacted]

  [redacted] change control for the removal of shelving and re-arrangement of Right Chamber of [redacted] Freezer. Change was closed on 06 Jul 2022, within its due date (08 Jul 2022) but no check on the effectiveness had been conducted as part of the Change control.

  [redacted] risk assessment covering; Building risk assessment, overall move, internal personnel, CD move, Chill move, BAU Processes, Regulatory, external stakeholders.

  Management of the project was described by [redacted] 3 meetings per month were taking place for the project along with local weekly meetings.

- **Personnel**

  The new structure was presented during the opening meeting and shared with the inspectors on 12 Jan 2023. The organisational chart included top management structure and the Quality team structure within the UK network. The nominated RPs for the new site at Bedford link were [redacted]

  Training record for [redacted] class 1 trunk driver, was reviewed, start date 02 Jan 2013.

- **Premises and Equipment**

  A tour of the new site took place, activities for finalising the facility were still ongoing. The main frame of the controlled room store (CD) was in place (~1000tons) and the segregation within the store was being finalised. The certificate from the german manufacturer was reviewed during the inspection. It was explained that access to the CD store would require 2 members of staff and having worked for [redacted] for at least 2 years. APIs would also be stored in the controlled room store, in a segregated area.

  A cold room was also being built and the mapping protocols for the warehouse, cold-chain and controlled drugs storage areas were requested along with the report for the electricity generator test. The back-up generator was being installed at the time of the visit and would be able to start operating within 2-3 min if loss of electricity would occur.

The mezzanine was split into 3 floors, 1st floor for automation picking, 2nd floor would be the GMP re-packaging area and where medical devices would be stored, and the 3rd floor was the freezers area.

123 Freezers were acquired and installed on the 3rd mezzanine floor. Mapping was arranged for 7 out of the 123 freezers by [redacted] Mapping activities were ongoing at the time of the inspection and a [redacted] engineer was present. The completed mapping report for freezer with [redacted] was requested as it was discussed with the engineer at the time.

EMS would be the temperature monitoring system used for the freezers-on the mezzanine floor only. [redacted] would be used for the rest of the building which was the one used at Bedford Site id [redacted] The change related to the introduction and implementation of the EMS system was covered under the installation of the [redacted] freezers; Change control [redacted] It was suggested that if the effectiveness of this change was successful, EMS could be deployed for the whole site.

24 hour security arrangements would be in place, the floor plan with cameras included, was reviewed and discussed with [redacted]. Security would be present at the gate and personnel would be looking at the cameras. Checks for staff before heading to their lockers would take place along with random checks to reduce the risk of thefts. A card access system would also be in place.

- **Documentation**

  Review of procedures was performed using paper copies however [redacted] the e-QMS software, was used for the management of standard operating procedures, forms, and work instructions. Another e-QMS was under evaluation to include management of Deviations, Complaints, Change controls and other related items. Procedures were version controlled and approved by a responsible person.

- **Operations**

  No current operations under the new site. However, procedure [redacted] issued 06 September 2022 was reviewed. It was noted that it had not been updated in line with the latest guidance for customer and supplier qualifications purporting to only dealing with specific individuals. The procedure had not been fully updated to reflect regulatory changes following the UK's exit from the EU and it still contained references to supply to Republic of Ireland, which was not authorised under the scope of the licence.

  [redacted] was reviewed.

  The procedure for controlled drugs was not reviewed as it would require an update as per the new Home Office guidance. The Home Office was expected for an inspection the same week as this inspection.

- **Complaints, Returns, Suspected Falsified Medicinal Products and Recalls**

  Processes were in place for the handling of customer complaints, returns and product recalls; [redacted] and [redacted] respectively.

  A process was in place for falsified medicines; [redacted]

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- **Outsourced Activities**

  The main outsourced activity included distribution. Contract with [redacted] (transport only contract) was approved by all parties on 14 and 15 Jun 2022. Subcontractors were listed in Appendix 2; [redacted] qualification documents were reviewed. Involved risk assessment and questionnaire and they were last qualified in 2019. As vans were not temperature controlled validated shippers were used for the transport.

- **Self-Inspection**

  A Self-inspection procedure was in place; [redacted]

- **Transportation**

  Transport would be conducted via their own fleet of dual temperature-controlled vehicles [redacted] Subcontractors would also be used but only at 2.5%. Examples have been listed under outsourced activity section.

- **Specific Provisions for Brokers**

  Not applicable to business model.

13. Other specific issues identified:
None.
14. Miscellaneous:
None.
15. Annexes attached:
N/A

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16. List of Deficiencies classified into critical, major and others:

1 CRITICAL
None

2 MAJOR
None

3 OTHER

3.1 The Change Control System was deficient in that there was no evidence of effectiveness checks being conducted for all key changes. Specifically, no check on the effectiveness of change had been conducted as part of Change control record [redacted] Removal of shelving and re-arrangement of right chamber of [redacted] freezer, which had been closed on 06 July 2022.

References: Guidelines on Good Distribution Practice Chapter 1, sub-section 1.2

3.2 Customer Qualification activities were deficient in that standard operating procedure [redacted] issued 06 September 2022 had not been updated in line with the latest guidance for customer and supplier qualifications purporting to only dealing with specific individuals. The procedure had not been fully updated to reflect regulatory changes following the UK's exit from the EU and it still contained references to supply to Republic of Ireland, which was not authorised under the scope of the licence.

References: Guidelines on Good Distribution Practice Chapter 5, sub-sections 5.3

4 COMMENT

4.1 Please provide copies of the following documents when available:

a Completed mapping report for freezer [redacted]

b Mapping protocol for the warehouse including cold-chain and controlled drugs storage

c The report from the tests on the electricity generator test

d Photographs of the controlled drugs storage with racking. Please ensure that placement of any CCTV and temperature monitoring devices are also captured.

17. Inspectors' Comments:

Response provided on 17 Jan 2023 has been accepted. Items listed under 4.1 will be supplied during regular meetings with MHRA and before mid-April.

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18. Recommendations:

**Your application for variation to a wholesale dealer's authorisation [WDA(H) 43086] granted pursuant to Regulation 18 of the Human Medicines Regulations 2012 (a "wholesale dealer's licence") will be recommended to the licensing authority.*

Site and authorisation pursuant to Regulation 18 of the Human Medicines Regulations 2012 (a "wholesale dealer's licence") will next be inspected as part of the MHRA's risk-based inspection programme, the frequency of inspection being determined by the nature of the activities the licence holder undertakes and previous compliance history. The risk profile of a company may change over time and consequently provisional re-inspection dates given in this report may change.

The provisional date for the next inspection of this licence is January 2026.

19. Summary and conclusions:

Within the scope of the inspection, the company operates in accordance with the principles of good distribution practice referred to in regulation C17 of the Human Medicines Regulations 2012.

The GDP certificate reflects the status of the inspected site at the time of the inspection noted above. Inspections of other sites that are named on the licence may cause this certificate to be withdrawn if Regulatory action against the licence is taken by the Licensing Authority.

20. The inspection report should be signed and dated by the Lead Inspector:

Name: [redacted]

Signature:
[redacted]

Organisation:

MHRA

Date: 01 Feb 2023

Distribution of Report: [redacted]