Medicines & Healthcare products Regulatory Agency

MHRA

# GDP INSPECTION REPORT

## WDA(H) 14172/5680

[redacted]

**ISSUED BY:**

[redacted]

**GDP Inspectors**

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Medicines & Healthcare products Regulatory Agency

MHRA

**File Ref:** **Insp GDP 14172/5680-0021**
**Inspection Date:** **19/11/2019**
**Company:** [redacted]

## GDP Inspection Report

| | | |
|---|---|---|
| **1.** | **Report Reference no.:** | Insp GDP 14172/5680-0021 |
| **2.** | **Inspected site(s) and contact details:** | |
| [redacted] Site contact: [redacted] | | |
| **3.** | **Authorised operations:** | |
| ☐ Procurement<br>☒ Holding<br>☒ Supply<br>☐ Export<br>☐ Brokering<br>☐ Other activities: (please specify) | | |
| **4.** | **Inspection date(s):** | 19/11/2019 |
| **5.** | **Inspector(s):** | |
| **Name(s) of the Inspector(s).**<br>[redacted]<br>**MHRA** | | |
| **6.** | **References:** | Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 14172 |

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## 7. Introduction:

**Business Background**

[redacted] are a specialist third party logistics provider to the healthcare sector.

The site inspected in Bedford is the main distribution site and also holds an MIA, WDA(V) and API registration

The company provide 3 levels of service to their customers:

[redacted]

The inspection focused primarily on an incident of theft reported by the company.

**Review of WDA(H)**

**MEDICINAL PRODUCTS**

☒ with a Marketing Authorisation in EEA country(s)

☒ without a Marketing Authorisation in the EEA and intended for EEA market*

☐ without a Marketing Authorisation in the EEA and intended for exportation

**Medicinal products with additional requirements**

☐ Products according to Art. 83 of 2001/83/EC

- ☒ Narcotic or psychotropic products
- ☒ Medicinal products derived from blood
- ☒ Immunological medicinal products
- ☐ Radiopharmaceuticals (including radionuclide kits)

☐ Medicinal gases

☒ Cold chain products (requiring low temperature handling)

☐ Other products: (please specify here or make a reference to Annex 5)

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**Date of previous inspection:**

Names of Inspectors involved in previous inspection: [redacted]

Date of last inspection: 24/10/2017

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

Major deficiencies identified relating to the control of outsourced activities as a contract acceptor and deviation management. Other deficiencies had been identified with regards to self-inspections and management review. Corrective measures had been put in place and inspection case folder closed out.

**Major changes since the previous inspection**:
Change of Senior Vice President for [redacted]

Additional of a new RP [redacted]

20% increase of personnel across [redacted]

| **8. Scope of Inspection:** |
|---|
| Routine inspection assessing compliance with the Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) and the Human Medicines Regulations 2012 as amended. |
| **9. Inspected activities:** |
| GDP Inspection of all GDP activities, operations, records and documentation under the licence pertaining to this site; Holding, Supply. |
| **10. Activities not inspected:** |
| |
| **11. Personnel met during the inspection:** |
| [redacted] |

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

- **Quality Management**

The electronic Quality Management was not reviewed in detail at this inspection due to the focus of the visit. Nonetheless, most processes were reviewed.

Processes were in place in relation to change control, deviation management and incorporating Corrective/Preventative Actions and quality risk management.

However, it became evident that these formal processes had not been reflected in practice, particularly in relation to the theft [redacted]

- **Personnel**

Due to the significant delays involved with notification to the Competent Authority of the theft, the role of the RP was examined. It was the opinion of the Inspectors that the demand of the role of RP on a sole individual in an organisation of this scope and size was inappropriate, evidenced by the delays in reporting and investigation. It was the opinion of the Inspectorate that the Licence Holder had failed to adequately resource this office.

Resourcing of the quality and Responsible Person functions were examined. The organisation utilised a dedicated RP and quality support at the [redacted] facility. All other functions were shared and based out of the Bedford site. It was proposed that the deputy RP was to undertake a role as Responsible Person.

Delegation of duties was defined within formal processes. This process referred to deputy RP consultation of clients, the licence holder and Competent Authority. Delegated duties included the management of returns, work instructions and procedures. It was the opinion of the MHRA that the role of RP was insufficiently resourced to effectively manage operations. The [redacted] was proposed to be named a Responsible Person. [redacted] intending to be named as Responsible Person, it was not intended that this would be the [redacted] primary duty.

The company intended to name the [redacted] as Responsible Person within 3 months. The company was advised this would likely trigger an inspection.

There were an adequate number of trained and competent personnel available to carry out wholesale activities. Training records of security staff were reviewed. Although there were no specific processes pertaining to searching, temperature monitoring and general GDP awareness training had been conducted and appeared acceptable.

- **Premises and Equipment**

The premises utilised [redacted] CCTV cameras to cover operations.

Temperature monitoring was defined within formal processes. This included the monitoring of temperature alarms by Security personnel. Processes appeared to adequately describe the EU GDP functions conducted by security staff.

Controlled Drugs storage areas were examined. The primary CD storage room was compliant to Home Office grade 6 terms and consisted of [redacted] pallet spaces of storage. The facility at the time of inspection did not hold any cold chain CDs and did not have the capacity to do so. The bottom pallet space layer of the holding room consisted of smaller volumes, loose packs, of which most picking was completed.

[redacted] CCTV cameras were in place to cover the entirety of operations. These appeared acceptable. Access was limited to authorised staff members only. Picked storage areas were located within the sealed area, where lanes were allocated to other licenced sites. When product was ready for despatch, this was then moved into the staging area. Several other – 70-90◦C freezers were in place; however these were described only and were not formally inspected for compliance.

A walk-in freezer containing [redacted] stock was in place. This was described as designated for vaccines; however, it was noted packaging material, specifically conditioned packs, were located within the premises. These did not appear to have been date stamped to ensure conditioning compliance with procedures. Furthermore, there was a significant build-up of ice located within the premises which should have been examined post inspection.

A staging area, where cross docking and despatch operations were conducted was examined. It is believed the incident occurred within this area. CCTV was examined and seen to encompass most of the area. It was noted that views may have been obstructed by tall pallets. Inconsistent wrapping and finalisation of pallets were observed, where staff may have been in a position to remove inventory.

- **Documentation**

Processes relating to documentation control were not reviewed in detail at this inspection.

Reliance for demonstrating compliance was primarily placed on electronic records.

A process was in place for version control of documents.

- **Operations**

A review of controlled drug picking activities was examined. The picking process consisted of an operative receipting an allocation reference, which was scanned into a handheld device and directed the operative to storage locations. These were in turn scanned and a check of the location and product conducted on site, prior to a final scan of products to finalise the transaction. These were held in appropriate, secure units within the controlled drug handling area and appeared well controlled.

[redacted]

The company was noted to have CCTV coverage in this area which was being reviewed.

The security operations of the company were examined. Several areas of weakness were identified; specifically [redacted] As a result, search practices had been identified as deficient, however it was unclear as to exactly what the company intended to do to rectify this; including, a review of search policy, extra search training, a review of locker search policies, and a policy of not checking bags in vehicles. It was acknowledged that a 100% search of vehicles and bags was in place since this incident was identified. The ongoing viability of this policy was uncertain.

Discussions around the use of security options at facility egress points and enhanced security measures around vehicles searches were discussed. The company were examining how to implement this. Further conversations around the registration of vehicles were discussed.

A list of customers potentially impacted had been identified, however it had not been filtered past controlled drug areas. It was suggested that the customer list should be revised down to lane areas to better assess risk to products and clients, whom may have had diverted medicines.

Security arrangements have been defined within formal processes.

There was an SOP that detailed arrangements pertaining to vehicle loading and picking routes. It was reasonable to suggest that shipments had likely been tampered with or damaged in either pallets or boxes. It was deemed likely that boxes may be missing, or opened, which may have been a cause of concern. It was further identified that pallets were not consistently wrapped at the top, which would further support anti-tampering functions.

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

Complaints around short stock receipts were examined. Given that stock counts were consistently acceptable due to the nature of goods being selected post transaction assembly, the trending of non-substantiated complaints were discussed. This mechanism may have identified a trend which could have been linked back to staff members. It appeared possible to the Inspectors that packaging may have been damaged while attempting to remove inventory. The company were asked to consider damaged inventory or packaging complaints against customers to provide further insight. It was noted when interviewed that there was an indication that a complaint may not be recorded if the customer did not wish to substantiate them.

It was noted the company had failed to report this theft to the MHRA for 6 weeks and this information was provided upon enquiry by the Inspector.

Returns and recall activities were not examined.

- **Outsourced Activities**

A process was in place for accepting and monitoring outsourced activities as contract acceptor.

Outsourced activities pertaining to security were examined.

It was stated that the selection of security provisions was not overseen by quality, nor commented on, by the Responsible Person or Quality group. This was considered to be a significant failure. It was unclear as to how the effectiveness of these checks were examined. It was the opinion of the Inspectors that this was within the remit of EU GDP, due to the nature of stock security and potential diversion and should have had quality oversight.

The contract with the Security agents were reviewed. It was noted this contract included responsibilities of temperature monitoring and CCTV monitoring, which was not being consistently applied.

- **Self-Inspection**

The self-inspection procedure was not formally examined, however template documentation pertaining to the process were reviewed.

A record pertaining to a self-inspection encompassing security was examined. It was noted that this identified [redacted] cameras located at the site and detailed security provisions. This did not examine security processes. It was noted an ANPR camera was listed on site, however, was not in use. The reason for this was undocumented.

Although the record appeared sufficiently detailed, it lacked information pertaining to camera considerations or appropriateness, locker search policies, or specific process reviews.

- **Transportation**

The processes relating to transportation were not reviewed in detail at this inspection.

- **Specific Provisions for Brokers:** N/A

| **13. Other specific issues identified:** |
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| |
| **14. Miscellaneous:** |
| N/A |
| **15. Annexes attached:** |
| N/A |

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

### 1. CRITICAL

None observed.

### 2. MAJOR

**2.1 The quality management system was deficient in that:**

2.1.1 An incident of theft described within deviation [redacted] was insufficient in scope and not detailed enough to justify mitigating actions taken by the company. Examples include, but are not limited to:

- The investigation did not fully consider all lines of reasonable enquiry, e.g. shift workers or line management approaches.
- The deviation record did not fully consider the impact of work attire policies such as wearing coats in the warehouse.
- The deviation record did not consider the use of vehicles known to have been owned by the staff member concerned.
- The deviation record did not fully consider a review of the complaints process in Relation to the investigation.
- Immediate identified actions did not directly relate to the root cause analysis; specifically, the use of coats, training of security staff, the use of the 4% randomisation function, or review of locker search policies.
- There was no evidence of a documentation of whistle blower programme schemes or requests for information from staff.

2.1.2 A subsequent CAPA report had not been raised to document actions taken from incident [redacted]

2.1.3 There was no evidence, or identification, of processes, procedures of systems requiring review following the incident.

2.1.4 [redacted] and associated actions had not formally considered the full breadth of impact of the identified risk against all other [redacted] sites where cross docking functions and despatch operations occurred.

2.1.5 [redacted] did not fully consider training and processes pertaining to security personnel.

2.1.6 Risk assessments and processes requiring change control in relation to the incident had not been conducted in accordance with Good Distribution Practice (GDP) undertaken pertaining to [redacted]

2.1.7 [redacted] had not fully considered all investigation matters, such as the assessments of complaints relating to damaged packaging complaints.

2.1.8 Management review had not been formally documented pertaining to the critical incident identified by way of deviation record [redacted]

2.1.9 There was evidence of non-compliance against SOP [redacted] where several timelines had not been adhered to; including, but not limited, to client notification, raising of CAPA, closing of deviations and review of processes, which had not been justified.

**Reference: EU GDP Chapter 1, sub-section 1.2, 1.4 & 1.5**

**2.2 The control of outsourced activities was deficient in that:**

2.2.1 The Responsible Person or delegated deputies had not reviewed, could demonstrate oversight of, nor been consulted during the appointment of security contract providers identified via tendering processes and could therefore not be demonstrated to be compliant with EU GDP, as evidenced by [redacted]

**Reference: EU GDP Chapter 7, sub-section 7.2, 7.3**

**2.3 The Licence Holder and Responsible Person had failed to ensure that the company's operations were following the requirements of relevant UK legislation and EU Good Distribution Practice (GDP). This was demonstrated by, but not limited to, there being evidence that:**

2.3.1 Insufficient mechanisms or facilities had been implemented to fully protect stock from risk of theft or diversion by corrupt actors within the supply chain, including but not limited to evidence of an inefficient application of search or security policies on the premises, and a lack of wider consideration of review within the distribution network.

2.3.2 The Licence Holder had failed to appropriately support the office of Responsible Person which appeared under resourced, evidenced by the inappropriate timeframes in capturing and documenting incidents of theft.

2.3.3 The Responsible Person had failed to notify the Competent Authority of a suspected theft or diversion of medicines, including controlled substances such as [redacted] and [redacted] where the organisation was aware of this up to 6 weeks before the notification date.

2.3.4 The Quality Management System could not be demonstrated to be effective, by way of no formal CAPA, Change Controls or Risk Assessments having been raised pertaining to [redacted] despite having been identified as an area of Critical non-compliance 15 weeks previously.

2.3.5 Self-inspections pertaining to security had not detailed considerations around processes applied to security personnel.

**Reference: The Human Medicines Regulations 2012 43(3) & 45(1)**
**EU GDP Chapter 2, 3, 6, 8 sub-section 2.2, 2.3, 3.1, 6.5, 8.2**

**2.4 Operations were deficient in that:**

2.4.1 SOP [redacted] was not truly reflective of activities conducted on site, in that it was reasonable to suggest that shipments had likely been tampered with or damaged in either pallets or boxes to enable theft contrary to procedural expectations:

2.4.2 The process did not include the requirement to report product tampering or damages to management.

2.4.3 Existing processes that had facilitated the incident, such as the wrapping of pallets, had not been changed and standardised to prevent future reoccurrence. Therefore, there was inadequate reassurance that all risks surrounding the identification of damaged pallets had been mitigated within the procedure.

2.4.4 [redacted] was insufficient in scope and did not detail the process for conducting bag searches, resulting in a lack of assurance that searching mechanisms were effective.

**Reference: EU GDP Chapter 3, sub-section 3.2 & Chapter 5, sub-section 5.5, 5.7, 5.8**

## 3. OTHER

**3.1 Documentation was deficient in that:**

3.1.1 There was evidence of two different document versions appearing in the CD quarantine area.

3.1.2 Deviation [redacted] did not have an initiation date.

**Reference: EU GDP Chapter 4, sub-section 4.2**

**3.2 It could not be demonstrated that packaging materials located within a freezer described as for [redacted] stock storage had been appropriately controlled.**

**Reference: EU GDP Chapter 5, sub-section 5.6**

| 17. Inspectors' Comments: |
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| 4.1 The company must consider mechanisms to efficiently manage damaged stock, of which some was observed to have been quarantined in situ for over 12 months. |
| 4.2 The company is requested to provide a copy of the security report, as well as the position of [redacted] following recommendations made. |
| 4.3 The freezer inspected utilised to store [redacted] stock was observed to have had a significant build-up of ice. |
| 4.4 The company should consider how to ensure all service level complaints may be captured. |

| **18. Recommendations:** |
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| *Continued support of your wholesale dealer's authorisation (WDA(H) 14172) pursuant to Regulation 18 of the Human Medicines Regulations 2012 [SI 2012/1916] (a "wholesale dealer's licence") will be recommended to the licensing authority.*<br><br>*Site and authorisation pursuant to Regulation 18 of the Human Medicines Regulations 2012 [SI 2012/1916] (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".*<br><br>The provisional date for the next inspection of this site is May 2021. |
| **19. Summary and conclusions:** |
| Within the scope of the inspection, the company operates in accordance with the Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) and the Human Medicines Regulations 2012.<br><br>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. |

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| **20. The inspection report should be signed and dated by the Lead Inspector:** |
|---|
| **Name:** [redacted]<br>**Signature:**<br><br>**Organisation:**<br>MHRA<br><br>**Date:** 03/01/2020<br><br>Distribution of Report: [redacted] |