Medicines & Healthcare products
Regulatory Agency

MHRA

GDP INSPECTION REPORT

WDA(H) 32879/93706

VERTICAL PHARMA RESOURCES LIMITED

ISSUED BY:

[redacted] GDP Inspector

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Medicines & Healthcare products Regulatory Agency

MHRA

File Ref: **Insp GDP 32879/93706-0023**
Inspection Date: **28/06/2022 & 20/07/2022**
Company: **VERTICAL PHARMA RESOURCES LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 32879/93706-0023
2. Inspected site(s) and contact details:	
VERTICAL PHARMA RESOURCES LIMITED 41 CENTRAL AVENUE WEST MOLESEY KT8 2QZ UNITED KINGDOM	
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)	
4. Inspection date(s):	20/07/2022
5. Inspector(s):	
Name(s) of the Inspector(s). [redacted] **MHRA**	
6. References:	Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 32879

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7. Introduction:

Business Background

The company was established in 2001 and focused on the supply of unlicenced medicines and clinical trial products primarily within medicinal products.
The company undertook significant supply of THC containing medicines under MS operations.

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

Date of previous inspection:

Name(s) of Inspector(s) involved in previous inspection: [redacted] (1 day)

Date of last inspection:28 – 30th June 2022

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

GMP centric inspection – previous findings not applicable to GDP focused inspection.

Major changes since the previous inspection:
Commissioning of new storage facility – variation pending.

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 and the Human Medicines Regulations 2012.

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9. Inspected activities:
GDP Inspection of all GDP activities, operations, records and documentation under the licence pertaining to this site; Procurement, Holding, Supply, Export
10. Activities not inspected:
None.
11. Personnel met during the inspection:
[redacted]
12. Inspectors findings and observations relevant to the inspection and deficiencies:

- **Quality Management**

Deviation management was examined. The following GDP records were inspected:
[redacted] – Failure of air conditioning unit & temperature excursion
[redacted] – Failure to follow processes by procurement team
[redacted] – Power failure
These appeared appropriately managed.

Additional QMS topics were inspected during the GMP inspection and were not re-visited as part of GDP functions.

A change control relating to the proposed use of the new premises was examined, defined as [redacted] Although generally acceptable, it was noted that no consideration of procedural changes or risk management of stock movement had been fully documented at the time of inspection.

The company maintained an incident log of unexpected events, which were trended. The following records were examined:

[redacted] – Temperature excursion upon goods receipt.
[redacted] – Temperature excursion upon goods receipt.
[redacted] – Damaged product received from supplier.
[redacted] – Goods receipted out of storage conditions [redacted].
[redacted] – Products received without purchase order raised.
[redacted] – No purchase order raised or import permit obtained.
[redacted]
[redacted] – QC Internal audit not completed in schedule
[redacted]
[redacted]
[redacted]

These were broadly acceptable.

Quality risk management was examined. It was noted that limited GDP risks had been considered, primarily around transportation functions. The assessment of operations was considered within this context.

Deviation [redacted] was inspected, where a self-inspection had identified that not all suppliers of medicines had been qualified, due to the supplier initially having been set up for other activities. The company had not assessed fully the risk of this incident and could not define how many suppliers did or did not hold WDA(H).

Management review was examined by way of examining the previous minutes undertaken in February 2022. This was broadly acceptable with evidence of Licence Holder attendance.

The management of outsourced activities was inspected. An audit schedule was examined, and outputs of audits were inspected. It was noted [redacted] and [redacted] were to be audited this year, with [redacted] completed in January 2022. This report was examined.

- **Personnel**

Training procedures were examined.

A staff list was reviewed, compared with a job function matrix utilised by the company. This appeared broadly acceptable.

Training records were examined for the RPs, [redacted] and two warehouse staff.

It was noted that the Quality Director job description had not been updated to include RP and RPi functions.

The responsibilities of the RP were defined within job descriptions for the Executive Director and were broadly acceptable.

The company described GDP awareness training as being included within a GxP training package, which was reviewed. Whereas this was broadly acceptable, it was not exhaustive of GDP.

- **Premises and Equipment**

The premises consisted of a purpose-built warehouse, constructed in 2004, of over 19,000 square feet in totality located on an industrial estate. Further details of the premises were detailed within the preceding GMP report, however, of note for GDP matters was that a secure storage unit located within a mezzanine flooring space had been utilised for storage functions prior to temperature mapping. It was noted no temperature monitoring was being conducted within this premises, and an air conditioning unit placed within the premises had not been validated.

A second proposed premises were inspected, located off the building patch of which a variation was in the process of being submitted for. This was a 7,000 square foot facility, with capacity for approximately 150 pallet spaces. Additional mezzanine flooring and office space was located on site but was not utilised for medicine storage and not mapped as a result. The site was covered by digital CCTV security cameras both internally and externally, with a police linked alarm system and roller shutter covering the staff entrance when not in use. An HVAC system had been installed two months prior, which was observed above racking. A temperature mapping exercise had been completed, however, temperature probes for the identified hot and cold spots had not been received as of yet. The temperature mapping report and the equipment specifications was examined. Ingress and egress to the new premises consisted of a full-length roller shutter which could be rolled back during adverse weather conditions. This premises were not to hold controlled substances, nor would cold chain storage be conducted.

A protocol for the proposed premises was examined which appeared generally acceptable. 43 loggers were utilised across the entirety of proposed storage spaces on the premises for a period of 7 days. It was noted the premises was utilised to store some pallets of miscellaneous, non-pharmaceutical materials, which would support representative conditions. Summary information appeared to indicate that during the 7-day period, the temperature of the premises was between 17.47 and 24 degrees Celsius. The calibration for the proposed loggers appeared acceptable, with acceptable temperature ranges validated to an accuracy of 0.5 degrees

Celsius against a UKAS calibration standard. These were to be remotely monitored and log data to be transmitted wirelessly.

- **Documentation**

  Processes and key documentation were generally observed to be version controlled and appropriately indexed, with clear authorisation.

  Documentation was readily available for inspection.

  Document management processes were not explicitly examined as part of this inspection.

- **Operations**

  The company had no processes to identify or otherwise control the procurement of PLGB products and to ensure they were only supplied on an appropriate basis.

  The company had not developed or implemented processes or controls pertaining to introduced medicines. There were no defined processes detailing functions to be carried out under Responsible Person for Import and Importation functions, authorised under the WDA(H).

  The company did not have processes in place detailing reporting to the Licencing Authority in the event of a theft detection.

  Supplier and customer qualification functions were examined.

  Supplier qualification was defined within SOP[redacted] for API and manufacturing supplies, and SOP[redacted] for WDA(H) supplies. SOP[redacted] was inspected for the purpose of this inspection. This process included requirements to assess documentation and vendor questionnaires to qualify accounts. A list of vendors and their qualifications was examined. This data was controlled via a spreadsheet, populated by quality officers and available to procurement staff. Mechanisms for assessing the MHRA suspended and terminated list were in place within the process. It was noted there were no mechanisms for assessing the validity of persons purporting to represent a company within processes.

  A sampling of vendor qualification records was examined for[redacted] It was noted that records pertaining to assessment of company legitimacy were inconsistent, and only available for[redacted] Described processes however appeared acceptable.

  Customer qualification was divided into wholesaler and pharmacy supply and defined within SOP[redacted], which was generally acceptable. This process defined customer qualification by type and included the use of blocks against licence terms where licences were not held, e.g. preventing controlled drug sales to non-authorised wholesalers. MHRA suspended and terminated lists were also checked. It was noted some suppliers of "special obtains", which did not usually supply medicines, had procured medicines from suppliers they had not qualified.

  Customer authorisations for pharmacy, hospital, hospice, and dental practices were examined and appeared generally acceptable.

  Records pertaining to supply to[redacted] and[redacted] were examined, as well as a dip sample of[redacted]

  Export functions were inspected. There were no processes detailing export functions and C88 documentation was not available for inspection.

  Supply of unlicenced medicine processes were examined and appeared generally acceptable.

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

  The following complaints were examined:
  [redacted] – Medicines delivered to wrong address (08/04/2022)
  [redacted] – Medicines left outside address (17/09/2021)
  [redacted] – Medicine delivered to wrong address (12/08/2021)
  [redacted] – Medicine delivered to wrong address (27/08/2021)
  [redacted] – Medicines left outside address (20/07/2021, also included in [redacted]
  [redacted] – Medicines delivered outside address (07/07/2021 & 20/07/2021 over four deliveries)

  It was noted these were classified as minor occurrences and no firm trending appears to have been established within these records. Further, it was noted the information provided by [redacted] was erroneous in terms of next steps taken. A root cause appears to be the falsification of data in at least one instance, which has been considered a minor observation by the company.

  Further complaints were examined:
  [redacted] – Delays in delivery to Northern Ireland
  [redacted] – Delayed shipment
  [redacted] – Missing product later found
  [redacted] – Multiple delivery issues
  [redacted] – Missing controlled substance in delivery
  [redacted] – Missing controlled substance in delivery
  These were found to be broadly acceptable and proportionate.

  Returns functions were examined, defined within SOP [redacted] This appeared robust, with a defined timeline of returns acceptance of 5 days for WDA(H) holders and 24 hours for non-WDA(H) holders. Records of returns were examined and considered acceptable.

  Falsified medicines awareness was examined and found to be broadly acceptable, with reporting mechanisms to the Licencing Authority considered.

  Recall activities were covered within the GMP inspection and were not re-visited within GDP matters.

- **Outsourced Activities**

  Outsourced activities were examined.

  A written agreement with [redacted] was inspected. The written agreement was generally acceptable however, it was noted that not all provisions had been adhered to. For example, [redacted] had not provided [redacted] with oversight or visibility of training materials utilised, nor route mapping data. The company had not audited sub-contracting functions.

- **Self-Inspection**

  GDP Self-inspection functions were examined, which were undertaken on a department basis.

  Previous self-inspection records pertaining to qualification of customers and suppliers were examined. It was noted that a review of all GDP functions, such as bona fide qualification, had not been inspected during the previous self-inspection.

- **Transportation**

  Transport functions were outsourced to [redacted] and considered within outsourced activities.

- **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:

CRITICAL
None observed

MAJOR
2.1 Operations were deficient, in that:
2.1.1 There were no processes to identify or otherwise control the procurement of PLGB products and to ensure they were only supplied on an appropriate basis.
2.1.2 There were no processes, systems or controls pertaining to introduced medicines.
2.1.3 There were no defined processes detailing functions to be carried out under Responsible Person for Import and Importation functions, authorised under the WDA(H).
2.1.4 There were no processes pertaining to the monitoring of unusual sales patterns.
2.1.5 There was no consideration of reporting stolen medicines to the Licencing Authority.
2.1.6 There were no processes pertaining to exportation management and C88 documentation was unavailable for inspection.
2.1.7 There was evidence that not all medicinal product suppliers had been fully qualified, such as [redacted]
GDP Chapter 5, sub-section 5.3, 5.4, 5.5, 5.7, 5.8, 5.9

2.2 It could not be demonstrated that goods were being consistently delivered into secure custody; specifically, it was noted complaints [redacted] (over four deliveries) all pertained to incorrect deliveries made over a 10 month period. In particular, the nature of these mis-deliveries presented a risk to public health.
GDP Chapter 9, sub-section 9.2

OTHER
3.1 Quality management systems were deficient, in that:
3.1.1 Change control [redacted] had not considered process amendments pertaining to the premise or the management of inventory between units.
3.1.2 Deviation [redacted] lacked data supporting the rationale of CAPA actions.
GDP Chapter 1, sub-section 1.2

3.2 Training was deficient, in that the job description of the Quality director had not been updated to include RP & RPi functions.
GDP Chapter 2, sub-section 2.2

3.3 Premises and equipment were deficient, in that:
3.3.1 No mapping had been conducted prior to the commissioning of a controlled storage area for use on the mezzanine floor.
3.3.2 No risk assessment pertaining to medicinal products located within this area had been conducted.
3.3.3 No temperature monitoring was being conducted within the area referred to in 3.3.1 and 3.3.2.
3.3.4 Temperature adjustment equipment, consisting of a portable air conditioning unit, had not been adequately qualified prior to use.
GDP Chapter 3, sub-section 3.2, 3.2.1

3.4 Outsourced activities were deficient, in that:
3.4.1 [redacted] had not supplied the company with training materials for approval.
3.4.2 There had been no inspection or audit of sub-contracting functions.
3.4.3 No route mapping had been provided to the company.
3.4.4 The audit of [redacted] did not recommend a re-audit date.
GDP Chapter 7, sub-section 7.2, 7.3

3.5 Self-inspection functions were deficient, in that the entirety of GDP had not been encompassed in self-inspection reports.
GDP Chapter 8, sub-section 8.2

17. Inspectors' Comments:
The company should consider the rationale of naming the Licence Holder as a Responsible Person on the licence, in line with MHRA Guidance Note 6.
18. Recommendations:
Continued support of your wholesale dealer's authorisation (WDA(H) 32879) 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".*
19. Summary and conclusions:
Within the scope of the inspection, the company operates/does not operate 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.

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

Name:

[redacted]

Signature:

[redacted]

Organisation:

MHRA

Date: 11/06/2023

Distribution of Report: [redacted]