



Australian Government
Department of Health
Therapeutic Goods Administration

s22
s22

DHL Supply Chain Australia Pty Limited
2-28 Ironbark Close Berrinba
Queensland 4117

Ref: **PH22/20611**

Dear s22

RE: GMP INSPECTION of DHL SUPPLY CHAIN AUSTRALIA Pty LIMITED

Please find attached the inspection report for the inspection that took place at your site in Berrinba site 4117 Queensland on the 17 – 18th November 2022.

Your response(s) to the deficiencies reported in the post inspection letter have been evaluated and have been accepted. Effective implementation will be reviewed at the next GMP inspection.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

Signed and authorised by Lead Inspector

s22

Manufacturing Quality Branch
Date: 18/02/2023

E-mail: s22@health.gov.au



Australian Government
Department of Health
Therapeutic Goods Administration

Inspection Report

Manufacturer:	DHL Supply Chain Australia Pty Limited
Inspected site	2-28 Ironbark Close Berrinba Queensland 4117
Activities carried out by manufacturer:	☐ Manufacture of finished medicinal product ☐ Manufacture of intermediate or bulk ☐ Packaging ☐ Laboratory testing ☐ Release for supply ☒ Other: Storage
Type of inspection:	☒ Initial inspection ☐ Re-inspection ☐ Full inspection ☐ Special inspection ☐ Reduced scope inspection Applicable sections of the <i>Therapeutic Goods Act 1989</i>: ☒ section 37(2)(b) (licence application) ☐ section 40B(10)(a) (licence variation) ☐ section 40(4)(b) (re-inspection of licensed site) ☐ section 25(1)(g) (overseas in relation to registration) ☐ sections 26(1)(g), 26A(3) (overseas in relation to listing)
Scope of Inspection	The manufacturer's compliance with the PIC/S Guide to Good Manufacturing Practice for Medicinal Products - 1 July 2018 with specific focus on the storage only.
Inspection dates:	17 – 18 th November 2022 = two half days = 1 full day.
Inspector	s22
Manufacturing Standard used:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products - 1 July 2018
References:	Manufacturing Licence number: File reference numbers: PH22/20611 & E22-520776

Introduction

DHL Supply Chain (Australia) Pty. Ltd started in Australia in 1998 and is part of the global DHL distribution network. The Healthcare & Life Science division has a number of facilities across Australia engaged in the contract storage, distribution, secondary packaging and release for supply of therapeutic products on behalf of clients. Products handled include pharmaceuticals, medical devices, veterinary products, clinical trial materials and cosmetics.

Date of previous inspection: Not Applicable (Initial Inspection).

Names of inspectors involved in previous inspection: Not Applicable.

Brief report of the inspection activities undertaken

Scope of inspection

No	Manufacturing Type	Sterility	Manufacturing Class	Dosage Form	Product Code	Manufacturing Step
1	Medicine/Device manufacture	Sterile & Non Sterile	Not Applicable	All Dosage Forms	Not Applicable	Storage

- The manufacturer's compliance with the PIC/S Guide to Good Manufacturing Practice for Medicinal Products - 1 July 2018 with specific focus on the storage.
- Initial inspection of the new site at 2-28 Ironbark Close Berrinba site **was performed remotely / virtual** with no physical presence on site by the inspector.

Inspected areas

The inspection was conducted in accordance with an inspection plan presented to DHL Berrinba Queensland site.

Primary or secondary packaging work will not be carried out or the manufacturing of any therapeutic product at this site; it is dedicated to storage only.

Personnel met during the inspection

Refer to the Inspection Attendance Sheet

Inspection findings and observations

Major changes since the previous inspection: Not Applicable

Future Planned Changes: Not Applicable

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

Not Applicable (Initial Inspection).

Quality Management

The inspector reviewed the manufacturer's Quality Management System(QMS) according to the requirements of the PICS Guide to Good Manufacturing Practice (GMP) and found it to be compliant.

The site had a Quality Policy that applied to the integrity of the products.

DHL had written procedures defining the company's approach to quality risk management (QRM) and it was observed that QRM was embedded into relevant QMS systems, such as Change Control (CC). Risks were identified and managed via an Excel Spreadsheet (password protected)with timelines established. Risk reviews were performed biennial for critical control points. Risk methodology was predominately quantitative analysis with a risk priority number determined and risk reduction performed. The inspector reviewed some QRM examples that were well assessed and documented following a QA review and closure if appropriate.

The arrangements for the management of non-conformances /deviations was specified in a procedure; which outlined the process for the recording, an issue and the investigation to enable the Corrective Actions & Prevention Action (CAPA) to follow. In the event of a temperature excursion will be managed as a non-conformance with clients to be notified.

The Change Control (CC) process was detailed in a Standard Operating Procedure (SOP) with a flow chart and suitable reference to supporting documentation. Changes were managed in accordance with a documented CC procedure and were suitable recorded. The CC procedure had classifications for: Critical Change, Major Change, or significant Change with definitions defined.

CC was entered into an electronic system called [s47G](#) that had varying access levels and each users had a unique password. Suitable fields for change proposal, impact assessment and evaluation by QA at different time points that culminated in an effectiveness check and disposition determination. Changes proposed to clients were also notified. The inspector reviewed some CC records which were of a good standard.

Release for Supply activities were documented in a procedure and the responsibility were appropriately assigned to the Quality Lead or Compliance Managers. This ensured conformity to the GMP requirements and included review of Quality Agreement/s were conducted as part of the release process. DHL sites (as applicable) have the ability to verify the requirements and conditions of the Marketing Authorisation for products released.

DHL (Berrinba Queensland) does not provide input into the Product Quality Review.

Personnel

There was a Life Sciences & Healthcare Organisational Chart showed the separation of Production and Quality Assurance (QA). Each had different job descriptions and responsibilities that also included some GMP duties.

The arrangements for training were outlined in a procedure that described the requirements for induction and on-going staff training. An electronic system called s47G managed the training record storage and other QMS modules. The production managers or supervisors were responsible for identifying their staff training competency, procedural knowledge and review of subsequent updates. Training topics and refresher modules were performed annually and included GMP and Good Distribution Practice (GDP).

Premises and Equipment

The premises was not formally reviewed due to the remote / virtual inspection. However, the company provide some photos of the facility and warehouse.

The site has round the clock security guard presence. The facility has warehouses with restricted access with the use of swipe card was restricted to DHL employees. Surveillance cameras were positioned in various areas of the site and within the facility. Signage was provided in the warehouse as appropriate. Movement of goods /inventory was performed manually and or via electronic controls. The DHL facility is a new modern warehousing facility with a sizable footprint. The arrival / departure of goods via truck is protected from the environment by an extended roof line to enable the dry loading/unloading of goods. The warehouse has external Rapid Roller Doors with metal shutters.

The warehouse facility had a significant pallet capacity and vertical racking. Cages were utilised for smaller sized goods or for items that required a locked quarantine status. Pallets and cages were identified via an attachment of label/s and identification placard. The warehouse had an inventory-controlled system called s47G that maintained the various status of the goods via electronic means and or physical control. Disposition determination was provided by the customer and recorded.

The company has a range of different temperatures from ambient temperatures of 15° – 25°C, to cold room conditions of 2° – 8°Celsius (C), as well as -20° C and – 70° C for s47G freezers. The range of temperatures were monitored by temp tail devices throughout the warehouse that provided continually monitoring via the s47G system. The upper and lower temperature limits were defined, and a breach would trigger an alert condition with SMS notification to management. Daily, monthly and biannual checks were performed and recorded with a disposition assessment determination. Other special storage was for Schedule 8 Drugs with vaults used.

A Preventative Maintenance (PM) procedure was in place along with an s47G that was utilised to trigger the PM /calibrations tasks according to a predetermined time point. A service report was generated of the tasks performed for review by management. PM and calibrations were performed either internal or external by approved contractors with agreements in place where required. Calibration instruments were certified to National Standards and checked. The inspector reviewed a few PM & calibrations and the information recorded was appropriate with the results suitable confirmed.

Documentation

The company's documentation system was being phased out over a two-year period with a hybrid approach in use. The master documents were stored, controlled, and recorded appropriately by QA. An SOP was available for document control and the procedures reviewed were within the two-year expiry period. Procedure change had an effectivity date applied for training purposes. A revision history of updates was recorded in the SOP. A controlled document was suitable identifiable with a controlled copy stamp. Superseded controlled document were archived electronically.

Production

The Validation Mater Plan was not reviewed during the inspection due to time constraints.

s47G qualification was not performed due to time constraints however other DHL sites have been inspected by the TGA and computer validation would have been reviewed.

The warehouse Cool Room number 1 was temperature mapped in August 2021. The Installation, Operational & Performance qualifications (IQ, OQ and PQ) were performed. Calibrated temp tails were used in varying locations as identified through the temperature mapping studies. This included worst case scenarios with both the lowest and highest rack level locations selected. Cool Room 1 was empty on the initial qualification that was performed for 7 days during the summer and winter seasons. The data was downloaded and checked by the validation specialist and the results met the acceptance criterion. No temperature excursions occurred during the validation. The validation was accepted by QA and Operations management for working status.

Quality Control

Not applicable as product testing for release was provided by the relevant client.

Outsourced Activities

The inspector reviewed a s47G agreement for the computer procurement, review and approved for execution information that was signed by both parties and current at time of the inspection.

Complaints and Product Recall The raised NC form goes to the responsible department for processing with QA raising a CAPA (if required) and performing the close out and notifying the customer.

The site managed complaints via a joint quality agreement. DHL Quality Operations Manager recorded a complaint in a logbook and forwarded the matter onto the client for investigation and resolution.

Recall arrangements for managing product recalls were defined in a procedure. The client was responsible, for e-mail notification to DHL on managing of product recalls. DHL were responsible for participating and storing of the recalled product or returning it back to the client.

Self-Inspection DHL had established a programme for self-inspection with a yearly schedule in place. A controlled check list was used, and observations were recorded as Minor and Major with definitions in place. Following the self-inspection, a report was generated from the review of the QMS and other GMP impacting processes. QA oversight of the self-inspection process was performed and CAPA were raised where applicable and tracked to completion.

Compliance with Marketing Authorisations Clients were responsible for the registration of products on the ARTG. DHL had implemented a system for the verification of Marketing Authorisation conditions that was based on a written declaration form from the client.

Specific Annexes The Annexes of the Standard applicable to the inspection were Annexes 1, 11 & 15.

Other specific issues identified

None

Site Master File

Site Master File (SMF) was made available prior to the inspection and was assessed to be adequate

Miscellaneous

Samples taken:

None

Distribution of Report:

TGA and DHL Supply Chain (Australia) Pty Ltd

Attachments:

List of any attachments (e.g.) Inspection attendance sheet

List of Deficiencies observed during the inspection

Critical

Non-Observed

Major
Non-Observed

Minor
Non-Observed

Comments

Summary and conclusions

Assessment of manufacturer's responses

A response to the deficiencies reported to the manufacturer was received on 17 of November 2022. Following requests for further information, a final satisfactory response was received on 17/11/2022.

The manufacturer's corrective actions have been evaluated and accepted, based on the agreement that all corrective actions will be carried out as described in the inspection close out correspondence.
17 – 18th November 2022

Final evaluation and recommendations:

1. The manufacturer operates in accordance with the relevant GMP requirements.
2. TGA records have been updated to show a final compliance rating of your facility of A1: good compliance with the manufacturing standard established under the *Therapeutic Goods Act 1989*.
3. The next re inspection is expected to be performed within 12 months.
4. The duration of the next inspection is estimated at this time to be 1 days.

Signed and authorised by

s22

Inspector

Manufacturing Quality Branch

Date: 18/02/2023

E-mail: s22@health.gov.au

DEFINITIONS

Marketing Authorisation

Compliance with regulatory requirements specified in the ARTG and any other requirements imposed by a relevant Delegate of the Secretary, upon product listing or registration.

Examples of regulatory requirements include but not limited to the following: compliance with registered formulations, special storage and transportation conditions, shelf life, labelling, batch release testing requirements etc.

Critical Deficiency

A deficiency in a practice or process that has produced, or may result in, a significant risk of producing a product that is harmful to the user. Also occurs when it is observed that the manufacturer has engaged in fraud, misrepresentation or falsification of products or data.

Major Deficiency

A non-critical deficiency that:

- has produced or may produce a product which does not comply with its marketing authorisation; and/or
- indicates a major deviation from the Good Manufacturing Practice; and/or
- indicates a major deviation from the terms of the manufacturing licence or GMP approval (overseas manufacturers); and/or
- indicates a failure to carry out satisfactory procedures for release of batches; and/or
- indicates a failure of the person responsible for QA/QC to fulfil his/her duties; and/or
- consists of several other deficiencies, none of which on its own may be major, but which may together represent a major deficiency and should be explained and reported as such.

Other Deficiency

A deficiency that cannot be classified as either critical or major, but indicates a departure from good manufacturing practice.

A deficiency may be “other” either because it is judged as minor, or because there is insufficient information to classify it as major or critical.

One-off minor lapses or less significant issues are usually not formally reported, but are brought to the attention of the manufacturer.

Note:

1. Classification of a deficiency is based on the assessed risk level and may vary depending on the nature of products manufactured, e.g. in some circumstances an example of major deficiency may be categorised as critical.
2. A deficiency that was reported at a previous inspection and not corrected may be reported in a higher classification.



Australian Government
Department of Health
Therapeutic Goods Administration

s22

DHL Supply Chain Australia Pty Ltd
150 Talbot Road
Hazelmere
Western Australia 6055

Ref: PH23/15245

Dear s22

RE: GMP INSPECTION of Company DHL Supply Chain Australia Pty Ltd – Hazelmere WA

Please find attached the inspection report for the virtual initial inspection that took place at your Talbot Road, Hazelmere WA site on the 29th May 2024.

Your response(s) to the deficiencies reported in the post inspection letter have been evaluated and have been accepted. Effective implementation will be reviewed at the next GMP inspection.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely,

(Signed electronically; contains no visible signature)

s22

Lead Inspector
Manufacturing Quality Branch
Date: 27th June 2024

Tel: s22
E-mail: s22@health.gov.au



Australian Government
Department of Health
Therapeutic Goods Administration

Manufacturer:	DHL Supply Chain Australia Pty Ltd – Hazelmere WA
Inspected site/s:	150 Talbot Road, Hazelmere, Western Australia 6055
Activities carried out by manufacturer:	☐ Manufacture of finished medicinal product ☐ Manufacture of intermediate or bulk ☐ Packaging ☐ Laboratory testing ☐ Release for supply ☒ Other: Storage
Type of inspection:	☒ Initial inspection ☐ Re-inspection ☒ Full inspection ☐ Special inspection Applicable sections of the <i>Therapeutic Goods Act 1989</i>: ☒ section 37(2)(b) (licence application) ☐ section 40B(10)(a) (licence variation) ☐ section 40(4)(b) (re-inspection of licensed site) ☐ section 25(1)(g) (overseas in relation to registration) ☐ sections 26(1)(g), 26A(3) (overseas in relation to listing)
Scope of Inspection:	Storage of Sterile and Non-Sterile All Dosage Forms
Inspection date/s:	29 th May 2024
Inspector/s:	s22 (Lead Inspector)
Manufacturing Standard used:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 01 May 2021 (Referred to as GMP code in this report)
References:	Manufacturing Licence number: MI-2023-LI-12749-1 File reference number/s: PH22/21549

Introduction

DHL Supply Chain Australia Pty Ltd – Hazelmere site, known hereafter as DHL Hazelmere is a site that is used for the storage of a variety of products and this licence is intended to include the storage of sterile and non-sterile medicines. DHL is a global transport and logistics company, owned by Deutsche Post. Australia wide there are just over 5100 employees over 56 locations and looks after 252 customers.

The Hazelmere site was established in 2020 has a pallet capacity of just over 16,400 over an 18,050sqm site. The site is able to store product at 15 to 25°C, as well as the specialist storage temperature of 2 to 8°C, -20°C and -70°C cold chain capacity along with dangerous goods storage capabilities. The site stores pharmaceutical, medical devices, 4PL and technology products on the site and looks after a 37 Healthcare customers. The site at present has ISO 9001 certification along with medicines and poisons licence.

Date of previous inspection: Not applicable as this was an initial inspection

Names of inspectors involved in previous inspection: Not applicable as this was an initial inspection

Brief report of the inspection activities undertaken**Scope of inspection**

As covered in the previous table.

Inspected areas

General areas covered at the main site included warehousing for the site. The secondary site was inspected for the step of storage. In addition, the quality system and associated records for compliance to the GMP code were reviewed.

Personnel met during the inspection

Please refer to the Inspection Attendance Sheet.

Inspection findings and observations

Major changes since the previous inspection:

- Not applicable as this was an initial inspection

Future Planned Changes:

- No future planned changes disclosed.

Action taken since the last inspection

Not applicable as this was an initial inspection

Quality Management

DHL Hazelmere had implemented an effective system of quality management that met the requirements of the GMP code.

The company had established an appropriate procedure for quality risk management. The system linked to other relevant company quality management systems.

The company had established an appropriate system to manage and investigate planned and unplanned deviations and non-conformances and implement corrective and preventative actions (CAPA). The inspector reviewed some

examples of deviations and found that DHL Hazelmere had recorded and documented the investigation of issues to an appropriate depth. The staff reviewed the registers and conducted detailed trending.

DHL Hazelmere had implemented an appropriate change control system. The system covered manufacturing changes to the facility, equipment, materials, processes and documentation. The company assessed the impact and consequences of the proposed change requests on the storage, validation and impact on the associated licence.

The company undertook biannual Quality Management Reviews with all of the Senior management. All aspects of the quality management system were discussed including process improvements and product conformity.

DHL Hazelmere was not required to manage an appropriate system for release for supply.

Personnel

DHL Hazelmere had established position descriptions for key personnel and company organisation charts provided clear reporting and authority flows. The inspector confirmed that the heads of production and quality were independent.

The company had established a compliant electronic system s47G for training and assessment of all personnel. The company also trended training as part of the regular weekly reports. The inspector reviewed training procedures, plans and records and found no issues.

DHL Hazelmere had implemented appropriate arrangements for personal hygiene practices, including clothing of personnel and visitors in the areas of the warehouse.

The company had implemented appropriate systems to ensure that staff with infectious diseases, or other relevant health issues could not adversely affect the stored product. Medical examinations were conducted upon recruitment.

Premises and Equipment

The design for personnel and material flows were appropriate for the activities undertaken on site. Staff had maintained good house-keeping. The inspector found the site to be clean and tidy at the time of the inspection.

The warehouse had separate locations for goods receipt, staging, sampling, quarantine, storage, rejected goods and returned goods. All areas of the warehouse were air-conditioned and temperature mapped. The areas of storage included 15 - 25°C, 2 - 8°C fridge, a -20°C freezer and -70°C ultra-low temperature freezer as well as dangerous goods storage and a number of vaults for the storage of secure scheduled goods. A data acquisition system s47G monitored the temperature via data loggers throughout the various areas of the warehouse to ensure storage conditions were maintained within the required specifications. Any deviations from the storage temperatures resulted in emails and text messages to various staff for acknowledgement and rectification. There were a number of staff that reviewed the data for the warehouse temperature storage conditions.

Status was controlled electronically in the DHL Hazelmere inventory management system. The reject areas were locked and the electronic status systems added extra security and would not allow picking or use of rejected goods.

The company had appropriately maintained the facility to a high standard.

The company had established compliant maintenance and calibration systems. The inspector found that the maintenance and calibration records and SOPs

reviewed demonstrated that planned schedules had been adhered to and storage equipment was appropriately managed and maintained to a high standard.

DHL Hazelmere had implemented an appropriate system for pest control at both sites. The system included documented procedures, approved chemicals, device location maps, control devices for rodents and crawling insects, and relevant records of activities undertaken. A contract pest control company was utilised to visit the site on a regular basis or more frequently as required.

The company had implemented an appropriate process for secure waste disposal that ensured products were unusable and unrecoverable. The process was managed through a manifest and included a record of the destruction for the secure waste.

Documentation

DHL Hazelmere had implemented an electronic documentation management system. The system allowed employees to view company documents at workstations throughout the site. The company required SOPs to be reviewed at least every 3 years to ensure that they remain current. The SOPs were appropriately detailed and the company had maintained them to reflect current practice.

The company undertook a comprehensive back-up of electronic data that was hosted from s47G. The company ensured multiple back-ups occurred and the back-ups were appropriately challenged and maintained.

DHL Hazelmere had implemented a policy to ensure that GMP relevant records were stored securely for specified periods meeting or exceeding minimum cGMP requirements.

Production

The inspector reviewed the processes and procedures relating to the storage of all therapeutic products covered under the company licence. The company had established detailed instructions for the cleaning of equipment and storage areas and had maintained usage/cleaning records for areas.

The company received the goods in a number of covered docks via rapid roller doors with air curtains to restrict the ingress of pests into airlocks of ambient storage and directly into the airlocks of 2 - 8°C storage. This allowed for the goods to be taken directly into the warehouse staging areas with minimisation of temperature storage discretions. Once received in the warehouse the goods were then placed in the staging areas where they were checked for quality and integrity and receipted accordingly. The goods were then labelled with an identity and barcoded then scanned and stored into the appropriate racking.

On instruction from the customer via the purchase order the stock was picked, prepared, transacted in s47G and prepared for outbound transportation.

The company had established a compliant supplier qualification and control system. The vendors were assessed and qualified for each material / system supplied, according to DHL Hazelmere procedure. The process could include reviewing vendor information through vendor questionnaires or on-site GMP inspections for checking of compliance to company specifications as required. The inspector reviewed several examples of the supplier qualification reports and found no issues.

Products were receipted into the company inventory management system s47G for management of stock control.

DHL Hazelmere had established a documented procedure to manage the return of goods. The system required a returned to be raised in s47G before goods

could be accepted back onto site. The company then contacted the customer for further instructions. The company considered the client based strategy / decision making for an appropriate assessment of the control of goods for storage.

The company had documented site validation requirements in the validation master plan (VMP). The inspector reviewed this document and found that it had appropriately covered all relevant areas for the site. DHL Hazelmere maintained appropriate logs and schedules to manage current requalification and new validation project activities.

DHL Hazelmere had appropriately documented equipment qualification requirements in several company SOPs. The inspector reviewed the company Equipment Validation for the Dangerous Goods Temperature Mapping conducted in 2022 and found this to be of a high standard with no issues.

The company had established a computer validation master plan to ensure that all relevant computer systems used for GMP activities would be validated and a risk assessment on validation for computer based systems. Given that the company utilises company-wide computer systems and these had been reviewed at other inspections there was no requirement to review the associated validations.

Quality Control Not applicable

Contract Manufacture and Analysis The company had established appropriate GMP agreements with all customers and contractors.

Complaints and Product Recall The company had established an appropriate system for receipt, recording, investigation and analysis of customer complaints using the CAPA management process. The inspector found no issues.

The inspector reviewed the system for product recalls and found it to be compliant. A mock recall was conducted annually, if no real recalls had been undertaken.

Self-Inspection The company had a compliant system for self-inspection.

Compliance with Marketing Authorisations DHL Hazelmere had no requirement to comply with the marketing authorisation apart from the assurance that the product was stored appropriately.

Specific Annexes The Annexes of the Standard applicable to the inspection were Annexes 11, 15 and 19.

Other specific issues identified
None

Site Master File

The company provided a copy of their SMF and while the document appropriately covered the company activities undertaken, it was noted that this document was still under draft.

Miscellaneous

Samples taken:

None

Distribution of Report:

Company and TGA files PH23/15245

Attachments:

None

List of Deficiencies observed during the inspection

Nil deficiencies issued during the inspection.

Comments

Any comments made to the company, in reference to their response to correct deficiencies raised at the inspection, during the closeout process can be found in the close out record.

Summary and conclusions

Assessment of manufacturer's responses

Not applicable

Final evaluation and recommendations:

1. The manufacturer operates in accordance with the relevant GMP requirements.
2. TGA records have been updated to show a final compliance rating of your facility of A1: good compliance with the manufacturing standard established under the *Therapeutic Goods Act 1989*.
3. The next re inspection is expected to be performed within 36 months.
4. The duration of the next inspection is estimated at this time to be 1 day.

(Signed electronically; contains no visible signature)

s22

Lead Inspector
Manufacturing Quality Branch
Date: 27th June 2024

Tel: s22
E-mail: s22 @health.gov.au

DEFINITIONS

Marketing Authorisation

Compliance with regulatory requirements specified on the ARTG and any other requirements imposed by a relevant Delegate of Secretary upon product listing or registration.

Examples of regulatory requirements include but not limited to the following: compliance with registered formulations, special storage and transportation conditions, shelf life, labelling, batch release testing requirements etc.

Critical Deficiency

A deficiency in a practice or process that has produced, or may result in, a significant risk of producing a product that is harmful to the user. Also occurs when it is observed that the manufacturer has engaged in fraud, misrepresentation or falsification of products or data.

Major Deficiency

A non-critical deficiency that:

- has produced or may produce a product which does not comply with its marketing authorisation; and/or
- indicates a major deviation from the Good Manufacturing Practice; and/or
- indicates a major deviation from the terms of the manufacturing licence or GMP approval (overseas manufacturers); and/or
- indicates a failure to carry out satisfactory procedures for release of batches; and/or
- indicates a failure of the person responsible for QA/QC to fulfil his/her duties; and/or
- consists of several other deficiencies, none of which on its own may be major, but which may together represent a major deficiency and should be explained and reported as such.

Other Deficiency

A deficiency that cannot be classified as either critical or major, but indicates a departure from good manufacturing practice.

A deficiency may be “other” either because it is judged as minor, or because there is insufficient information to classify it as major or critical.

One-off minor lapses or less significant issues are usually not formally reported, but are brought to the attention of the manufacturer.

Note:

1. Classification of a deficiency is based on the assessed risk level and may vary depending on the nature of products manufactured, e.g. in some circumstances an example of major deficiency may be categorised as critical.
2. A deficiency that was reported at a previous inspection and not corrected may be reported in a higher classification.

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Australian Government
Department of Health
Therapeutic Goods Administration

Manufacturing Quality Branch

Inspection attendance sheet

Manufacturer name:	DeL. Supply Chain Australia Pty Ltd
Manufacturer address:	150 Talbot Road, Hazelmere WA 6055
Inspection type:	Initial inspection (Virtual)
Inspection date/s:	29th May 2024
Inspector/s:	Lead Inspector: s22
Inspection standard:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 01 May 2021

Opening meeting starting time: 8:30am
Closing meeting starting time: 4:10pm.

Name (please print)	Position (please print)	Opening meeting (initials)	Closing meeting (initials)
s22			



Australian Government
Department of Health
Therapeutic Goods Administration

s22
s22

DHL Supply Chain Australia Pty Limited
1 Botero Place
Truganina
Victoria

Ref: PH22/21956

Dear s22 ,

RE: GMP INSPECTION of DHL Supply Chain Australia Pty Limited

Please find attached the inspection report for the inspection that took place at your Truganina, Victoria site on 07/03/2024.

Your response(s) to the deficiencies reported in the post inspection letter have been evaluated and have been accepted. Effective implementation will be reviewed at the next GMP inspection.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

Signed and authorised by Lead Inspector s22
Manufacturing Quality Branch
Date: 26/06/2024
Tel: s22
E-mail: s22 @health.gov.au



Australian Government
Department of Health
Therapeutic Goods Administration

Inspection Report

Manufacturer:	DHL Supply Chain Australia Pty Limited
Inspected site/s:	1 Botero Place, Truganina, Victoria
Activities carried out by manufacturer:	☐ Manufacture of finished medicinal product ☐ Manufacture of intermediate or bulk ☐ Packaging ☐ Laboratory testing ☐ Release for supply ☒ Other: <i>Storage of therapeutic goods</i>
Type of inspection:	☒ Initial inspection ☐ Re-inspection ☒ Full inspection ☐ Special inspection ☐ Reduced scope inspection Applicable sections of the <i>Therapeutic Goods Act 1989</i>: ☒ section 37(2)(b) (licence application) ☐ section 40B(10)(a) (licence variation) ☐ section 40(4)(b) (re-inspection of licensed site) ☐ section 25(1)(g) (overseas in relation to registration) ☐ sections 26(1)(g), 26A(3) (overseas in relation to listing)
Scope of Inspection	Storage of sterile and non-sterile therapeutic goods in all dosage forms
Inspection date/s:	7/03/2024
Inspector/s:	s22
Manufacturing Standard used:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products - 1 May 2021 + applicable annexes
References:	Manufacturing Licence number: MI-2022-LI-05296-1 File reference number/s: E22-567380

Introduction

DHL Supply Chain (Australia) Pty Ltd is part of the global DHL distribution network. The Healthcare division has a number of facilities across Australia engaged in the contract storage, distribution, secondary packaging and release for supply of therapeutic products on behalf of clients. Products handled include pharmaceuticals, medical devices, veterinary products, clinical trial materials and cosmetics.

DHL submitted an application to licence their warehouse in Truganina, Victoria that at the time of inspection was a secondary site under their existing manufacturing licence (ref: MI-01122004-LI-000260-1, 180 Parkwest Drive, Derrimut, Victoria, 3030). Upon authorisation and issuance of the new licence, DHL plan to voluntarily surrender the licence for the Derrimut warehouse.

Date of previous inspection: 8th July 2020

Names of inspectors involved in previous inspection: [s22](#)
(ref: MI-01122004-LI-000260-1).

Brief report of the inspection activities undertaken**Scope of inspection**

The scope of the initial inspection was to assess the manufacturer's compliance with the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 May 2021, PE009-15 relating to storage of sterile and non-sterile registered therapeutic goods in all dosage forms. Review of deficiencies identified at previous inspection under the previous licence (ref: MI-01122004-LI-000260-1).

Inspected areas

The inspection was conducted in accordance with an inspection plan presented to the company. This consisted of a review of the Pharmaceutical Quality System, warehouse facility, and related utilities and processes.

Personnel met during the inspection

Refer to inspection attendance sheet

Inspection findings and observations

Major changes since the previous inspection: Voluntary revocation of the licence for the Derrimut warehouse (ref: MI-01122004-LI-000260-1).

Future Planned Changes: No changes disclosed by the manufacturer.

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

The previous inspection findings were reviewed during this inspection and were found to have been satisfactory closed out.

Quality Management

The manufacturer had established comprehensive quality system for the purposes of meeting the PIC/S Guide to Good Manufacturing Practice for Medicinal Products - 1 May 2021.

The risk management procedure was available and described the processes of risk assessment and mitigation. Risk assessment was incorporated into quality management system procedures such as deviation management and change control.

There was an appropriate written procedure in place for the management of deviations and non-conformances, which included root cause analysis and implementation of corrective and preventive actions. There was also a requirement to review effectiveness of actions implemented prior to close out of critical and major deviations/non-conformances. A Register of deviations/non-conformances was available. The inspector noted some issues with the depth of investigations within deviation records reviewed (Deficiency 1).

The arrangements for managing changes, including all changes that may affect the quality of products, were documented in a procedure. The procedure required that all change requests be recorded and approved prior to implementation. QA approved the change and followed up the change to ensure that all activities had been completed prior to closing the change control documents. No issues were identified with the DHL's change control system.

DHL did not generate Product Quality Reviews (PQR) as the site was for storage only, DHL's involvement in PQRs was supplying storage temperature monitoring data to customers only.

There was no requirement to perform release for supply as the facility was authorised for storage of therapeutic goods only.

Personnel

The personnel structure of the manufacturer was identified in organisation charts with suitable separation between the Quality and Production streams. An organisation chart was available as part of the Site Master Plan and was up to date. The technical expertise, experience and knowledge of GMP of individual staff met during the inspection was deemed to be adequate.

Position descriptions were available for key personnel and these outlined responsibilities of the positions. The inspector found positions descriptions were generally satisfactory.

Training was specified in a procedure and included induction, GMP, safety and SOP training. There was also a documented requirement for annual refresher GMP training. The inspector reviewed selected training records for GMP staff at the site and did not identify any issues.

The inspector observed an adequate level of staff personal hygiene and gowning in accordance with the procedures.

Premises and Equipment

The 1 Botero Place site was commissioned in May/June 2020. This site occupies approx. 17,000m² under cover. The tour of the facility demonstrated that the design for personnel and material flows were appropriate for the activities undertaken on site. Staff had maintained good housekeeping. The inspector found the site to be clean, tidy and well organised at the time of the inspection.

DSC warehouse facilities are air-conditioned and maintained at 15°C to 25°C. There are also cool rooms (2°C to 8°C) and Freezers (-15-°C to -20°C) and (-60-°C to -90°C) to store Healthcare products and a -70°C customer specific freezer for laboratory reagents which were outside the scope of this inspection.

A data acquisition system automatically monitored temperatures of all

storage rooms/equipment via wireless data loggers to ensure storage conditions were maintained within their respective specifications. Laboratory staff reviewed the data for general warehouse temperature storage conditions via printouts that were periodically generated and verified.

Preventative maintenance and calibration requirements were defined in the company's procedures. Maintenance and calibration activities were primarily related to temperature control and monitoring activities. The inspector reviewed a number of maintenance records and did not identify any issues.

Pest control procedures and reports were available, no issues were identified with the management of pests onsite.

There was an appropriate procedure in place for waste disposal. No issues were identified with the management of waste.

Documentation

A system of document control s47G was in place for the management of procedures, forms and work instructions. All GMP documents were approved by QA. There were appropriate procedures in place for the archiving of hard copy batch documentation.

Procedures reviewed during the inspection were found to be current and satisfactory.

There was no requirement for the generation of Master Batch/Batch records as the site was authorised for the storage of therapeutic goods only.

Production

The manufacture had a supplier evaluation program which covered suppliers of materials and service providers.

Warehouse personnel checked the goods received for damages and against the Purchase Order or Advanced Shipping Notice, including the status (Released or Quarantined) as assigned by the customers. Goods were then receipted into the company's electronic inventory control system, s47G

Labels containing barcodes were generated from the WMS system and applied to the goods. Status of materials was controlled electronically. No issues had been identified with this process.

There was no requirement for reprocessing/reworking therapeutic goods onsite.

There was an appropriate Validation Master Plan (VMP) available. The VMP covered equipment and facility qualification, and computer, transport and packaging process validation. The VMP also described the requirements for revalidation and validation review. A validation schedule was available.

Equipment and facilities were qualified prior to use. The inspector reviewed selected equipment and facility qualification documents and found them generally acceptable, it was noted however that User Requirement Specifications had not been generated for several new equipment assets that had been introduced to the facility (Deficiency 2).

Quality Control

Not applicable.

Outsourced Activities

The manufacturer had GMP Agreements with contract givers and service providers. The inspector reviewed a number of Agreements and found them generally satisfactory.

Complaints and Product Recall	DHL used the non-conformance process to manage complaints. Complaint reports were required to be investigated, recorded and appropriate corrective actions implemented. The arrangements for managing product recalls were defined in procedure. The client was responsible for managing recalls. DHL provided the required information and the facility for storage of recalled product as determined by the client.
Self-Inspection	DHL had a procedure for internal audit and prepared an internal audit plan annually. The inspector reviewed the process and evidence of internal audits being carried out and did not identify any issues.
Compliance with Marketing Authorisations	Not applicable.
Specific Annexes	The Annexes of the Standard applicable to the inspection were Annexes 11 and 15 only.

Other specific issues identified

None.

Site Master File

A site master file (ref: SOP: 02608, effective May 26, 2023) which was an accurate reflection of the facilities' capability.

Miscellaneous**Samples taken:**

None

Distribution of Report:

DHL Supply Chain (Australia) Pty Ltd and TGA Trim File: D24-2625485

Attachments:

None

List of Deficiencies observed during the inspection**Critical deficiencies:**

None observed.

Major deficiencies:

None observed.

Other deficiencies:

1. The requirements of Clause 1.8 vii that any significant deviations are fully recorded, investigated with the objective of determining the root cause and appropriate corrective and preventive action implemented, was not fully met, for example in relation to CAPA 32597; power surge to s47G, leading to a temperature excursion, the following was observed:
 - a. The details of the temperature excursion were not documented (max/min temperature and time out of specification).
 - b. The actual product(s) stored in the unit and the associated storage conditions were not documented.

- c. A risk assessment had been performed, however without information on the details of the temperature excursion, or the associated storage requirements of the products being stored it was not clear how the risk assessment could be performed effectively.
 - d. As part of the remediation, a circuit breaker was installed on the ULT unit, however it was not demonstrated if the other installed identical ULT units were also fitted with circuit breakers.
2. The requirements of Annex 15, § 3.2 that the specification for equipment, facilities, utilities or systems should be defined in a URS and/or a functional specification. The essential elements of quality need to be built in at this stage and any GMP risks mitigated to an acceptable level. The URS should be a point of reference throughout the validation life cycle, was not fully met, for example, no URS (or equivalent document) was available in relation to the procurement, installation and qualification of the following equipment/facility installations:

s47G



Comments

No further comments.

Summary and conclusions

Assessment of manufacturer's responses

A response to the deficiencies reported to the manufacturer was received on 9/5/2024.

The manufacturer's corrective actions have been evaluated and accepted, based on the agreement that all corrective actions will be carried out as described in the inspection close out correspondence.

Final evaluation and recommendations:

1. The manufacturer operates in accordance with the relevant GMP requirements.
2. As discussed during the inspection and throughout the close out process, the following steps in manufacture, known as authorisations under section 37(2)(b) of the Therapeutic Goods Act 1989, have been submitted to the delegate for approval:

Storage of sterile and non-sterile registered therapeutic goods in all dosage forms.

3. TGA records have been updated to show a final compliance rating of your facility of select one of the following four by deleting the three not applicable ones: A1: good compliance with the manufacturing standard established under the Therapeutic Goods Act 1989.
4. The next re inspection is expected to be performed within 36 months.
5. The duration of the next inspection is estimated at this time to be 1 days.

Signed and authorised by Lead Inspector – s22

Manufacturing Quality Branch

Date: 26/06/2024

Courier address: 595 Collins Street, Melbourne, 3000, Victoria

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Australian Government
Department of Health
Therapeutic Goods Administration

Manufacturing Quality Branch

Inspection attendance sheet

Manufacturer name:	DHL Supply Chain Australia Pty Limited
Manufacturer address:	1 Botero Place, Truganina, Victoria 3029
Inspection type:	Initial Inspection (onsite)
Inspection date/s:	7th March 2024
Inspector/s:	s22
Inspection standard:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products - 1 May 2021

[illegible]

DEFINITIONS

Marketing Authorisation

Compliance with regulatory requirements specified in the ARTG and any other requirements imposed by a relevant Delegate of the Secretary, upon product listing or registration.

Examples of regulatory requirements include but not limited to the following: compliance with registered formulations, special storage and transportation conditions, shelf life, labelling, batch release testing requirements etc.

Critical Deficiency

A deficiency in a practice or process that has produced, or may result in, a significant risk of producing a product that is harmful to the user. Also occurs when it is observed that the manufacturer has engaged in fraud, misrepresentation or falsification of products or data.

Major Deficiency

A non-critical deficiency that:

- has produced or may produce a product which does not comply with its marketing authorisation; and/or
- indicates a major deviation from the Good Manufacturing Practice; and/or
- indicates a major deviation from the terms of the manufacturing licence or GMP approval (overseas manufacturers); and/or
- indicates a failure to carry out satisfactory procedures for release of batches; and/or
- indicates a failure of the person responsible for QA/QC to fulfil his/her duties; and/or
- consists of several other deficiencies, none of which on its own may be major, but which may together represent a major deficiency and should be explained and reported as such.

Other Deficiency

A deficiency that cannot be classified as either critical or major, but indicates a departure from good manufacturing practice.

A deficiency may be “other” either because it is judged as minor, or because there is insufficient information to classify it as major or critical.

One-off minor lapses or less significant issues are usually not formally reported, but are brought to the attention of the manufacturer.

Note:

1. Classification of a deficiency is based on the assessed risk level and may vary depending on the nature of products manufactured, e.g. in some circumstances an example of major deficiency may be categorised as critical.
2. A deficiency that was reported at a previous inspection and not corrected may be reported in a higher classification.