Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

INSPECTION REPORT

Parexel International Limited
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Section A Inspection Report Summary

Inspection requested by: MHRA

Scope of Inspection: Targeted inspection (remote) – variation to existing MIA(IMP) requested to implement oversight of QP-certified IMPs from approved countries

Licence or Reference Number: M IA(IMP) 12689

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Licence Holder/Applicant: Parexel International Limited

Details of Product(s)/ Clinical trials/Studies: [redacted]

Activities carried out by company:	Y/N
Manufacture of Active Ingredients	N
Manufacture of Finished Medicinal Products – Non sterile	Y*
Manufacture of Finished Medicinal Products - Sterile	Y*
Manufacture of Finished Medicinal Products - Biologicals	N
Manufacture of Intermediate or Bulk	N
Packaging – Primary	Y*
Packaging - Secondary	Y*
Importing Y	*
Laboratory Testing	N
Batch Certification and Batch Release	Y*
Sterilisation of excipient, active substance or medicinal product	N
Broker N	
Other: Oversight of import of QP-certified IMPs to GB from approved countries	Y

* Other licensed activities not in scope of this targeted inspection.

Name and Address of site(s) inspected (if different to cover): As cover page.

Site Contact: [redacted]

Date(s) of Inspection: 30 Nov 2021

Lead Inspector: [redacted]

Accompanying Inspector(s): Not applicable

Case Folder References: Insp IMP 12689/27547-0023

Section B General Introduction

B1 Background information

This inspection was a targeted review of systems and processes associated with implementation of the oversight process for import of QP-certified IMPs to GB from approved countries. There was no intention to supply direct to clinical trial sites, with all IMPs being received to the Pharmaceutical Services group and oversight checks performed prior to release for use in trials.

The company already holds a UK MIA(IMP).

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Previous Inspection Date(s): 11-12 Sep 2018

Previous Inspectors: [redacted]

B2 I nspected Areas

Targeted review of systems and processes associated with implementation of the oversight process for import of QP-certified IMPs to GB from approved countries.

- I mportation oversight process
- T emplate Technical Agreement
- Change Control linked to new process

Limitations / exclusions to inspected areas

This was not a full scope inspection for other licensed activities conducted by the site and specifically reviewed the provision implemented for the oversight of import of QP-certified IMPs into GB from approved countries.

All areas linked to other functions or licences were not assessed, e.g. common Quality systems were not assessed.(Refer to previous inspection)

B3 Key Personnel met/contacted during the inspection

Name In	itials	Position
[redacted]		

B4 Documents submitted prior to the inspection

Document	Version /Date of document	Reflected activities on site?
Site Master File	Not applicable – not requested for this targeted inspection N	Not applicable
Compliance Report	Not applicable – not requested for this targeted inspection	Not applicable
Comments: None		

Section C Inspector's Findings

C1 Summary of significant changes

Not applicable – implementation of systems and processes for import oversight of QP-certified IMPs to GB from approved countries.

Changes since previous inspection which are of particular relevance to compliance / risk rating, or which relate to inspection deficiencies are listed below:

Not applicable to this inspection.

Future planned changes which are of particular relevance to compliance / risk rating, or which relate to inspection deficiencies are listed below:

Not applicable to this inspection.

C2 Action taken since the last inspection

Not applicable to this inspection.

C3 S tarting Materials

General

Not applicable for this inspection – oversight processes for import of QP-certified IMPs from approved countries only.

Compliance with TSE Guidelines

Not applicable for this inspection – oversight processes for import of QP-certified IMPs from approved countries only.

API Compliance

Not applicable for this inspection – oversight processes for import of QP-certified IMPs from approved countries only.

C4 Pharmaceut ical Quality System

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An established quality system was in place and had been previously inspected, as the site already held an MIA(IMP).

Procedures relating to the core aspects of the quality system were not reviewed in detail unless specific changes had been required with respect to the implementation of the IMP import oversight process.

Oversight process

A detailed risk assessment and gap analysis based on the MHRA published guidance had been conducted and appropriate actions identified. Change control [redacted] was subsequently raised for the implementation of the oversight process.

Procedure [redacted] described the process for IMPs imported either from within or outside the EEA/EU and included clear process flow diagrams. No specific concerns were noted with how the process was described.

Procedure [redacted] described the receipt, handling and storage of study medication, non-medicinal products, randomisation lists and code break envelopes. This had not been specifically updated for implementation of the import oversight process, however the associated checks required remained appropriate for this activity.

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Forms associated with the receipt of IMPs [redacted] and study setup [redacted] included confirmation of EU QP certification and temperature data, and included local QP approval prior to release for use of the associated IMP.

C5 Personnel

No EEA-based QPs were nominated for inclusion on the licence at this time therefore a clarifying remark was not required on the licence for this.

C6 Premises and Equipment

Not applicable for this inspection – oversight processes for import of QP-certified IMPs from approved countries only.

C7 Document ation

Not applicable for this inspection – oversight processes for import of QP-certified IMPs from approved countries only.

C8 Product ion

Not applicable for this inspection – oversight processes for import of QP-certified IMPs from approved countries only.

C9 Qu ality Control

Not applicable for this inspection – oversight processes for import of QP-certified IMPs from approved countries only.

C10 O utsourced Activities

A template written agreement [redacted] had been updated to include the IMP importation oversight process.

C11 Complaints and Product Recall

Not included during this inspection. May be of interest at future inspections with respect to the ongoing review of the oversight process after implementation.

C12 Sel f Inspection

Not included during this inspection. May be of interest at future inspections with respect to the ongoing review of the oversight process after implementation.

C13 Distribution and shipment (including WDA activities if relevant)

Direct to site shipments were not intended to be managed under the site's processes, with all IMPs being received under the [redacted] prior to oversight verification and release to the Investigator for use. This was to be formally documented on the release form and no specific concerns were raised with the proposed process.

C14 Questions raised by the Assessors in relation to the assessment of a marketing authorisation

Not applicable

C15 A nnexes attached

Annex 1 site risk rating

Section D List of Deficiencies

D1 Cr itical

None

D2 M ajor

None

D3 O thers

None

D4 Com ments

None

Section E Site Oversight Mechanism

Site referred or to be monitored by:	Tick (✓)	Referral date	Summary of basis for action
Risk Based Inspection Programme	✓	[redacted]	[redacted]
Compliance Management Team			
Inspection Action Group			

Section F Summary and Evaluation

F1 Cl osing Meeting

Requested documents and supporting information were reviewed and questions / clarification requests were raised initially by email. No formal close-out meeting was held, and no post inspection letter issued.

F2 Assessment of response(s) to inspection report

Not applicable – no deficiencies were raised following this inspection.

F3 Documents or Samples taken

Not applicable; none retained beyond inspection process

F4 Final Conclusion/Recommendation, Comments and Evaluation of Compliance with GMP and GDP

The site operates in general compliance with the requirements of:

Compliance statement	Tick all statements that apply
GMP as required by the Human Medicines Regulations 2012 (as amended) and the Human Medicines (Amendment) Regulations 2019	
The Medicines for Human Use (Clinical Trials) Regulations 2004	✓
Regulation 5 of the current Veterinary Medicines Regulations	
Regulation C17 of the Human Medicines Regulations 2012 (as amended) and the Human Medicines (Amendment) Regulations 2019	

and is acceptable for the products in question.

Name of Inspector (s):

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Lead Inspector: [redacted] **D** **ate:** 30 Nov 2021

Accompanying Inspector: Not applicable **D** **ate:** Not applicable

Annex 1

GMP Site Risk Rating

(a). Inspection Findings

Critical deficiencies this inspection:	0 Last	inspection:	*
Major deficiencies this inspection:	0	Last inspection:	*
Other deficiencies this inspection:	0	Last Inspection:	*

* **Not applicable – this was a limited scope targeted inspection.**

(b). Provisional Rating based on Inspection Output (✓ applicable box)

Risk rating level	Input from current Inspection Findings (last inspection findings applicable to rating V only)	Provisional rating – this assessment	Final rating last assessment
0	Serious triggers outside the inspection cycle	[redacted]	
I	Critical finding		
II	>/= 6 Major findings		
III	<6 Major findings		
IV	No critical or Major findings		
V	No critical or Major findings from current or previous inspection and <6 other findings on each.		

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(c). Risk Assessment Inputs – discriminatory factors (✓applicable box)

[redacted]	None relevant (default)
	Significant concern over robustness of quality system to retain adequate control
	Significant failures to complete actions to close previous deficiencies raised at the last inspection
	Complex site
	Significant changes reported in Compliance Report
	Significant mitigating factors applied by the site
	Higher risk rating identified by other GxP and considered relevant to the GMP site
	Relevant site cause recalls, notifications to DMRC or rapid alerts since last inspection
	Nature of batch specific variations submitted since the last inspection give concern over the level of control
	Regulatory action related to the site
	Failure to submit interim update and/or failure to notify MHRA of significant change or slippage in commitments from post inspection action plan
	First Inspection by MHRA (does not require counter-signature for RR II)
	Other discriminatory factor (record details and justify below)

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(d). Inspectors Comments Related to Discriminatory Factors

[redacted]

(e). Risk Rating Result Incorporating Discriminatory factors (✓ applicable box)

Risk rating level	Inspection Frequency	Inspector Proposed Risk Rating (✓)
0	Immediate (as soon as practicable)	[redacted]
I	6 monthly	
II	12 months	
III	24 months	
IV	30 months	
V	30 months with 50% reduction in duration of the next inspection	

(f). Basis for risk-based acceptance of specific matters arising during the inspection

[redacted]

(g). GMP or GDP certificate conditioning remarks required as a result of risk-based decisions noted in section (f) above

[redacted]

(h). Conclusions

[redacted]

(i). Expert/ Operations Manager / Compliance Management Team (CMT) Comments (Risk rating level 0, I, II):

[redacted]

(j). Confirm Agreed Risk rating following this inspection:

Risk Rating:	Next Inspection target date:
[redacted]	

Notes regarding re-inspection and GMP certificate validity

1. The inspection schedule is based upon risk and resource. This date may change at any time due to factors not pertaining to your site.
2. The GMP certificate does not 'expire' it is provisionally assigned 3 year validity date. For external questions regarding your validity thereafter; please advise that this can be confirmed by contacting the inspectorate at gmpinspectorate@mhra.gov.uk