Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

INSPECTION REPORT

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Section A Inspection Report Summary

Inspection requested by: MHRA

Scope of Inspection: Re-Inspection on behalf of the MHRA IAG

Licence or Reference Number: MS/ MIA(IMP) 116

Licence Holder/Applicant: Not applicable

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Details of Product(s)/ Clinical trials/Studies: The site compounds products for chemotherapy, [redacted].

Activities carried out by company:	Y/N
Manufacture of Active Ingredients	N
Manufacture of Finished Medicinal Products – Non-sterile	N
Manufacture of Finished Medicinal Products - Sterile	Y
Manufacture of Finished Medicinal Products - Biologicals	N
Manufacture of Intermediate or Bulk	N
Packaging – Primary	N
Packaging - Secondary	Y
Importing	N
Laboratory Testing	N
Batch Certification and Batch Release	Y
Sterilisation of excipient, active substance or medicinal product	N
Broker	N
Other: *Specials and IMP activities*	Y

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

Site Contact: [redacted]

Date(s) of Inspection: 13-14th August 2019

Lead Inspector: [redacted]

Accompanying Inspector(s): [redacted]

Case Folder References: Insp GMP/GDP/IMP 116/525104-0012

Section B General Introduction

B1 Background information

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The site manufactures [redacted] products principally for [redacted] (the [redacted] of patient specific) and a number of private healthcare providers including [redacted] group). These involved up to a 4-hour turnaround time for orders for the Radcliff Trust, with deliveries throughout the day to the main site and one outreach clinic.

Currently products are single batches for Patient specific dosing and also batch processes (between 2 to 20 units depending on product type). No wholesale dealing activities had been undertaken.

The site is part of the Baxter EMEA compounding organisation which includes other sites in the UK at Mount Vernon and in the North West of England.

This was a focussed inspection on behalf of the IAG to review current ways of working and process improvements put in place since the last inspection; due to the nature of the findings from the inspection, and the use of the same quality system as the sister site at Mount Vernon; which is under the remit of IAG.

Previous Inspection Date(s): 21-22nd August 2018

Previous Inspectors: [redacted]

B2 Inspected Areas

Introductions, site overview, changes.

Quality Systems: Deviations, CAPAs, Change Control, Complaints, Recall, Batch rejections

Batch record review and release

Production Processes: Disinfection, sanitisation; storage, compounding, labelling

Environmental Monitoring

Distribution

Limitations / exclusions to inspected areas

Self-Inspection

Order Entry, Supplier Approval and controls

Outsourced activities

Training

Process validation

IMP activities

Management review processes

B3 Key Personnel met/contacted during the inspection

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[redacted]

B4 **Documents submitted prior to the inspection**

Document	Version /Date of document	Reflected activities on site?
Site Master File	SMF03M; 21 Feb 2019	Y
Compliance Report	09 August 2019	Y
Comments:		

Section C Inspector's Findings

C1 Summary of significant changes

Detailed changes are recorded in the pre-inspection compliance reports held in the case folder.

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

Changes in UK and EMA oversight roles.

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

Introduction of an [redacted] product equipment unit to [redacted] compounding

Introduction of electronic prescription management via SharePoint

C2 Action taken since the last inspection

There were repeat findings within quality systems and processes indicating a general lack of effective improvement.

C3 Starting Materials

General

Not reviewed at this inspection

Compliance with TSE Guidelines

Not applicable as licensed materials used

API Compliance

Not applicable

C4 Pharmaceutical Quality System

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Change controls

The change control to extend opening hours of the unit (7am to 11pm) to increase output and shift patterns for overnight work was reviewed [redacted] The change control was relatively detailed however the impact assessment did not consider whether a review of trends for Grade A monitoring was needed despite the increase in use of the [redacted] Also there was a lack of rationale and risk assessment for the additional environmental monitoring planning to ensure that [redacted] requirements were met throughout the extended shift times.

Deviation and Non-Conformities (NCRs)

The updated UK Compounding [redacted] was reviewed. This included additional detail to define that NCR Initial Assessment should occur within 1 day and on processing decision rational approaches.

Over [redacted] s were not closed within 30 days; including approx. 15 Significant NCRs (SNCRs). Some were still open after 150 days.

The [redacted] was also reviewed; this covered [redacted]" records. [redacted] records were used when the issue was detected internally for which there was a pre-determined or defined process in place to resolve the issue. Trends in [redacted]s were required to be escalated to NCR records, however no trending was being undertaken. In the past year; approximately [redacted] were raised yet only [redacted] were escalated to an NCR.

Several examples were reviewed:

- [redacted] related to rejection of Work Order [redacted] 1 due to particulates
- [redacted] related to rejection of Works Order [redacted] 0.1 due to the inability to locate the primary source product
- [redacted] related to the rejection of [redacted] due to incorrect fill weight
- [redacted] related to the rejection of Works Order [redacted] due to [redacted] product within the luer.
- [redacted] linked to a power failure which tripped the [redacted] systems
- [redacted] related to a final volume error
- [redacted] relating to a failure to correctly reconstitute product

Deficiencies were raised; see Section D relating to the procedures, controls and examples assessed.

C5 Personnel

Not reviewed at this inspection

C6 Premises and Equipment

The receipt process was reviewed, the site had the capability to deactivate any commercial stocks that were received with FMD controls. Commercial stock was broken down on receipt such that only the primary labelled container was retained, however the cartons and leaflets were not disposed of in a way to prevent any future misuse.

Materials were not segregated adequately or managed in the general storage areas or cold room. Deficiencies were raised, see section D.

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The Assembly and Order Preparation room areas were monitored via ceiling points only. Temperature records and the associated PQ validation [redacted] were reviewed related to temperature controls and mapping. Several deficiencies were raised; see Section D.

With respect to maintenance, the site adopted a 'yellow-card' system whereby ay member of staff noting issues in the facility that would need maintenance would attach the card for notification to engineers to rectify. However, there was a lack of formal systems in place to ensure that these yellow cards would be reviewed for impact on GMP to confirm if the issue needed escalating. Also, trays and racking for holding items such as vials and ampoules were not on a regular planned preventative maintenance schedule to confirm that these remained fit for use.

[redacted] were not monitored for temperature. Internal unit fridges had a temperature probe however temperature recordings were only taken for current temperatures once per day on form [redacted] (without and minimum or maximum details). A system report from [redacted] was printed on perforated [redacted] without any controls; annotations were not signed and dated and there was no independent review. Daily checks for absence of alarms were not recorded.

Baxter Repeater pumps were in use; with calibration prior to use on a daily basis. The associated form was not checked to ensure that this was completed on each day of use.

The site planned to introduce an [redacted] during the latter part of the year and was requested to provide updates on progress with this.

C7 Documentation

Various documents were reviewed as indicated through this report

C8 Production

The production process for [redacted] involved manual additions to standard bags of trace elements and other small volume raw materials and would usually be done in the morning session. The controls in place for this process however were considered to be lacking, such as operators observed not to follow the order of micro-additions stated on the [redacted] Other recurrent issues were noted around congested isolator areas in the working zones and the lack of segregation of [redacted] which could increase the risk of mis-selection where barcoding was not implemented for items that required batch number verification entry into [redacted] instead.

Aseptic pooling was not undertaken by the site. However, vials in use could be used across the entire session, potential for several hours and there lacked appropriate assessments such as potential for [redacted] in place to ensure this. A deficiency was raised for this. It was also noted that some vials for chemotherapy could be spiked and reused again, up to a maximum of five days in the [redacted] isolator according to procedure, however there was a lack of evidence of assessment and data to support this practice. [redacted] in use in the isolator also lacked formal controls on the number of times they could be reused for compounding product. The concerns around these practices meant that a major deficiency was raised.

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C9 Quality Control

The microbial monitoring reports since 2018 were reviewed to determine the level of contamination. Some noted finger dab adverse trending had been identified [redacted] and the supporting investigation was lacking in detail to determine the root cause.

C10 Outsourced Activities

Not reviewed at this inspection

C11 Complaints and Product Recall

The complaints process was covered by procedure [redacted]; though was not covered in detail as this had been covered at inspections of other sites in the company group. Examples of complaints were reviewed during the inspection including [redacted] which related to an [redacted] There were a number of issues related with this – notably that this complaint had not resulted in an alert to DMRC despite a recall of the product having taken place, and also the root cause identified environmental issues such as distractions, however no CAPA was raised to address this issue.

There was also concern that CAPA due dates to correct complaint issues were too prolonged, such as a procedural update with a due date of 6th Dec 19, to address [redacted] for a PN stability check issue raised in May 2019.

The [redacted] to DMRC, Product Hold, FA and recall [redacted] was the current document. [redacted] was in circulation across the UK group for approval and was due for implementation by 31 August 2019. This update included notification timelines for the DMRC and an overhaul of the annual mock/challenge process.

Records for [redacted] were reviewed on site; following previous communication with the DMRC. This related to invalid sanitisation cycles and also required an NCR to be raised to assess the root cause; which had not been progressed.

Deficiencies were raised, see section D.

C12 Self Inspection

Not reviewed at this inspection

C13 Distribution and shipment (including WDA activities if relevant)

Physical distribution activities for local requirements are managed via a dedicated [redacted] vehicle that shuttles between the Baxter suite and Oxford University Hospital. The records of the contract, audit from September 2015 and arrangements with Polar Speed were assessed. Deficiencies were raised, see section D.

The Storage, Packaging and Distribution of Compounded product [redacted] was also reviewed. This did not include details of physical processes for distribution beyond final shipper preparation as this was deemed as managed by [redacted] yet this was not reflected in any other document.

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

Not applicable

C15 Annexes attached: Annex 1 site risk rating

Section D List of Deficiencies

1 CRITICAL

None

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2 MAJOR

2.1 **Production controls were deficient in that**

2.1.1 Active containers were seen to be disposed of prior to second / post compounding checks to confirm correct volumes had been withdrawn; in contradiction to the [redacted] and [redacted]

2.1.1.1 [redacted] processes were not considered robust in that procedures were silent on what the end of session [redacted] processes should be for reconciling materials following completion of the manufacturing session.

2.1.2 There was an increased risk of mix-up observed during [redacted] as one raw material was not drawn up in the order stated on [redacted]

2.1.3 Operators were not observed to refer to the order of addition of materials when adding micro-additions to the [redacted]

2.1.4 [redacted] were lined up in close proximity to each other before the manual additions to the bag were made, increasing the risk of mix-up. *NOTE: this deficiency is a repeat from the inspection of the site in August 2018.*

2.1.5 There was no temperature monitoring of the [redacted] to confirm that vials; which could be held in the [redacted] for up to two weeks (isolator active time), were stored in the required conditions.

2.1.6 There were no appropriate checks on the conditions of products held within [redacted] fridges as temperature data was only recorded once daily as a current 'Snapshot' temperature with no minimum or Maximum temperatures noted.

2.1.7 The fridge within [redacted] was loaded to the maximum capacity; with all [redacted] within a single blue bag in the unit, with no possibility of product segregation.

2.1.8 Different ambient starting materials were placed into a single [redacted] within the [redacted] for future selection for unique orders.

2.1.9 There was a lack of validation and assessments to support part-used and [redacted] production which could be used throughout the production session.

2.1.10 There was no formal control system in production to prevent excessive re-use of [redacted]

2.1.11 Returned, unused vials could potentially be re-sanitised via VHP numerous times without limit.

GMP C4.1, C5.7, C5.8, C5.9, C5.26, C5.43, C5.61,
The supply of unlicensed medicinal products 'specials', MHRA guidance note 14.
https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials

2.2 **The Pharmaceutical Quality system was deficient in that:**

2.2.1 The Investigational and CAPA Systems were deficient in that:

2.2.1.1 Quality Incidents (CPIs) were not appropriately assessed for system impact, root cause or preventative measures, as evidenced by [redacted] NCR's were not raised for unacceptable levels of recurrence. *NOTE: this deficiency is a repeat from the inspections of this site and the Mount Vernon site in August 2018.*

2.2.1.1.1 Investigation [redacted] did not include any assessment or examination into the source or root cause of the particulate contamination and no detail on the level of repeat finding. *NOTE: this deficiency is a repeat of this issue that was originally raised at the Mount Vernon site in May 2019.*

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2.2.1.1.2 The increasing levels of particulate contamination was noted in the monthly Management review meetings, yet no formal NCR investigation or assessment had been undertaken; beyond a minuted requirement to assess the trend.

2.2.1.2 [redacted] trending was not undertaken on site to the detail required by the [redacted] Incidents procedure [redacted]

2.2.1.3 [redacted] relating to [redacted] failure was deficient in that:

2.2.1.3.1 This was not raised in a timely manner so that this could be considered during batch release,

2.2.1.3.2 There was no information recorded within the [redacted] to support the release of product that had already occurred during the investigation process. (There was no interim report or any formal assessment on file)

2.2.1.4 [redacted]s were not being completed in a timely manner; with approx [redacted] overdue over the last year; although it was noted this improved during 2019 individual records still were open [redacted] and 201 days.

2.2.1.5 [redacted] relating to a failure to correctly reconstitute product did not ensure a comprehensive review was undertaken to support an Operator error root cause with any CAPA beyond retraining. No assessment was made with regards to procedural improvements for reconstitution process checks or how to handle small vials whereby the label sizing makes checks difficult to perform.

2.2.2 Management Review processes were deficient in that:

2.2.2.1 Actions from the reviews were not raised within the formal site quality systems for traceability and tracking (outside meeting minutes).

2.2.3 Change control [redacted] regarding an increased output and associated shift pattern change was deficient in that:

2.2.3.1 It did not consider or review trends for [redacted] monitoring despite the increase in use of the isolators

2.2.3.2 There was a lack of rationale and risk assessment for the additional environmental monitoring planning to ensure that [redacted] requirements were met throughout the extended shift times.

2.2.4 The Management of the [redacted] relating to the product assessment and subsequent recall following an invalid parameter sanitisation cycle did not ensure that an NCR was raised to address why all the batches impacted were not correctly identified at the initial assessment stage, prior to customer communication.

2.2.5 CCTV footage was not retained as evidence for those segments involved in any investigation assessment.

2.2.6 Complaints were deficient in that:

2.2.6.1 [redacted] was deficient in that:

2.2.6.1.1 This matter resulted in a recall of the product that had not been reported to DMRC,

2.2.6.1.2 The root cause indicated 'environmental issues' such as distractions but did not result in CAPA to address this.

2.2.6.2 CAPA due dates to correct complaints were not timely, such as a procedural update with a due date of 6th Dec 19, to address [redacted] stability check issue raised in May 2019.

GMP C1.4(viii), C1.4(xiii), C1.4(xiv), C1.5, C1.6, C1.8(vii), C1.8(xi), C1.9(iv), C4.12, C8.15, C8.18, C8.21, C8.26
The supply of unlicensed medicinal products 'specials', MHRA guidance note 14.
https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials

2.3 **Sterility assurance was deficient in that:**

2.3.1 Some part-used vials could be stored in the chemotherapy isolators for up to five days prior to use, which had not been appropriately assessed from a microbial contamination perspective.

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2.3.2 End of session media fill procedures were ambiguous as to whether new or used syringes were required.

2.3.3 [redacted] into adverse finger dab trends lacked detail with respect to the investigation, such as if introduction of new operators to support the increased shift patterns or whether critical consumables such as the isolator gloves and pinhole trends were at fault.

GMP A1.64, A1.67, A15.1.1, A15.5.7,

3 OTHERS

3.1 **Material Controls were deficient in that:**

3.1.1 Cold Chain Products were not adequately segregated or controlled as evidenced by a mixed tray for two different (but similar packaging) products in one tray [redacted] and a tray of completely mixed products (at least 8 within a single tray) within the cold storage unit.

3.1.2 Materials were placed directly against the outer wall of the cold storage unit, and as such this did not allow adequate airflow.

3.1.3 [redacted] components were not adequately segregated or controlled where these were stored on open shelving underneath work benches without any formal separation.

3.1.4 Product trays were not consistently formally identified, with some trays having handwritten notes to confirm contents.

3.1.5 Product cartons used as starting materials were not defaced or any other formally controlled process to ensure that discarded cartons could not be retrieved from waste and potentially misused.

3.1.6 Material daily stock checks and usage controls were not robust or considered GMP processes; as evidenced by:

3.1.6.1 The form used for daily stock checks was not a controlled document and was not retained,

3.1.6.2 No investigations were carried out if the daily physical stock check showed a discrepancy to [redacted] whereby [redacted] was subsequently adjusted,

3.1.6.3 The forms were annotated without clear explanation or control to account for allocation of stock or additional stock being made available via [redacted]

3.1.6.4 Stock details were recorded on the reverse of forms to account for materials picked for [redacted] with [redacted] retrospectively updated based on the hand annotations.

GMP C3.18, C4.8, C4.1, C4.9, C5.2, C5.7, C5.21 Organisational Measures

3.2 **Facility controls, validation and maintenance was deficient in that:**

3.2.1 The racking for [redacted] gassing was not on any PPM schedule, to ensure condition was reassessed on a routine basis.

3.2.2 The 'yellow flag' maintenance cards were not formally reviewed to confirm if any GMP or quality assessments needed to be made

3.2.3 Mapping exercises of the Assembly and Prep room was deficient in that:

3.2.3.1 The protocol did not ensure that all storage locations were appropriately monitored to confirm all storage conditions (including under work benches and across all storage units).

3.2.3.2 No criteria were defined for uniformity of temperatures across the unit during mapping

3.2.4 Routine Assembly and Prep room FMS temperatures were noted with a variance of 5ºC window within a 10-minute window; and yet this did not trigger any review or assessment.

3.2.5 Temperature controls via the FMS were set with alarms at the temperature extremes (not with any alert levels) and alarms only occurred following a 15-minute excursion, without any consideration for on-going multiple temperature fluctuations of less than 15 minutes.

3.2.6 There was no evidence of any formal review of temperature or facility data (via FMS or [redacted] outs) to confirm that an appropriate assessment was completed.

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3.2.7 [redacted] reports were not identified on each page and annotations were not signed and dated

GMP C2.9(ii), C3.19, C3.34, C3.35, 4.10, A15.2.4
GDP 3.2.1

3.3 **Controls over the Distribution / courier service provided by PolarSpeed were deficient in that:**

3.3.1 The Technical Agreement (TA) did not cover any expectations on timelines for deliveries or the requirement for deviation if these were not meet,

3.3.2 The TA did not cover any controls over vehicles, drivers or validation,

3.3.3 The TA included a contacts list for the Baxter sites that was not readable,

3.3.4 The audit schedule for [redacted] was maintained at a 5-year interval despite the last inspection being a for-cause inspection and also where the full assessment of the QMS was not completed due to the ongoing integration of [redacted] The risk rating calculation did not take into account the use of subcontractors or change in business structure.

GMP C1.4(xvi), C1.8(ix), C7.4, C7.7, C7.14, C7.15,

4 COMMENTS

4.1 The site is required to keep inspectorate updated with progress for introduction of the [redacted] mixer auto-compounder; intended for use within [redacted] processing. This may trigger a desktop inspection that will be required prior to formal use, although this will be assessed further.

4.2 Interim updates will still be required from the site; this should include any details of significant complaints.

4.3 Please provide evidence that vial replacement within [redacted] loads as indicated by form [redacted] has been appropriately validated to confirm that e.g. a single [redacted] can be switched out for multiple smaller vials or needles. (This was mentioned during inspection but not progressed).

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]	
Compliance Management Team			
Inspection Action Group	✓	[redacted]	

Section F Summary and Evaluation

F1 Closing Meeting

The site accepted the deficiencies presented without dissention and committed to provide an appropriate remedial action plan.

A discussion of the process for referral to and oversight by the Compliance Management Team was held, with a statement that the information could be obtained by following the link that will be in the Post Inspection Letter if referred. A discussion was also held with regards to the ongoing oversight by IAG of the Baxter group.

F2 Assessment of response(s) to inspection report

A response was received 27th September 2019 which was not considered satisfactory. Additional clarification for several points was requested from the company on 4th October 2019 and further responses were received on 5th November 2019 which was deemed to be an improvement although timelines were still concerning and would need monitoring.

F3 Documents or Samples taken

Not applicable

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
Directive 2001/83/EC, Directive(s) 2003/94/EC and 2011/62/EU	
GMP as required by HMR 2012 (as amended)	✓
Directive 2001/20/EC	✓
Directive 2001/82/EC	
Article 84 and Article 85b(3) of Directive 2001/83/EC (GDP) and 2011/62/EU	

and is acceptable for the products in question.

The site is required to continue to provide updates on a quarterly basis to include the following: production volumes, staffing levels, Key Performance Indicators, open Quality Management System actions, status of Inspection response actions.

Name and Dated Signature of Inspector (s):

Signed: [redacted] **Dated:** 2nd December 2019

Accompanying Inspector: **Dated:** 4th December 2019

Annex 1

GMP Site Risk Rating

(a). Inspection Findings

Critical deficiencies this inspection:	0	Last inspection:	0
Major deficiencies this inspection:	3	Last inspection:	2
Other deficiencies this inspection:	3	Last Inspection:	6

(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]	[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 countersignature for RR II)
	Other discriminatory factor (record details and justify below)

(d). Inspectors Comments Related to Discriminatory Factors

The sister site Baxter Mount Vernon is at IAG for similar and more significant findings in terms on potential patient impact. Ongoing similar issues on site and across the group

(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	

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

Not applicable

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

GMP Certificate: *Not applicable*
GDP Certificate: *Not applicable*

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