Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

INSPECTION REPORT

Ria Generics Ltd
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Section A Inspection Report Summary

Inspection requested by: MHRA

Scope of Inspection: Routine Re-Inspection

Licence or Reference Number: MIA / WDA(H) 36282

Licence Holder/Applicant: Ria Generics Ltd

Details of Products: Importation from third countries

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	N
Manufacture of Finished Medicinal Products – Biologicals	N
Manufacture of Intermediate or Bulk	N
Packaging – Primary	N
Packaging - Secondary	N
Importing	Y
Laboratory Testing	N
Batch Certification and Batch Release	Y
Sterilisation of excipient, active substance or medicinal product	N
Broker	N
Other: Wholesale dealing, including introduced products	Y

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

Site Contact: [redacted]

Date of Inspection: 24 Sept 2025

Lead Inspector: [redacted]

Accompanying Inspector: [redacted]

Case Folder References: Insp GMP/GDP 36282/8148588-0012

Section B General Introduction

B1 Background information

Ria Generics Ltd was the MA holder for several UK and EU generic medicines manufactured in [redacted] The company held an MIA for importation and batch certification, and a WDA(H) for procurement, supply and export, along with authorisations for controlled drugs, cold chain and introduced products.

Previous Inspection Dates: 21 April 2022

Previous Inspector: [redacted]

B2 Inspected Areas

Licence review
Relationship between Ria Generics and [redacted]
Change control
Deviations
PQRs
Management review
Complaints
Recalls
Batch document review and QP certification
Introduced medicines
Outsourced activities

Limitations / exclusions to inspected areas

Control of starting materials
Self inspection

B3 Key Personnel met/contacted during the inspection

Name	Position
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

B4 Documents submitted prior to the inspection

Document	Version/Date of document	Reflected activities on site?
Site Master File	[redacted] June 2025	Y
Compliance Report	26 Apr 2025	Y
Comments: None		

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:

[redacted] had left the company and was no longer named as QP and Head of QA.

[redacted] was the current contract QP.

The named Head of QA was [redacted] who was noted to be a [redacted] employee.

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

None.

C2 Action taken since the last inspection

During the inspection it became evident that Ria Generics had moved away from using their own procedures and were now entirely reliant on the quality system of another organisation (see Section C4 below).

The inspectors also found that a previous inspection commitment had been reversed, and this had not been communicated to MHRA.

C3 Starting Materials

General

Not reviewed in any detail, though it was evident from the PQRs that the starting materials used by the contract manufacturing sites were verified against the Marketing Authorisations. Excipient risk assessments were reviewed as part of the product-specific dossier for each licensed medicinal product, used to support batch certification.

Compliance with TSE Guidelines

The contact manufacturers' TSE statements were reviewed as part of the product-specific dossier for each licensed medicinal product.

API Compliance

API audits and QP declarations were available (not reviewed on this inspection).

C4 Pharmaceutical Quality System

Communication with the site prior to the inspection indicated that Ria Generics were contracting out all QA functions to another MIA holder ([redacted]). It was stated that [redacted] *were responsible for managing all activities related to MIA and WDA compliance on behalf of Ria Generics*'. This was further supported by the provision of a document list, in which only the Site Master File and one SOP relating to controlled drugs were Ria Generics documents. All other SOPs were [redacted] procedures. It was also noted that [redacted] personnel initially requested that the inspection be held at their premises rather than the registered address of Ria Generics, since all PQS records were held on the [redacted] servers. It was stated that several other companies were also using [redacted] quality system in this way.

As Ria Generics no longer had their own procedures, it could not be demonstrated there was an effective quality system in place relating to the authorised premises. A major deficiency was raised.

Licence review

In July 2025, Ria Generics supplied some information to MHRA when applying for an extension to their GMP certificate. The inspector reviewing the information noted that MIA 36282 contained an error which required correction; the Ria Generics premises were authorised for QC testing, even though it was a domestic dwelling and all QC testing was contracted out. No variation had been submitted since this was highlighted to the company, and no actions had been raised in the quality system to address this at the time of the inspection.

Management Review

SOP [redacted] described the management meetings. The procedure was not definitive regarding attendance by Ria Generics (given the current operational model with the PQS being outsourced). However, the minutes from the last 2 management meetings were reviewed and a Ria Generics representative had attended both. The outputs included minutes and a slide deck. These contained various data related to the quality system and actions were raised and tracked from the management review.

Change Control

Ria Generics did not have their own change control procedure anymore. All changes since Sept 2023 had been raised within the [redacted] quality system.

There had been 49 changes raised in 2024, and 38 changes raised to date in 2025; most were minor variations to Marketing Authorisations.

Change control [redacted] still open at the time of the inspection) was raised in Aug 2025 to add [redacted] as a micro testing lab, as they were a subcontractor of [redacted] The change was initiated by [redacted] staff and approved by [redacted] management and the Ria Generics licence holder. [redacted]

Change control [redacted] (June 2023) was initiated to harmonise the SOPs between Ria Generics and [redacted] This appeared to be triggered by the decision to merge all SOPs and to no longer have separate SOPs for the two companies. The change control was approved by [redacted] the Ria Generics licence holder and the QP. There was no recognition that this change appeared to reverse the previous commitment made after the MHRA inspection in 2021, where it was agreed that all relevant documentation would be captured in the Ria Generics quality system

Deviations and CAPA

SOP [redacted] described the deviation process. The deviation log was reviewed. Deviations were compiled by QA Associates with record approvals solely from their leadership.

During the inspection, it was evident that deviation records were not fully self-explanatory or standalone, and a considerable amount of inspection time was spent trying to piece each story together. Interrogation of other company systems and discussion with other colleagues was required to gain clarity on the investigations.

[redacted] described a delayed self-inspection. The self-inspection itself had been completed but the report was delayed due to the inspector exiting the business. The record had a risk assessment ([redacted]), and this focussed solely on the risk of delay of the self-inspection and not the delay to remediate the actions. The self-inspection had been completed by the QP.

[redacted] described a temperature excursion during a shipment of [redacted] A root cause was identified and CAPA implemented at the CMO. The batch was supported using stability data and no issues were noted.

[redacted]described a decision to sample at the manufacturing site and not the UK warehouse to enable an expedited release based on some regulatory information that there was a risk that the product licence could be suspended. There was no documented risk assessment regarding product quality and patient risk given the company had knowledge of a potential issue with the bioequivalence study supporting the product ([redacted] There was no assessment on whether communication was required with the MHRA prior to batch certification. There was no technical justification or risk assessment to identify and manage any risks associated with sampling at the third country manufacturing site. There was no assessment of the 2023 manufacturing site audit report to ascertain whether it could support the finished product sampling activity. There was also no retrospective assessment of risk regarding impacted batches previously certified and on the market. The 2023 audit report of the manufacturing site [redacted] did not specifically cover the finished product sampling process and no formal CAPA was raised to address this. The 2024 audit report [redacted]did have specific reference to the finished product sampling process.

The deviation was not fully recorded and completed in a way that the chronology of activities concerning the processing of this medicinal product was traceable. Statements were made within the record and there was no supporting evidence attached to the record. Examples included the statement that the deviation was the result of a MAH decision and there was no documented evidence within the record to support this claim, the record did not fully describe both the communications from the EMA/MHRA regarding the incident and any actions or communications the company made. The record referred to a deviation attachment of a EMA communication but this could not be provided during the inspection. It was also not clearly documented within the record when in the chronology of activities, the certification occurred.

[redacted] described the certification of batches of [redacted], batches [redacted] and [redacted] without the skip lot microbial testing required in the specification. This was due to timing and the implementation of the Windsor framework and the requirement for 'UK only' on the packs. The record did not have a formal risk assessment regarding product quality and patient safety by proceeding with the certification without the skip lot microbial testing and there was no risk assessment regarding certification of the batch when not in compliance with the MA and in absence of a response from the MHRA granting a waiver. The company had completed the microbial testing and verbally stated the batch had not been distributed prior to receiving the testing results, although certification had occurred.

The record did not describe the full chronology of events including risks, rationale and decision points regarding the request for a waiver from the MHRA and the order / timing of actions taken by the company following this. There was no documentation of the additional safeguarding controls which the company verbally discussed in the inspection.

[redacted](CAPA regarding completion of microbial testing from deviation [redacted]) was reviewed and this showed that the TRF for the micro testing was completed on 02 Jan 2025. No issues were noted.

Product Quality Review

PQRs were generated for all commercialised licensed products and were all designed to cover a calendar year. The contract manufacturing sites would provide their own PQR and then [redacted] would compile a covering report which summarised the CMO PQR and added UK-specific topics such as MA variations, UK QC testing and customer complaints. The current PQR schedule indicated that all reports were on track with the target dates.

The current PQR for [redacted] covered the calendar year 2024 and included [redacted] batches manufactured at [redacted] The PQR from the manufacturer was reviewed, along with the covering PQR compiled by [redacted] The reports were suitably detailed in line with expectations.

The [redacted] PQR included a deviation related to a temperature excursion; [redacted] was raised in Feb 2024 when a temperature of 43°C was noted during the shipment of two batches of [redacted] (label storage condition was NMT 25°C). The temperature was above 25°C for 24 hours, and above 40°C for 3 hours. The investigation determined that the root cause was inadequate control of the pallets at the airport, when the shipment was split and the pallets were held in an uncontrolled area for a period of time. There was 6 months of data at accelerated stability conditions which indicated that the excursion was unlikely to have a detrimental effect on the batches. A batch-specific variation was submitted and one of the batches placed on stability.

C5 Personnel

[redacted] was the licence holder and appeared to be the only Ria Generics employee. There was a contract QP, and all other staff were employees of [redacted] as indicated by their email addresses and confirmed by [redacted]

The licence holder's job description was limited to activities under the WDA(H). It did not mention any importation activities under the company MIA.

The contract QP was named on both the Ria Generics and [redacted] MIAs. The contract with Ria Generics was dated July 2024, and required that the QP adhered to Ria Generics SOPs, even though no such procedures existed. The agreement was also out of date as it still referred to FMD serialisation. It also failed to mention remote QP certification, which was commonly used.

C6 Premises and Equipment

The licensed premises were a domestic dwelling, with no products handled on site.

C7 Documentation

All procedures were in the name of [redacted], with the exception of the SMF and one SOP relating to controlled drugs. No quality records were held at the licensed premises, with all documentation held electronically on the [redacted] server.

Importation and QP certification

The company was importing approximately [redacted] batches per year, including [redacted] in the last quarter prior to the inspection.

The documentation for a recently imported batch of [redacted] was reviewed. This included the goods receipt note, transport temperature data and the UK sampling plan. Detailed checks of the batch documentation were carried out by [redacted] QA, prior to final QP certification. no specific issues were noted.

Introduction under the WDA(H)

[redacted] was entitled [redacted] This applied to shipments from third countries (typically [redacted]) and destined for supply into third countries such as [redacted]. It was noted that although [redacted] owned this SOP and carried out the day-to-day tasks, [redacted] were not authorised for Introduction under their own [redacted]

[redacted] had both been supplied to [redacted] under the WDA(H) as *Introduced* products. The most recent shipments had been in 2023. The records related to a batch of [redacted] were reviewed (transported by sea from [redacted] to [redacted] then subsequently exported from [redacted] to [redacted] The documents included the delivery note and invoice from the [redacted] CMO (dated 28 April 2023), receipt by the UK contract warehouse (dated 6 June), and a number of documents relating to the export to [redacted] (export CHIEF entry on 19 July, C88 form and proof of delivery from the [redacted] customer dated 28 Aug). However, some omissions were noted; it was unclear whether the delivery from [redacted] had been imported for free circulation or placed under another customs regime, and there was a lack of clarity over whether the batch had been stored in a bonded warehouse in the UK prior to export. A major deficiency was raised.

C8 Production

Not applicable. All production was contracted out to various CMOs in [redacted]

C9 Quality Control

UK QC testing of imported batches was contracted out to [redacted] Ria Generics had recently added [redacted] to the MIA, and there was a pending change control to add [redacted]

Samples for UK import testing were taken after importation, rather than using the contract manufacturers to take the samples.

C10 Outsourced Activities

Ria Generics had commissioned an audit of [redacted] carried out by an independent QP in May 2024. No specific issues were noted with the audit report.

There was a technical agreement between Ria Generics and [redacted] last updated in Sept 2023. This included delegation of all QA activities to [redacted]. The Ria Generics licence holder was responsible for approving SOPs, attending the management review meetings, reviewing internal audit reports, and reviewing all changes / deviations / CAPA / OOS / complaints / PQRs. The agreement was not up to date, as it still referred to commissioning of FMD serial numbers which were no longer applicable in the UK. It was also out of date in regard to the contract UK labs that were used for QC testing.

Audit reports for two contract manufacturers were reviewed. [redacted] were audited in July 2023 by the then-QP, covering [redacted] and [redacted]

over 2 days. [redacted] were audited in June 2025 by an independent QP. The audit covered [redacted] and [redacted] products, and the audit raised 5 major deficiencies. The company response was also provided. No specific issues were noted.

C11 Complaints and Product Recall

Complaints

SOP [redacted] described the process for managing complaints. The market complaint trend report from 01 Jan – 30 Jun 2025 was reviewed. No issues were noted.

Complaint [redacted] from 20 May 2024 was reviewed. This concerned a report from the MHRA around a suspected falsified product [redacted] and [redacted] and a reported adverse event of a high rise in blood pressure after the patient took the medication. The report showed pack photographs and documented comparisons with genuine stock. The company ascertained it was a genuine product. There was evidence that the complaint was forwarded to the PV service provider for additional follow up and there was an internal reference number from the PV provider. No issues were noted.

Recalls

SOP [redacted] described the process for batch recall. Two mock recalls were reviewed, one relating to [redacted] and one related to [redacted] The final report for mock recall [redacted] included a reconciliation that was inaccurate. It indicated the batch was fully reconciled and was approved. The data contained within the report stated that there was a total released quantity of [redacted] warehouse had [redacted] and that the total distributed was [redacted] These numbers indicated more stock was distributed than was released. This was not noted during the approval process of the mock recall.

Additionally, mock recall [redacted] was initiated at 17.38 and was supposed to represent an out-of-hours situation. This was not a true representation of an out of hours situation as it may still be within the working day for UK colleagues and therefore did not fully test the effectiveness of the recall process in these conditions. Evidence from the formal GMP record of the mock recall of this timing could not be provided during the inspection and only email evidence could be provided. The records showed that the Ria Generics representative was aware of the recall.

It was noted that the technical agreement between Ria Generics and [redacted] stated that the final decision to enact a recall fell to [redacted] rather than the MA holder.

C12 Self Inspection

There was evidence that self-inspections had been undertaken as there was a deviation relating to a missed timeline for a self-inspection report, and the record indicated the deficiencies noted.

The self-inspection process was not inspected in detail.

C13 Distribution and shipment (including WDA activities if relevant)

There were multiple wholesale functions that Ria Generics were authorised for, which [redacted] were not. For example 1.3 (introduction), 2.4 (export), 3.3 (cold chain) and 4.5 (traditional herbals). In addition, Ria Generics had not traded in any cold chain products or traditional herbal medicines and did not have supporting procedures in place.

[redacted] were used for storage and distribution.

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

None

C15 Annexes attached

Annex 1 site risk rating

Section D List of Deficiencies

D1 Critical

None

D2 Major

2.1 The Licence Holder had not ensured that Ria Generics had an effective pharmaceutical quality system in place, as evidenced by:

2.1.1 The SOPs from the previous Ria Generics quality system had been removed from use in 2023 and replaced by SOPs from another licence holder ([redacted] As such, Ria Generics no longer had an effective PQS in place specific to their licensed operations.

2.1.2 The decision to stop using the Ria Generics PQS and instead use [redacted] procedures contradicted a previous inspection commitment. The response to the 2021 MHRA inspection included a commitment to ensure that all relevant documentation would be captured in the Ria Generics quality system. This was not taken into account by either Ria Generics or [redacted] when removing Ria Generic's procedures, and was not communicated to MHRA.

2.1.3 All quality documentation relating to Ria Generics operations were held by another licence holder ([redacted]

Reference: EU GMP Chapter 1 (Principle), 1.3, 1.5, 2.4

2.2 The Pharmaceutical Quality System was deficient, as evidenced by:

2.2.1 The impact of deviations was not adequately assessed in accordance with quality risk management processes. For example, but not limited to:

2.2.1.1 Deviation [redacted] described a decision to take samples at the third country manufacturing site rather than the UK warehouse, to enable an expedited release based on regulatory information that there was a risk that the product licence could be suspended. The deviation was insufficiently documented, in that:

2.2.1.1.1 There was no risk assessment regarding product quality and patient risk given the company had knowledge of a potential issue with the bioequivalence study supporting the product.

2.2.1.1.2 There was no assessment on whether communication was required with the MHRA prior to batch certification.

2.2.1.1.3 There was no technical justification or risk assessment to identify and manage any risks associated with sampling at the third country manufacturing site.

2.2.1.1.4 There was no assessment of the previous 2023 manufacturing site audit report to ascertain whether it could support the finished product sampling activity. (Note: The 2023 audit of the manufacturing site did not specifically document inspection of the finished product sampling process and no CAPA was raised to address this. It was covered in the 2024 audit report).

2.2.1.1.5 There was no retrospective assessment of risk regarding impacted batches previously certified and on the market.

2.2.1.2 Deviation [redacted] described the release of a batch without the skip lot microbial testing required in the specification. The deviation was deficient in that:

2.2.1.2.1 There was no formal risk assessment regarding product quality and patient safety by proceeding with the certification without the skip lot microbial testing.

2.2.1.2.2 There was no risk assessment regarding certification of the batch when not in compliance with the MA and in the absence of a response from the MHRA granting a waiver.

2.2.2 Deviations were not fully recorded and completed in such a way that all significant activities concerning the processing of a medicinal product were traceable. For example, but not limited to: 2.2.2.1 Deviation [redacted] stated that the deviation was the result of a MAH decision, but there was no documented evidence within the record to support this claim. The record did not fully describe both the communications from the EMA/MHRA regarding the incident nor any actions or communications the company made. The record referred to a deviation attachment of an EMA communication, but this could not be provided during the inspection.

2.2.2.2 Deviation [redacted] did not describe the full chain of events including risks, rationale and decision points regarding the request for a waiver from the MHRA and the order / timing of actions taken by the company following this. There was no documentation of any additional safeguarding controls.

2.2.3 In regard to the management of recalls: 2.2.3.1 The final report for mock recall [redacted] ncluded a reconciliation that was inaccurate. However it indicated the batch was fully reconciled and the report was approved. The data contained within the report stated that there was a total released quantity of [redacted] warehouse had [redacted] and that the total distributed was [redacted] These numbers did not reconcile.

2.2.3.2 The effectiveness of the arrangements in place for recalls was inadequate in that mock recall [redacted] intended to represent an out-of-hours situation, was initiated at 1738 on a working day. Additionally, evidence of this timing documented in the quality system could not be provided.

Reference: EU GMP 1.4 (xiv), 1.8 (vii), 1.13 (i, ii), Chapter 4 (Principle), 4.8, 8.29, 8.30, Annex 16 (1.5.6 i, 3.1 i)

2.3 Introduction under WDA(H) 36282 was not appropriately controlled:

2.3.1 Ria Generics was reliant on [redacted] staff to conduct and document all licensed activities, including Introduction under the WDA(H). [redacted] were not authorised for introduction.

2.3.2 The records for a shipment of [redacted] in 2023, supplied from [redacted] via the UK to a customer in [redacted] were lacking in detail as evidenced by:

2.3.2.1 There was no documented copy of the customs entry for the incoming shipment from [redacted] so it was unclear whether the batch was declared for import or placed under a different customs regime.

2.3.2.2 It was unclear whether the goods were held in a bonded warehouse whilst in the UK. The relevant procedure indicated that it should have been in a bonded warehouse, but the batch-related documentation indicated that it was not placed in one.

2.3.2.3 The batch was exported to [redacted] under a customs code of [redacted] which was used when goods in free circulation were being exported from the UK to a country outside the EU. This implied the batch had been imported to the UK for free circulation, which was not appropriate for medicines without a UK PL which were not intended for UK supply.

Reference: Human Medicines Regulations (Reg 18), EU GDP 4.2

D3 Others

3.1 Documentation was not up to date or accurate, as evidenced by:

3.1.1 The site licences were not kept up to date, in that:

3.1.1.1 Although Ria Generics were made aware in July 2025 that MIA 36282 contained an error regarding authorisation for QC testing, no variation had been submitted to correct the error and there was no pending action in the quality system to capture this requirement.

3.1.1.2 WDA(H) 36282 contained authorisation for cold chain products, and for traditional herbals medicines. Ria Generics had never traded these products and did not have processes in place to ensure cold chain capability.

3.1.2 The Licence Holder's job description was limited to activities under the WDA(H). It did not mention any activities related to importation under MIA 36282.

3.1.3 The technical agreement between Ria Generics and [redacted] was out of date:

3.1.3.1 It still referred to the commissioning of FMD serial numbers which were no longer applicable in the UK.

3.1.3.2 It was out of date in regard to contract UK QC laboratories.

3.1.3.3 The agreement stated that the final decision to enact a recall fell to [redacted] rather than the MA holder.

3.1.4 The technical agreement with the contract QP required revision, in that:

3.1.4.1 It still referred to FMD serialisation, which was no longer required in the UK.

3.1.4.2 There was no reference to remote QP certification, which was stated to be common practice.

Reference: EU GMP 2.3, 4.5, 7.14

D4 Comments

4.1 The inspectors will liaise with PCL to correct MIA 36282 in regard to [redacted]

4.2 Please provide an electronic copy of the company presentation.

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 Closing Meeting

The inspection findings were outlined, and it was explained that a suitably robust response was required in order to avoid a potential referral to the Compliance Management Team (CMT).

F2 Assessment of response(s) to inspection report

An initial response was provided on 24th Oct 2025, with additional information submitted on 11th Nov. The final responses were accepted by the inspectors, and the potential escalation to CMT oversight was avoided.

F3 Documents or Samples taken

None

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	N/A
Regulation 5 of the current Veterinary Medicines Regulations	N/A
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.

Names of Inspectors:

Lead Inspector: [redacted] **Date:** 14th Nov 2025

Accompanying Inspector: [redacted] **Date:** 14th Nov 2025

Annex 1

GMP Site Risk Rating

(a). Inspection Findings

Critical deficiencies this inspection:	0	Last inspection:	0
Major deficiencies this inspection:	3	Last inspection:	3
Other deficiencies this inspection:	1	Last Inspection:	4

(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.		

(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

[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	

[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

[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