Medicines & Healthcare products Regulatory Agency

PHARMACOVIGILANCE INSPECTION REPORT

Pharmacovigilance System Name: MSD

MHRA Inspection Number: Insp GPvP 53095/19534521-0008

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ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Event
CAPA	Corrective and Preventative Action
CCDS	Company Core Data Sheet
CHMP	Committee for Medicinal Products for Human Use
CRO	Contract Research Organisation
DCP	Decentralised Procedure
DHPC	Direct Healthcare Professional Communication
DSUR	Development Safety Update Report
EMA	European Medicines Agency
EU	European Union
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practice
GVP	Good Vigilance Practice
HCP	Healthcare Professional
IB	Investigator's Brochure
ICH	International Conference on Harmonisation
ICSR	Individual Case Safety Report
KPI	Key Performance Indicator
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MedDRA	Medical Dictionary for Regulatory Activities
MRP	Mutual Recognition Procedure
NAP	Nationally Authorised Product
NIS	Non-Interventional Study
PAES	Post-Authorisation Efficacy Study
PASS	Post-Authorisation Safety Study
PBRER	Periodic Benefit Risk Evaluation Report
PIL	Patient Information Leaflet
PRAC	Pharmacovigilance Risk Assessment Committee
PSMF	Pharmacovigilance System Master File

PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
PVA	Pharmacovigilance Agreements
QA	Quality Assurance
QMS	Quality Management System
QPPV	Qualified Person responsible for Pharmacovigilance
RMM	Risk Minimisation Measures
RMP	Risk Management Plan
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDEA	Safety Data Exchange Agreement
SmPC	EU Summary of Product Characteristics
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
UK	United Kingdom
XEVMPD	eXtended Eudravigilance Medicinal Product Dictionary

SECTION A: INSPECTION REPORT SUMMARY

Inspection type:	Statutory National Inspection
System(s) inspected:	Merck Sharp & Dohme (UK) Limited (MSD (UK) Ltd) MHRA UK PSMF No: [redacted]
Site(s) of inspection:	Merck Sharp & Dohme (UK) Limited (MSD (UK) Ltd) 120 Moorgate, London, EC2M 6UR
Main site contact:	[redacted] UK/Ireland PV Lead and UK National Contact Person for PV Merck Sharp & Dohme (UK) Limited (MSD (UK) Ltd) 120 Moorgate, London, EC2M 6UR Tel: [redacted] or via the main MSD (UK) Ltd switchboard in the UK, [redacted] Facsimile Number: [redacted] Email: [redacted]
Date(s) of inspection:	22nd - 26th September 2025 (on-site) 18th – 19th September 2025 (off-site data review, Lead Inspector only)
Lead Inspector:	[redacted]
Accompanying Inspector(s):	[redacted]
Previous inspection date(s):	13th-17th June 2016
Purpose of inspection:	Inspection of pharmacovigilance systems to review compliance with UK and EU requirements.
Products selected to provide system examples:	Not applicable
Name and location of UK QPPV:	[redacted] Global Qualified Person for Pharmacovigilance (GQPPV) Office of the GQPPV MSD Europe Belgium SRL Boulevard du Souverain, 25, 1170 Watermael-Boitsfort, Bruxelles, Belgique Tel: [redacted] or via the main MSD (UK) Ltd switchboard in the UK, [redacted] Facsimile No: [redacted] Email: [redacted]
Global PV database (in use at the time of the inspection):	[redacted]
Key service provider(s):	Individual Case Safety Report (ICSR) processing – IQVIA Translation – CQ Fluency Medical information (UK and Ireland) – ProPharma Group MIS Ltd Literature screening – ProQuest LLC PV Audits – Arriello Ireland Ltd PV SMaRT support - Veeva Systems
Inspection finding summary:	0 Critical finding(s) 0 Major finding(s) 4 Minor finding(s)

Date of first issue of report to MAH:	12 December 2025
Deadline for submission of responses by MAH:	01 March 2026
Date(s) of receipt of responses from MAH:	23 February 2026
Date of final version of report:	06 March 2026
Report author:	[redacted] Senior Pharmacovigilance Inspector Inspection report responses reviewed by [redacted], Pharmacovigilance Inspector

SECTION B: BACKGROUND AND SCOPE

B.1 Background information

MSD was selected for routine inspection as part of the MHRA's statutory, national pharmacovigilance inspection programme. The purpose of the inspection was to review compliance with currently applicable UK and EU pharmacovigilance regulations and guidelines. In particular, reference is made to The Human Medicines Regulations 2012 as amended, Commission Implementing Regulation (EU) No 520/2012 and the EU good pharmacovigilance practices (GVP) Modules as modified by the guidance note 'Exceptions and modifications to the EU GVP that apply to UK MAHs and the licensing authority'.

A list of reference texts is provided at Appendix I.

Merck Sharp & Dohme LLC. (referred to as "MSD" or "the company" hereafter) is a subsidiary of Merck & Co., Inc., Rahway, N.J., USA. MSD is a trade name of Merck & Co., Inc., with headquarters in Rahway, N.J., U.S.A.

Areas of focus for MSD include Cardio-Metabolic Disorders, Immunology, Infectious Diseases and Vaccines, Neuroscience, Oncology, and Animal Health. The main activities for pharmacovigilance (PV) occur within the Global Clinical Safety and Pharmacovigilance (GCS&PV) organisation, which is part of MSD Research Laboratories.

Organon separated from MSD on 2nd June 2021. Transfer of Marketing Authorisations from MSD to Organon was complete at the time of inspection for the EEA and UK. Where applicable, where MSD still holds Marketing Authorisations (MA) outside of the EEA/UK, Organon is delegated to manage the PV system.

For significant delegation of pharmacovigilance tasks see Section A above.

At the time of inspection MSD held [redacted] licences in the UK. [redacted] products were marketed of which [redacted] Category 1 products and [redacted] Category 2 products. [redacted] products were subject to Additional Monitoring, these were: [redacted]

B.2 Scope of the inspection

The inspection included a review of the global pharmacovigilance system and was performed at MSD's offices in 120 Moorgate, London, EC2M 6UR. Personnel from MSD attended the site in order to participate in the inspection.

The inspection was performed using interviews and document review (including outputs from the global safety database and listings of medical information enquiries and product complaints). The systems reviewed during the inspection are highlighted in the Pharmacovigilance Inspection Plan (attached as Appendix II).

The use of Artificial Intelligence (AI) for case processing and PSUR production was not reviewed in detail and it is recommended that these areas are subject to closer review during a subsequent pharmacovigilance inspection.

B.3 Documents submitted prior to the inspection

The company submitted a PSMF (Version [redacted] – 14AUG2025) to assist with inspection planning and preparation. Specific additional documents were also requested by the inspection team and provided by the company prior to the inspection.

Documents provided prior to the inspection, are listed in the pre-inspection document request sheet held by the MHRA.

B.4 Conduct of the inspection

In general, the inspection was performed in accordance with the Inspection Plan.

The inspection included two scheduled office-based inspection days for the Lead Inspector, which was held on 18th -19th September 2025. The purpose of these office-based inspection days was to analyse the ICSR line listings and to review documentation relating to the global safety database and associated systems.

A closing meeting was held to review the inspection findings at Merck Sharp & Dohme (UK) Limited (MSD (UK) Ltd) 120 Moorgate, London, EC2M 6UR on 26th September 2025. It was planned that as review of documentation was not fully complete at the close of the on-site inspection, a further closing meeting would be held during the following weeks if there were any significant changes to the findings. On review of further documentation, no further significant findings were noted and it was mutually agreed by the MHRA inspection team and MSD that a further closing meeting was not required.

A list of the personnel who attended the closing meeting is contained in the Closing Meeting Attendance Record, which will be archived together with the inspection notes, a list of the documents requested during the inspection and the inspection report.

SECTION C: INSPECTION FINDINGS

C.1 Summary of significant changes and action taken since the last inspection

Since the previous inspection in 13th-17th June 2016 the company had made the following changes to the pharmacovigilance system:

- Individual Case Safety Report (ICSR) processing moved to a fully in-house service as of December 2022 when the contract with IQVIA was terminated
- Organon separated from MSD on 2nd June 2021. Transfer of Marketing Authorisations from MSD to Organon was complete at the time of inspection for the EEA and UK
- Global Safety Database: [redacted] MSD's implementation of [redacted] product was put into production on 10 February 2025. The previous system was [redacted] based on [redacted] and has been retired along with some associated ancillary systems: [redacted]

C.2 Definitions of inspection finding gradings

Critical (CR): a deficiency in pharmacovigilance systems, practices or processes that adversely affects the rights, safety or well-being of patients or that poses a potential risk to public health or that represents a serious violation of applicable legislation and guidelines.

Major (MA): a deficiency in pharmacovigilance systems, practices or processes that could potentially adversely affect the rights, safety or well-being of patients or that could potentially pose a risk to public health or that represents a violation of applicable legislation and guidelines.

Minor (MI): a deficiency in pharmacovigilance systems, practices or processes that would not be expected to adversely affect the rights, safety or well-being of patients.

Comment: the observations might lead to suggestions on how to improve quality or reduce the potential for a deviation to occur in the future.

The factual matter contained in the Inspection Report relates only to those things that the inspection team saw and heard during the inspection process. The inspection report is not to be taken as implying a satisfactory state of affairs in documentation, premises, equipment, personnel or procedures not examined during the inspection.

Findings from any inspection that covers products authorised in respect of Northern Ireland which are graded as critical or major will be shared with the EMA, EU competent authorities and the European Commission.

C.3 Guidance for responding to inspection findings

Responses to inspection findings should be clear, concise and include proposed actions to address both the identified deficiency and the root cause of the deficiency. Consideration should also be given to identifying and preventing other potential similar deficiencies within the pharmacovigilance system.

Responses should be entered directly into the table(s) in section C.4. The following text is intended as guidance when considering the information that should be entered into each of the fields within the table(s). 'Not applicable' should be entered into the relevant field if the requested information is not appropriate for the finding in question.

Root Cause Analysis Identify the root cause(s) which, if adequately addressed, will prevent recurrence of the deficiency. There may be more than one root cause for any given deficiency.
Further Assessment Assess the extent to which the deficiency exists within the pharmacovigilance system and what impact it may have for all products. Where applicable, describe what further assessment has been performed or may be required to fully evaluate the impact of the deficiency e.g. retrospective analysis of data may be required to fully assess the impact.
Corrective Action(s) Detail the action(s) taken / proposed to correct the identified deficiency.
Preventative Action(s) Detail the action(s) taken / proposed to eliminate the root cause of the deficiency, in order to prevent recurrence. Action(s) to identify and prevent other potential similar deficiencies should also be considered.
Deliverable(s) Detail the specific outputs from the proposed / completed corrective and preventative action(s). For example, updated procedure/work instruction, record of re-training, IT solution.
Due Date(s) Specify the actual / proposed date(s) for completion of each action. Indicate when an action is completed.

Further information relating to inspection responses can be found under 'Inspection outcomes' at: https://www.gov.uk/guidance/good-pharmacovigilance-practice-gpvp

C.4 Inspection findings

C.4.1 Critical findings

No critical findings were identified from the review of pharmacovigilance processes, procedures and documents performed during this inspection.

C.4.2 Major findings

No major findings were identified from the review of pharmacovigilance processes, procedures and documents performed during this inspection.

C.4.3 Minor findings

MI.1 Data Management

Finding MI.1

There were a number of ICSRs from studies in the global safety database which had been assigned the incorrect study type, such that they may have appeared in the wrong tabulation in PSURs and potentially other ad-hoc reports that used the field Study Type as a search criterion and/or as an output.

Examples included:

Protocol [redacted] The correct Report Type was Study, the correct Study Type was Other Study. However, there were 17 cases where Study Type was incorrectly displayed in the Line Listing (LL) output as Interventional Study due to case processing errors:

[redacted]

Protocol [redacted] The correct Report Type was Study and the correct Study Type was Other Study. However, there were 5 cases where Study Type was incorrectly recorded as Interventional Study.

[redacted]

Summary data provided during the inspection (specifically in Document Request [redacted]) showed numerous other protocols where Study Type assigned to cases differed within the same protocol. A selected sample of these are shown in the table below. It is noted that in some instances differences in Study Type may be correct due to different treatment arms etc within the same protocol but these do not appear to account for the majority of Case Type discrepancies.

Protocol ID	Interventional - Study Type (Study Type[s] that were associated with Interventional Cases)	Non-Interventional - Study Type (Study Type(s) that were associated with Non-Interventional Cases)
	Study Type: Clinical Trial	Study Type: Other Studies
	(Case Count)	(Case Count)
[redacted]	48	239
	45	665
	49	233
	227	6
	27	6
	44	5
	123	39
	371	128
	76	24
	29	6
	233	4
	70	24
	119	46
	241	65

For UK authorised products, MSD is requested to carry out a full analysis of incorrect case type, study, type and study sub-type etc to ensure that cases are correctly categorised for the purposes of PSURs and for any other downstream pharmacovigilance activities including ad-hoc reports that might be provided to the MHRA.

Root Cause Analysis

[redacted]

[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

MI.2 Collection and collation of safety information / ICSR processing

Finding MI.2
Thirty inbox items created between 14 March 2025 and 05 September 2025 in the PV inbox of the global safety database ([redacted]) had not been processed and were in an incomplete status at the time of the inspection, due to workload management/assignment process. This resulted in one inbox item ([redacted] that included safety information not being routed to the global case processing team and expedited to the regulatory authorities. It was confirmed verbally by MSD and in a document request that 29 out of 30 inbox items were assessed at the time of creation but left in an incomplete status due to human error as they did not require to be processed within the database (e.g. the item contained no safety information, or the item was a candidate for rejection for other reasons). However, one inbox item [redacted] initially received on 04 April 2025, was a valid serious report of adrenal insufficiency related to [redacted] which required processing. This case was still in the PV inbox at the time of the inspection. The case was submitted to the MHRA and EMA during the inspection on 24 September 2025. Although the requirement to monitor the inbox daily and identify inbox items that required review or processing was described in SOP [redacted] version [redacted] dated 10 February 2025, this finding suggests that that the process was not sufficiently robust to ensure that the risk of missing relevant safety information was minimised.
Root Cause Analysis
[redacted]

Further Assessment	
[redacted]	
Corrective Action(s)	
[redacted]	
Deliverable(s)	**Due Date(s)**
[redacted]	
Preventative Action(s)	
[redacted]	
Deliverable(s)	**Due Date(s)**
[redacted]	

MI.3 Procedural documentation

Finding MI.3
The AI tool [redacted] which used [redacted] was being used in a pilot project to generate first drafts of PSURs. It was noted that the pilot process had been used to draft PSURs which were submitted to RAs, and submission of PSURs to the MHRA using this AI process was anticipated in January 2026. (A [redacted] PSUR covering the six-month period 04 November 2024 to 03 May 2025 was produced using the AI enhanced process and will be used to satisfy the one-year reporting interval as one of two six-month reports; the due date to the MHRA is 12 January 2026). There were no procedural documents which (1) made any reference to the use of AI during production of PSURs and (2) referred to how performance of the PSUR AI was being monitored and how feedback was being provided to the AI vendor. It is not accepted that no procedural documents are required because this is a pilot project.

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)
[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

MI.4 Signal Detection

Finding MI.4
The rationale for agreeing to change the frequency of signal detection for each product was not documented for [redacted] As per SOP [redacted] (Version [redacted] Effective Date: 19 December 2024) , authorized products were eligible to change the tier (and thus frequency) of aggregate review based on criteria outlined in Appendix 6 Product Tiering Methods and Tiering Framework for Safety Surveillance Review. The framework ensured assessment of parameters such as how long the product had been approved and on the market for, the risk/safety profile, volume of reports, new risks identified within a class and manufacturing

changes etc. Whilst there was documentation of which aspects were considered during the assessment, the exact rationale for agreeing to amend the frequency was not specifically documented for each product. The Risk Management Safety Team meeting minutes, in which the change of tier was discussed, recorded the agreement to change the tier but did not include the reason(s).
Root Cause Analysis
[redacted]
Further Assessment
[redacted]
Corrective Action(s)
[redacted]
Deliverable(s) / **Due Date(s)**
[redacted]
Preventative Action(s)
[redacted]
Deliverable(s) / **Due Date(s)**
[redacted]

C.4.4 Comments

Minor delay in the conduct of daily reconciliation of [redacted]

There was a minor delay in the conduct of a daily reconciliation to ensure that all medical enquiries with AEs entered into [redacted] system had been sent to and acknowledged by PV, as per [redacted] version [redacted] dated 27 September 2024.

The Designated Point of Contact (DPOC) personnel were responsible for generating a daily report from [redacted] to ensure receipt by PV team as per [redacted] The daily reconciliation for 07 July 2025 was conducted 8 days late by the [redacted] affiliate on 15 July 2025 due to an oversight by DPOC responsible for the task. DPOC took the decision

at the time to not raise any deviation for this as the retrospective report confirmed that cases were correctly routed and acknowledged according to the SOP timelines.

SECTION D: CONCLUSIONS AND RECOMMENDATIONS

D.1 Conclusions

The factual matter contained in the Inspection Report relates only to those things that the inspection team saw and heard during the inspection process. The Inspection Report is not to be taken as implying a satisfactory state of affairs in documentation, premises, equipment, personnel or procedures not examined during the inspection. It is recommended that you review whether the inspection findings also apply to areas not examined during the inspection and take appropriate action, as necessary.

The responses to the inspection findings, which include proposed corrective and preventative actions, do appear to adequately address the issues identified. No additional responses are required at this time. When the company has adequately implemented the proposed corrective and preventative actions, the pharmacovigilance system will be considered to be in general compliance with applicable legislation.

D.2 Recommendations

The Lead Inspector has recommended that the next MHRA inspection is performed as part of the routine risk-based national inspection programme.

APPENDIX I REFERENCE TEXTS

- The Human Medicines Regulations 2012 (Statutory Instrument 2012 No. 1916) as amended.
- Commission Implementing Regulation (EU) No 520/2012.
- Guideline on good pharmacovigilance practices (GVP).
- Exceptions and modifications to the EU guidance on good pharmacovigilance practices that apply to UK marketing authorisation holders and the licensing authority.

APPENDIX II PHARMACOVIGILANCE INSPECTION PLAN

MHRA INSPECTION NUMBER	TBC	**DAY**	1
PHARMACOVIGILANCE INSPECTION OF	MSD	**DATE**	Monday 22Sep2025
LOCATION	Merck Sharp & Dohme (UK) Limited 120 Moorgate London EC2M 6UR	**START TIME**	12.00

Purpose of Interview	**Session Lead**	**Staff to be interviewed**
Opening Meeting 12.00 Review of scope of inspection and inspection plan **Company Presentation** Overview of the company, the pharmacovigilance system and the quality system Please describe any recent significant changes to the pharmacovigilance system and any major ongoing issues *(approx. 30 minutes)*	[redacted]	Attendees: [redacted] - PV Lead UK and Ireland [redacted] - Global Qualified Person for Pharmacovigilance (GQPPV) [redacted] - Associate Vice President, Head International Pharmacovigilance [redacted] - Executive Director, Regulatory Affairs [redacted] - Executive Director, Quality Assurance, Global Pharmacovigilance Quality Head [redacted] - Director, Deputy Qualified Person for Pharmacovigilance [redacted] - Global Qualified Person for Pharmacovigilance Office Physician and Senior Director, Office of the Global QPPV [redacted] (Remote) - UK Country Executive Medical Director UK & ROI

Data migration and Go-live of [redacted] (14.00-16.00 with breaks as required) PARALLEL SESSION To include but not limited to: • Data migration into [redacted] (scope, planning, execution, validation etc) • User training • Go-live • Ongoing issues Please provide an overview presentation (maximum 20 minutes). Please provide the p*resentation slides in advance of the session by COB 18 September 2025.* Please be prepared to demonstrate any relevant systems and show principal documents.	[redacted]	Interviewee(s): [redacted] - Associate Vice President, Head International Pharmacovigilance [redacted] - Director, Deputy Qualified Person for Pharmacovigilance [redacted] - Global Qualified Person for Pharmacovigilance (GQPPV) [redacted] - Senior Director, PV Operations and Global Process Enablement [redacted] - Senior Director, Business System Management & Innovation [redacted] - Director, MRL IT Enablement & User Advocacy (EUA) [redacted] - Director, Business System Management & Innovation [redacted] - Principal Safety Data Manager, Global Pharmacovigilance Case Management [redacted] - Director, PV Systems Support [redacted] (Remote) - Senior Specialist, Software Engineering [redacted] (Remote) - Director, Business System Management & Innovation

Collection and collation of safety data (1400-1630 with breaks as required) PARALLEL SESSION Including but not limited to: • Collection of safety data from local affiliates • Collection of safety data from license/contract partners • Collection of safety data from solicited sources (MRPs, PSPs, non-interventional studies etc excluding interventional studies) • Web, Mobile and Digital channels Please provide a brief overview presentation (maximum 20 minutes). Please provide the p*resentation slides in advance of the session by COB 18 September 2025.* Please be prepared to demonstrate any relevant systems and show principal documents.	[redacted]	Interviewee(s): [redacted] - PV Lead UK and Ireland [redacted] - Associate Director, PV [redacted] - Associate Director, PV [redacted] - Associate Director, DPOC Lead [redacted] - Global Qualified Person for Pharmacovigilance Office Physician and Senior Director, Office of the Global QPPV [redacted] - GQPPV Office Support Officer- Associate Director [redacted] (Remote) - Executive Director, Pharmacovigilance Partner Strategy & Management [redacted] (Remote) - Associate Director, Pharmacovigilance Partner Strategy & Management [redacted] (Remote) - Compliance Officer, Enterprise Digital Governance (WMS SME) [redacted] (Remote) - Compliance Officer, Enterprise Digital Governance [redacted] (Remote) - Associate Director, Non-interventional Research Excellence and Governance [redacted] (Remote) - Director, Pharmacovigilance Partner Strategy and Management (PV-PSM) [redacted] (Remote) - Associate Director, Clinical Safety Strategic Operations (CSSO)
Document Review	-	Inspectors only

N.B. The Inspection Plan may need to be amended during the inspection.		

MHRA INSPECTION NUMBER	TBCInsert inspection number	**DAY**	2
PHARMACOVIGILANCE INSPECTION OF	MSD	**DATE**	Tuesday 23 Sep2025
LOCATION	Merck Sharp & Dohme (UK) Limited 120 Moorgate London EC2M 6UR	**START TIME**	0900

Purpose of Interview	**Session Lead**	**Staff to be interviewed**
ICSR data flow and ICSR processing 0930-1200 (with breaks) Including but not limited to: • End-to-end ICSR process flow (per PSMF module 3.3.1a • Data flow within [redacted] • Database configuration • ICSR processing Please provide an overview presentation (maximum 20 minutes). Please provide the p*resentation slides in advance of the session by COB 18 September 2025.* Please be prepared to demonstrate any relevant systems and show principal documents.	[redacted]	Interviewee(s): [redacted] - Associate Vice President, Head International Pharmacovigilance [redacted] - Global Qualified Person for Pharmacovigilance (GQPPV) [redacted] - PV Lead UK and Ireland [redacted] - Associate Director, PV [redacted] - Senior Director, Audits and Inspections [redacted] - Senior Director, Business System Management & Innovation [redacted] - Principal Safety Data Manager, Global Pharmacovigilance Case Management [redacted] - Director, PV Systems Support [redacted] - Director, Business System Management & Innovation
Retrieval of ICSR data 12.15-13.00 Including but not limited to:	[redacted]	Interviewee(s): [redacted] - Associate Vice President, Head International Pharmacovigilance

• Retrieval of data for regulatory reports, metrics, ad-hoc purposes Please be prepared to demonstrate any relevant systems and show principal documents.		[redacted] - Global Qualified Person for Pharmacovigilance (GQPPV) [redacted] - PV Lead UK and Ireland [redacted] - Senior Director, Audits and Inspections [redacted] (Remote) - Senior Director, PV Operations and Global Process Enablement [redacted] (Remote) - Associate Director, Quality & Compliance Management (QCM) [redacted] - Director, MRL IT Enablement & User Advocacy (EUA) [redacted] (Remote) - Associate Director, PV-Operations & Global Process Enablement [redacted] (Remote) - Product Analyst, MRL GCS&PV RxLogix Managed Services Team [redacted] - Senior Director, Head of CSRM Business Process and Systems [redacted] - Senior Principal Scientist, Drug Safety [redacted] - Associate Director, Regional Pharmacovigilance (PV) Officer [redacted] - Director, MRL IT Enablement & User Advocacy (EUA)
LUNCH	-	-
Signal detection and RSI 1400-1630 (with breaks) • Signal detection activities	[redacted]	Interviewee(s): [redacted] - Associate Vice President, Head International Pharmacovigilance

• Maintenance of Reference Safety Information (RSI) including submission of safety variations, implementation of updated product information, communication of safety information updates Please provide brief overview presentations for each subtopic above (maximum 15 minutes each). Please be prepared to demonstrate any relevant systems and show principal documents.		[redacted] - Global Qualified Person for Pharmacovigilance (GQPPV) [redacted] - PV Lead UK and Ireland [redacted] - Associate Director, PV [redacted] - Senior Director, Head of CSRM Business Process and Systems [redacted] - Senior Principal Scientist, Drug Safety [redacted] (Remote) - Executive Director, Global Labeling Head [redacted] **(Remote)** - Senior Director, Global Labeling, OpEx Lead [redacted] - Executive Director, Regulatory Affairs [redacted] - Associate Director, Regulatory Affairs [redacted] - Senior Specialist, Regulatory Affairs
N.B. The Inspection Plan may need to be amended during the inspection.		

MHRA INSPECTION NUMBER	TBC	**DAY**	3
PHARMACOVIGILANCE INSPECTION OF	MSD	**DATE**	Wednesday 24Sep2025
LOCATION	Merck Sharp & Dohme (UK) Limited 120 Moorgate London EC2M 6UR	**START TIME**	0900

Purpose of Interview	**Session Lead**	**Staff to be interviewed**
Document review and possible ad-hoc interviews		
LUNCH	-	-
Document review and possible ad-hoc interviews		
N.B. The Inspection Plan may need to be amended during the inspection.		

MHRA INSPECTION NUMBER	TBC	**DAY**	4
PHARMACOVIGILANCE INSPECTION OF	MSD	**DATE**	Thursday 25Sep2025

LOCATION	Merck Sharp & Dohme (UK) Limited 120 Moorgate London EC2M 6UR	**START TIME**	0900
Purpose of Interview	**Session Lead**	**Staff to be interviewed**	
Document review and possible ad-hoc interviews			
LUNCH	-	-	
Document review and possible ad-hoc interviews			
N.B. The Inspection Plan may need to be amended during the inspection.			

MHRA INSPECTION NUMBER	TBC	**DAY**	5
PHARMACOVIGILANCE INSPECTION OF	MSD	**DATE**	Friday 26Sep2025
LOCATION	**Error! Reference source not found.**	**START/END TIME**	0900-1300
Purpose of Interview	**Session Lead**	**Staff to be interviewed**	

Document review and possible ad-hoc interviews	-	
Inspectors meeting (time TBC)	-	Inspectors only
Closing meeting (time TBC)	[redacted]	All welcome
N.B. The Inspection Plan may need to be amended during the inspection.		