

Assessment Report

Medicines and Healthcare Products Regulatory Agency

Assessment dates 28/01/2020 to 10/02/2020
Assessment Location(s) London (000), Hertfordshire (007)
Report author [REDACTED]
Assessment Standard(s) ISO 9001:2015



Executive summary

Medicines and Healthcare Products Regulatory Agency continues to demonstrate compliance and deliver intended results (as assessed) to the requirements of their core management system and ISO 9001:2015.

There are however several areas that may pose a risk to maintaining compliance:

1. Gap in the resource of Quality Lead for the Agency
2. Gap in the resource of Quality Lead for IE&S
3. Disconnect between the NIBSC and MHRA (SC10) management system processes
4. Out of date procedures due to Brexit impact

The ISO 9001 certificate is covering a single management system, if there is a disconnect between the processes and the management of control of the processes the certificate will be at risk.

The Management System has demonstrated that it is aimed to support the strategic direction and progress in achieving objectives was observed.

Strengths and weaknesses have been discussed with the client throughout the audit.

The outcome of the audit is as follows:

4 minor nonconformities were raised in relation to:

- ~ Internal audit process
- ~ Nonconforming process
- ~ Infrastructure change control process
- ~ Documents control process

Recommendation of continued certification.

I would like to thank all those who participated in the audit

Assessment conclusion

BSI assessment team

Name	Position
[REDACTED]	Team Leader

Assessment conclusion and recommendation

The audit objectives have been achieved and the certificate scope remains appropriate. The audit team concludes based on the results of this audit that the organization does fulfil the standards and audit criteria identified within the audit report and it is deemed that the management system continues to achieve its intended outcomes.

RECOMMENDED - Corrective Action Plan Required ('Minor' findings only): The audited organization may be recommended for continued certification, based upon the acceptance of a satisfactory corrective action plan for all 'Minor' findings as shown in this report. Effective implementation of corrective actions will be reviewed during the next surveillance audit.

You are required to identify the cause and implement corrections and corrective actions required to address all nonconformities before your next BSI assessment relating to the certificate against which the nonconformities were raised.

Use of certification documents, mark / logo or report

The use of the BSI certification documents and mark / logo is effectively controlled.

VRMM -**Publishing safety communication including updated product information, DSU, DHPCs****VRMM -****Communicating information on ADRs using a number of different methods including DAPs, ASPRs****VRMM -****ADR reporting and Signal Management for Medicinal Products :**

Evidence:

The VRMM - Managing Editor of job safety updates demonstrated the process.

- Internal audit report:

VRMM 06-2019 by SK, scope: Safety communications ~ dated 08/2019

- Effectiveness reviewed by annual internal audits

- SOP:

Drug Safety Updates bulletin, published monthly:

VRM017/05 Production of Drug Safety Update ~ dated 11/2019

DHPC Direct Healthcare Professional Communications:

VRM020/07 Communication of drug safety issues/Direct Healthcare Professional Communications ~ dated 09/2019

Urgent alerts:

Guidance but not a formal SOP

- Roles and Responsibilities: INsight hosts Organisational chart, updated monthly

- Risk: Lead no longer allowed by UK due to Brexit, however comments are still allowed. This leaves uncertainty in the process going forward

- Support:

DHPC template provided by EMEA

- Sampled:

December 2019 Agenda of Drug Safety update planning meeting

Drug safety update published on gov.uk website ~ dated 16/12/2019

October 2019 Agenda of Drug Safety update planning meeting

Drug safety update published on gov.uk website ~ dated 18/10/2019

DHPC - re: Insuman ~ dated 10/10/2019

DHPC seen on the Letters and drug alerts page of Gov.uk

- Internal audit report:

VRMM internal audit programme 2017-2019

VRMM 04/2019 by SK, scope: VRMM - Management and reporting of ADR's and communicating information on ADR's ~ dated 06/2019, 1 NC

Pharmacovigilance CA log

VRMM65 from Audit ref: VRMM 04-2019 ~ closed 7/2019

- SOP:

VIRG0101/09 Input Verification of Adverse Drug Reaction Report ~ dated 07/2019

VIRG0102/09 Data capture of adverse drug Reaction Reports ~ dated 07/2019

VIRG0103/08 QA & Commit of Adverse Drug Reaction Reports ~ dated 07/2019

- Roles and Responsibilities: INsight hosts Organisational chart, updated monthly

- Risk: Meeting legislative target dates, mitigated through daily report run and analysed to ensure legislative target dates are met

ADR's monitored and analysis reported as follows:

Monthly report on divisional level

Quarterly on an agency level

- Support

Sentinel

Empirica Signalling software

SOP's communicated through the INsite SharePoint site

- Sample:

Ref: ADR 22467753-001 ~ dated 15/01/2020

QA check & comment ~ dated 22/01/2020

- SOP:

VIRG0402/05 Provision of Interactive Drug analysis Prints (iDAP) to the website ~ dated 06/2018

- Sampled:

The VRMM - Pharmacovigilance Information Unit Manager demonstrated the Interactive Drug Analysis Profile.

- SOP:

VIRG0603/11 Signal assessment & Signal Detection meetings ~ dated 03/2019

Signal workflow (assessment of total body of evidence)

- Sampled:

SA 18984586 ~ dated 25/10/2019, no further action required

SA 18742109 ~ dated 29/01/2019, review required and completed

SA 18760427 ~ dated 19/02/2019, review required and completed

VRMM:

Pharmacovigilance audit strategy iss.5 ~ dated 04/2019, include process risk matrix

Audit programme, Annex A

- Internal auditor training record - Quality Management System Auditor Training Course, two days, 7 and 8th April 2016, IRCA and approved and certified.

Overall:

- Planned activities have been realised
- Planned results have been achieved