



Medicines & Healthcare products  
Regulatory Agency

## **Medicines and Healthcare products Regulatory Agency (MHRA) Quality Management Systems Statement of Compliance**

### **Company Details**

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| <b>Company Name</b>                      | Medicines and Healthcare products Regulatory Agency (referred to as 'The Agency' in this document)                                                                                                                                                                                                                                          |
| <b>VAT Number</b>                        | GB888849726                                                                                                                                                                                                                                                                                                                                 |
| <b>Registered address</b>                | 10 South Colonnade<br>Canary Wharf<br>London<br>E14 4PU<br>United Kingdom                                                                                                                                                                                                                                                                   |
| <b>Registration Number</b>               | The MHRA is a UK Government Agency and so does not have a company registration number                                                                                                                                                                                                                                                       |
| <b>Manufacturing address</b>             | Blanche Lane<br>South Mimms<br>Potters Bar<br>Hertfordshire<br>EN6 3QG<br>United Kingdom                                                                                                                                                                                                                                                    |
| <b>Quality Assurance contact details</b> | Named person: Jennifer Padley<br>Phone: 01707 641517<br>Email: <a href="mailto:Jennifer.padley@mhra.gov.uk">Jennifer.padley@mhra.gov.uk</a>                                                                                                                                                                                                 |
| <b>Invoicing contact details</b>         | Named person: Audrey Blanchard<br>Phone: 020 3080 6000<br>Email: <a href="mailto:accounts.payable@mhra.gov.uk">accounts.payable@mhra.gov.uk</a>                                                                                                                                                                                             |
| <b>Sales team contact details</b>        | Named person: Steven Moate<br>Phone: 01707 641140<br>Email: <a href="mailto:standards@nibsc.org">standards@nibsc.org</a>                                                                                                                                                                                                                    |
| <b>Anti-bribery</b>                      | The Agency maintains an 'Anti-Fraud, Bribery and Corruption Policy'. MHRA is committed to undertaking all mandatory counter fraud processes and to complying with the Government Functional Standard GovS 013: Counter Fraud ('the Functional Standard'). All staff complete a mandatory Conflict of Interest (COI) declaration every year. |
| <b>Anti-slavery</b>                      | The Agency follows Government Policy on 'Tackling Modern Slavery in Government Supply Chains'.                                                                                                                                                                                                                                              |
| <b>Data protection/GDPR</b>              | The Agency handles all personal data related to member of the public, manufacturers, customers, and other stakeholders in accordance with the Data Protection Act 2018 and the UK General Data Protection Regulations.                                                                                                                      |

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| <b>Significant organisational changes</b> | New Chair of the Board: January 2025<br>New Chief Executive Officer: April 2025<br>New Chief Strategy Officer: June 2025<br>New Chief Medical and Scientific Officer: TBC |
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**Information regarding Quality Management Systems (QMS) and associated processes**

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| <b>Quality standards and certifications</b> | The Agency holds certification for ISO 9001, ISO 17025, two HTA Licenses (research and Human Application) and a European Directorate for the Quality of Medicines (EDQM) Attestation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Quality Manual</b>                       | The Agency maintains a Quality Management System that is documented in a Quality Manual held on an electronic document control system.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Quality Policy</b>                       | The Agency maintains a Quality Policy that is held on an electronic document control system.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Document control</b>                     | The Agency maintains a document control system that manages documents that cover all scientific activities as well as governance documentation. Documents held in this system have a unique reference number, are version controlled, reviewed at regular intervals, have one named owner, and a team of reviewers and approvers. Documents in this system are protected from unintended or unauthorised use, loss and amendment.                                                                                                                                                                                                                                                                                      |
| <b>Records Management</b>                   | All activities undertaken within the Agency are accurately recorded, attributable, authorised, stored, protected and retained as per internal procedures and storage and retention policy. Records can be in the format of but not limited to, electronic, paper-based, laboratory notebook, reports, certificates, protocols, instructions for use, and these can originate from internal or external sources.                                                                                                                                                                                                                                                                                                        |
| <b>External Inspections/ Audits</b>         | The Agency is audited by the following external assessment bodies: the British Standards Institute (BSI), the UK Accreditation Service (UKAS), the European Directorate for the Quality of Medicines (EDQM), the Human Tissue Authority (HTA) and the World Health Organisation (WHO).                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>External Inspection/Audit Schedule</b>   | <ul style="list-style-type: none"> <li>- ISO 9001 certification 3-yearly by British Standard Institute (BSI)</li> <li>- ISO/IEC 17025 accreditation 4-yearly by United Kingdom Accreditation Services (UKAS)</li> <li>- Human Tissue Authority (HTA) annually</li> <li>- Mutual Joint Audit (MJA) EDQM 5-yearly attestation</li> <li>- WHO Pre-qualification assessment 5-yearly</li> </ul>                                                                                                                                                                                                                                                                                                                            |
| <b>Business continuity</b>                  | The Agency maintains Business Continuity plans that cover all work area activities and infrastructure maintenance, that are reviewed on an annual basis.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Internal audit programme</b>             | The Agency employs a rigorous internal Quality Management System and Safety Management System audit programme to cover all activities that are performed under a QMS or SMS, on a 3 and 4-year rotational basis. The frequency of each individual audit is managed using a risk-based approach, considering significant staff changes, process changes, new products and the results of previous audits. They are a mix of practical observational, horizontal, vertical and records-based audits. Audits are performed by the Quality Team and by trained, volunteer internal auditors from across different areas of work. Volunteer auditors are not permitted to audit their own area of work, and the same person |

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|                                                                   | would not audit the same work area twice in a row to maintain impartiality.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Management responsibilities</b>                                | Senior Management in the Agency are ultimately responsible for the effectiveness and implementation of the QMS. They ensure that quality policy and objectives are established and reviewed and that the importance of these is communicated. They are responsible for ensuring adequate resources are available for the implementation of the QMS and all activities. They are responsible for the engagement of staff with the QMS and that it is communicated appropriately. They are also responsible for supporting other roles in the implementation of the QMS. |
| <b>Standard Operating Procedures / Policies</b>                   | The Agency maintains SOPs, policies, procedures and work instructions for all activities performed under a quality or safety management system, and for areas of work that fall outside of a QMS or SMS. These documents are controlled appropriately and kept on an electronic document control system. The documents are maintained, reviewed and updated by staff that are deemed competent in the procedures.                                                                                                                                                      |
| <b>Complaints</b>                                                 | All complaints made to the Agency are logged on the Agency Complaints system and investigated thoroughly. A root cause will be established and documented along with immediate corrections and corrective actions and an effectiveness review will be implemented. The Agency maintains KPIs regarding complaint handling regarding timeframes for addressing and responding to complaints. The Agency meets its KPIs for turnaround times for complaint handling 80-90% of the time.                                                                                  |
| <b>Change control/Planned Deviations</b>                          | There is a procedure in place for the assessment, implementation and monitoring of change controls (CC) and planned deviations (PD). Any CC or PD must be logged, assessed and evaluated by subject matter experts for risk and impact of the change. Changes and deviations are approved by Senior Management and reviewed and approved by the Quality Assurance team and/or the Health and Safety team as required. Changes may also undergo validation or revalidation as necessary.                                                                                |
| <b>Anomalies (unexpected deviations) and Issues</b>               | All anomalies and issues raised within the Agency are logged and undergo a thorough investigation to identify the root cause of the issue and the events that led to the anomaly or issue being identified. Immediate and longer-term corrective actions are taken to rectify the anomaly or issue and prevent its recurrence in the future. An effectiveness plan will be implemented to determine how effective the corrective actions were and to determine if further action is required                                                                           |
| <b>Managing non-compliances from internal and external audits</b> | Any non-compliances (NC) resulting from an internal or external audit are documented on audit report forms and the auditee is given 4 weeks to investigate the NC and perform the investigation and root cause analysis. Immediate corrections and corrective actions are put in place to rectify the NC and prevent it from occurring again and an effectiveness review will also take place at the next audit to ensure that the corrective actions were effective, and the NC has not reoccurred.                                                                   |
| <b>Out of specification results</b>                               | An out of specification result will initiate an investigation by an independent party or area supervisor to determine the cause. A full investigation will be undertaken and documented to determine the root cause and suitable corrective actions will be put in place.                                                                                                                                                                                                                                                                                              |

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| <b>Non-conforming products</b>           | All non-conforming products are fully investigated to establish the root cause, and appropriate actions will be taken immediately to notify the customers and remove the product from the catalogue. Relevant information will be provided to customers as necessary, and support will be provided if needed. All events are logged and investigated as appropriate and may result in the non-conforming product being discarded, reworked or replaced. |
| <b>Trending issues</b>                   | Outputs from internal and external audit, anomalies, complaints, non-conforming product and out of specification results are trended and regularly reported to staff and Senior Management for review and input. Similarly, outputs from annual management reviews are evaluated to identify patterns and trends. The monitoring of these trends and the performance evaluation of issues feeds into an on-going process of continual improvement.      |
| <b>Document retention and withdrawal</b> | The Agency follows a Retention and Disposal Schedule that lays out both legislative and regulatory guidance on how to actively manage all information, through to its destruction. The Schedule is informed by The National Archives (TNA) and Department of Health and Social Care (DHSC) guidelines and other applicable legal requirements.                                                                                                          |

### **Suppliers and supplier approval**

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| <b>Purchasing and supplier qualification</b> | Suppliers utilised by the Agency must undergo an evaluation process, in which they must complete a set of qualification and technical questions. This process includes examining their suitability to be a government supplier and will capture and evaluate their financial, health and safety, environmental and quality eligibility. Services procured by the Agency are documented in service agreements. |
| <b>Critical Supplier qualification</b>       | All suppliers of critical items are examined to ensure they have the appropriate accreditation or compliance in place. The Agency requires a copy of an ISO 9001 certificate or equivalent, or the completion of a self-assessment. These suppliers are reviewed at regular intervals.                                                                                                                        |
| <b>Sub-contractors QMS qualification</b>     | All subcontractors for critical processes and procedures are evaluated to ensure that they have the appropriate accreditation or compliance in place. The Agency requires a copy of the appropriate ISO certificate or the completion of a self-assessment.                                                                                                                                                   |

### **Training and competence**

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| <b>Job descriptions and responsibilities</b> | All staff working in the Agency hold a current job description detailing relevant roles and responsibilities. There is a robust recruitment process in place to ensure that all staff have the appropriate qualifications, skills and experience to undertake intended roles. |
| <b>ISO and QMS Training</b>                  | All staff working in Quality Management System (QMS) related activities are required to undergo the relevant QMS training and hold the relevant signed and authorised training forms.                                                                                         |
| <b>Training</b>                              | All staff in the Agency are required to hold records of qualifications, training and on-going maintenance of competency. The relevant certificates or proof of training are also required to be stored in                                                                     |

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|                   | personnel training records. Staff are provided opportunities for formal and on-the-job training, as appropriate.   |
| <b>Competency</b> | All staff maintain competency for their roles and responsibilities on an on-going basis and hold relevant records. |

**Equipment**

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| <b>Equipment records</b>                        | All equipment used in the Agency is required to have an associated equipment record that details the type and individual details of the equipment, make, model and serial number, the qualification and on-going maintenance and calibration frequency and details, as well as the history of the equipment, its calibrations, services, faults and repairs including current status of use. |
| <b>Qualification of equipment</b>               | All equipment must be installed, qualified and validated before use to ensure that it's fit for its purpose and functioning correctly.                                                                                                                                                                                                                                                       |
| <b>Maintenance and calibration of equipment</b> | Equipment within the Agency is maintained, serviced and calibrated as and when required, within stipulated servicing and calibration intervals and requalified/revalidated as necessary.                                                                                                                                                                                                     |
| <b>Equipment faults</b>                         | Any equipment faults are investigated and actioned by the appropriately trained staff or engineers. Faults and the associated outcome (repair or disposal) will be documented on the equipment record and the equipment status updated and labelled accordingly.                                                                                                                             |
| <b>Pipette calibration</b>                      | All pipettes are calibrated annually and checked accordingly on a routine basis.                                                                                                                                                                                                                                                                                                             |

**Infrastructure**

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| <b>Site cleanliness</b>                                     | The site is maintained to a high standard and is kept clean, tidy and well maintained by a team of cleaners, scientific and maintenance staff dependant on classification or work area. Facilities such as toilets and kitchen facilities are cleaned appropriately daily. For areas where cleaning staff are not permitted, scientific staff undertake the task of keeping their areas maintained.       |
| <b>Site maintenance</b>                                     | Maintenance issues that occur across site are logged on an electronic Maintenance management system that raises work orders for the maintenance team to action. This team have KPIs for timelines to deal with issues, depending on level of severity and risk.                                                                                                                                           |
| <b>Utilities</b>                                            | All utility suppliers are governed by Crown Commercial Services who dictate the contracts the Agency holds every year.                                                                                                                                                                                                                                                                                    |
| <b>Lighting and ventilation</b>                             | Lighting and ventilation systems are maintained by internal maintenance staff. For both lighting and air handling units, clean rooms, high containment and critical areas are serviced every 6 months, and the rest of the site is serviced every year. Emergency lighting is also serviced annually. Air conditioning units are serviced by an external provider annually.                               |
| <b>Trend management of temperature-controlled equipment</b> | The Agency uses a Trend Building Management system that is supplied and under contract with an external supplier, who regularly maintain the sensors and manage the software. The day-to-day management of the equipment is done by in-house maintenance staff. As above, all high-containment, clean room and critical areas are serviced every 6 months, and the rest of the site is serviced annually. |

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| <b>IT software</b> | The Agency operates a suite of digital tools to manage software but also to provide protected monitoring across the agency to detect and defend against cyber threats and vulnerabilities.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>IT security</b> | <p>The MHRA operates an information security management system (ISMS) that is aligned to all industry and Government standards, including ISO 27001 and NIST. Furthermore, our maturity against these standards is measured by NCSC CAF and the NHS DSPT. Within our ISMS we operate a robust security risk management system aligned to ISO 27005 and Government standards. This means cyber security risks to the Agency's network and data are routinely identified, assessed, managed and escalated, when required. The Agency has a comprehensive governance process in place to manage risks, including board level visibility. The MHRA security maturity is routinely audited by bodies such as the Government Internal Audit Authority. The Agency conducts a programme of annual independent security testing. We operate a hierarchy of security controls relevant to the needs of the Agency. Software maintenance, upgrading and patching is a key component of this.</p> |
| <b>IT training</b> | All Agency staff are required to undergo IT Security training on an annual basis.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

### Manufacturing

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| <b>Facilities</b>            | The Manufacturing team operate and maintain filling and cleanroom facilities and activities under ISO 9001 certification. This is achieved with routine cleaning regimes and controlled processes and procedures in place. They undergo regular shutdowns so that inspections of infrastructure and equipment can be undertaken as well as deep clean regimes and routine servicing can take place. Clean room environments are maintained as required and environmental monitoring is ongoing. |
| <b>Procedures</b>            | All policies and procedures for the manufacturing facility activities and the associated clean rooms are clearly defined in SOPs and Codes of Practice(s) (CoPs) that are held on the Agency's electronic document control system.                                                                                                                                                                                                                                                              |
| <b>Environmental control</b> | The Manufacturing team maintain clean rooms compliant with grade ISO 7, with designated ISO 5 areas. Weekly environmental monitoring takes place, with monthly air sampling. Settle plates are used to monitor the microbial levels in the cleanrooms during filling activities. There is a clearly documented cleaning schedule undertaken by internal staff, and there are routine deep cleans undertaken as per procedure by an external company during facility shutdowns.                  |
| <b>Critical consumables</b>  | All critical items required for fills are inspected and evaluated upon arrival, before being assessed as fit for purpose and put into use. The critical items, such as ampoules, vials and stoppers, are tested against defined criteria.                                                                                                                                                                                                                                                       |
| <b>Packaging</b>             | All packaging clearly identifies product name, product codes, lot or batch number and where required or applicable, the expiry date.                                                                                                                                                                                                                                                                                                                                                            |

**Storage and Distribution**

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| <b>Adequate storage facilities</b> | Storage facilities for products and temperature sensitive materials are maintained under controlled conditions at the required temperatures, and the site maintains cold storage at -150°C, -70°C, -20°C and +4°C. All temperature-controlled storage equipment is monitored and alarmed where an alarm will sound if the temperature falls outside of set tolerance ranges and this is monitored 24/7. |
| <b>Shipping requirements</b>       | Storage and shipping conditions for products are agreed and detailed that inform the distribution team of preparation, packaging and temperature conditions for the transportation of samples.                                                                                                                                                                                                          |
| <b>Packaging supplies</b>          | Packaging supplies are provided by ISO 9001 certified companies. Digital temperature loggers can be used at the customer's request. In addition, the Dispatch team use WarmMark stickers to indicate if the package has breached a certain threshold during transit.                                                                                                                                    |
| <b>Shipping couriers</b>           | All couriers used by the Agency must undergo the appropriate Tender process for new suppliers. During this process, their quality requirements will be examined. The courier companies are held to certain KPIs, and performance monitoring and regular stakeholder meetings take place to ensure continued good service.                                                                               |
| <b>Shipping paperwork</b>          | All products are shipped with the relevant paperwork including commercial invoices, dispatch notes, permits, COAs and certificates of origin. IFUs can be found on the website and will also be emailed after confirmation of purchase. Additionally, to meet the needs of certain countries, photos of labels can be provided in advance.                                                              |