CURRICULUM VITAE

Claire Glenister

BA (Hons), PCQI

Pharmaceutical Industry Consultant

Recognised Areas of Expertise

Graduate quality professional with 22 years experience in the pharmaceutical sector; 15 years in pharmaceutical manufacturing and a further 7 years in Good Distribution Practice as an MHRA inspector and, subsequently, Operations Manager. Qualified Lead Auditor. Proven excellent communication skills, both verbal and written, and an outstanding ability to lead teams and manage work cross-functionally at all levels. Prince2 qualified and effective project manager.

- Leading GDP Inspections at complex sites/companies across the UK
- QMS in pharmaceutical manufacturing
- Role and responsibilities of the Responsible Person
- Management and leadership
- Transportation and storage requirements for GDP
- Identifying licencing requirements for complex business models
- Global supply chain management
- Training in EU GDP Regulatory requirements
- MHRA GDP inspection preparation and remediation consultancy

Professional Qualifications and Accolades

- Practitioner for the Chartered Quality Institute (PCQI)
- Completion of MHRA GDP Inspector training course and certification.
- Completion of Quality Assurance Management Development Programme (internal to GSK).
- Completion of ISO 9000:2000 training
- Completion of RSSL Auditor/Lead Auditor training.
- GlaxoSmithKline Certified Auditor
- PRINCE 2 Practitioner
- City and Guilds NVQ level 2 certificates in 'Facilitating learning through individual coaching, (C25) and 'Conducting non competence based assessments' (D21)
- CQI module D1 – Quality Principles

- CQI module D2 - Quality Management
- CQI module D3 – Quality Tools and Techniques
- Recipient of a Global Manufacturing and Supply Regional Award for 'Performance and Improvement'.

Current Employment

- Independent Consultant working on behalf of ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry

Career History

COVID Response Operations Manager and GDP Inspector - MHRA (March 2020 – August 2020)

- Development and management of remote Risk Based Inspection Programme for GDP to ensure effective use of available resource and expertise during the pandemic.
- Management of operational response in managing resource for GDP.
- Liaison with other government departments to ensure a joined-up approach
- Maintaining open communications with key stakeholders to ensure overview of industry issues and shortages.

Operations Manager and GDP Inspector - MHRA (February 2018 – March 2020)
as for the GDP Inspector role. In addition:

- Development and management of Risk Based Inspection Programme for GDP to ensure effective use of available resource and expertise.
- Direct management of GDP inspectors.
- Recruitment of new GDP inspectors.
- Delivering training in QMS to global audiences
- Management of MHRA GDP Symposium
- Liaison between stakeholders and internal departments to resolve issues and identify expectations relating to GDP.

GDP Inspector – MHRA (Jan 2013 – February 2018)

- Organised and conducted GDP inspections in accordance with Human Medicine Regulations 2012 and EU GDP.
- Worked with other regulators in accordance with the European Commission Compilation of Community Procedures.
- Inspection, review and approval of new sites and companies applying for Wholesale Dealers Authorisations.
- Escalation of non-compliant sites and companies to the Inspection Action Group for review and associated follow-up work/inspections.
- Used inspection outputs and intelligence to determine appropriate risk ratings for sites and companies in accordance with the Risk Based Inspection Programme.
- Organisation of annual GDP Symposium.
- Presenting to large and small groups of stakeholders.

Supply Quality Lead and Regulatory Conformance and Audit Support– GlaxoSmithKline (March 2012 – January 2013)

- Lead Supply Quality Management site based activities at Ware.
- Investigation and management of vendor complaint.
- Management of local system supplier approvals.
- Batch rejection and return to vendor where appropriate.
- Effectively managed site preparation and control room for internal audits.
- Supported Supplier Quality Shared Service with requests for information and documentation as appropriate.

Site Compliance Auditor – GlaxoSmithKline (Nov 2005 – May 2011)

- Managed delivery of the Site Operational Compliance Audit programme and associated corrective and preventive actions (CAPA), ensuring that all departments met the requirement of the Global Manufacturing and Supply Quality Management System (QMS).
- Lead auditor for internal site audits.
- Trained and developed direct reports.
- Promoted open communication and provided consultancy to ensure effective CAPA's, in doing so transforming the site working practices and culture.
- Effectively managed site preparation and control rooms for both internal and regulatory (external) audits.
- Played a key role in site implementation and use of corporate Quality Management System (QMS).
- Successfully managed Global project to define internal auditing process as part of QMS Implementation. Ensured acceptance criteria were fully met and secured stake-holder buy-in.
- Successfully coached and mentored inexperienced direct reports to auditor level to enhance team performance.
- Conducted risk based audits, conducting initial research, scheduling activity and following-up remedial, corrective and preventive actions effectively.
- Able to identify and escalate high risk process gaps and ensure effective closure.
- Effectively facilitated stakeholder focus groups using six sigma techniques to create robust processes.
- Ensured all site departments met the requirement of the current Global Manufacturing and Supply QMS.
- Successfully promoted audit identified best practices to routinely improve efficiency across site.
- Presented site compliance systems to external regulators.

Non-Manufacturing Quality Manager – GlaxoSmithKline (Feb 2004 – Nov 2005)

- Provided quality support and advice to all critical areas of the manufacturing value stream, including engineering, warehousing, logistics, technical and security.
- Promoted and ensured QMS within areas of responsibility.
- Supported the quality improvement groups within areas of responsibility.

- Developed and implemented a self inspection audit programme for all areas of the site.
- Regularly performed gap analyses of current standards to ensure ongoing compliance to a developing QMS system and changing regulatory requirements.
- Managed the quality aspects of the internal problem notification system.
- Reviewed and approved change controls with quality implications.

Site Complaints Manager – GlaxoSmithKline (Oct 2001 – Feb 2004)

- Managed and lead the team responsible for co-ordinating and processing all product complaints associated with the Ware site.
- Communicated complaint trending and investigations to the site quality team and corporate level management.
- Launched new complaints department with standard ways of working to increase awareness of complaints across the business, this included implementing a process for identifying corrective actions to root causes.
- Initiated projects to mitigate any trends identified.
- Positive feedback received from the FDA and other regulatory auditors regarding current complaint systems and procedures.
- Led initiative to agree consistent reporting and effective trending of complaints across global MDPI sites on behalf of a functional group.
- Successfully trained out complaint investigation methods to allow the adoption by the USA Site.
- Member of the Global Performance Measures Team as Complaints section owner. Received a Regional Award for activities in this area.
- Presented complaints data to external regulators.

Quality Co-ordinator – GlaxoSmithKline (Jan 1999 – Oct 2001)

- Co-ordinated the product complaint process and batch sentencing across the site.
- Improved GMP awareness in production and support areas by coaching staff members.
- Advised staff on quality related issues.
- Developed a close working relationship with other areas to ensure batch usage decisions and documentation reviews were effectively carried out.
- Undertook Deviation investigations ensuring adequate CAPA were put in place.
- Improved then managed the process used for recording and tracking outstanding actions resulting from validation and change control.

T**echnical Operator and Work-place Trainer** – GlaxoSmithKline (Dec 1997 – Jan 1999)

- Responsible for training new members of staff in the operation of line machinery and procedures.
- Managed the coordination of materials and staff in the respiratory product stream.
- Deputy line leader role.