CURRICULUM VITAE

Richard Andrews

MSc
EPIC Business Director
and Pharmaceutical Industry Consultant

Recognised Areas of Expertise

Accomplished quality professional with over 35 years experience working within Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) environments both in industry and for the UK medicines regulator (MHRA) where most recently as an Inspectorate Unit Manager he had overall responsibility for the GMP and GDP Inspectorates. Richard's 18 years experience at the MHRA spanned the licensing and inspection of pharmaceutical manufacturers and distributors both in the UK and overseas, the development and implementation of regulations and European guidelines relating to pharmaceutical manufacture and distribution, the management of risk and noncompliance in these sectors and collaboration with other European and International regulatory authorities. Prior to joining the MHRA Richard worked in the pharmaceutical industry for 17 years focusing mainly on the manufacture of bulk active pharmaceutical ingredients (API), gaining experience of process development and technical support and holding managerial positions in both Quality Assurance and Production.

- 18 years with the UK MHRA
- Excellent managerial and organisational skills. Responsible for managing over 40 GMP and GDP Inspectors and the GMP/GDP Inspection programme, whilst at MHRA
- Expert at performing GMP and GDP inspections across a wide variety of dosage forms and variety of organisations in the UK and overseas.
    - Trained by MHRA to conduct GMP inspections in the UK and Overseas of:
        - API manufacturers, importers and distributors
        - Sterile and Non-Sterile manufacturing sites
        - Commercial and NHS 'Specials' manufacturing units including Radiopharmacies

    - Sterile API manufacturers
    - Parallel importers
    - Contract laboratories
    - Gamma Irradiation sites
    - Medicinal gas manufacturers
    - Excipient manufacturers
    - Storage and distribution sites
- EMA/EU Expert Inspector
- EU and EMA Inspection preparation and remediation consultancy.
- Pharmaceutical Quality Management Systems
- Training in EU GMP Regulatory requirements

Current Employment

- Business Director for ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry

Career History

Inspectorate Unit Manager
Medicine and Healthcare Products Regulatory Agency Aug 14 – Mar 20

- Provided sound leadership to the GMP and GDP inspection teams.
- Liaised with other Unit Managers to provide Inspectorate wide support across all GXP disciplines and take forward the Inspectorate strategy.
- Provided expert knowledge on regulations, guidance and the inspection process.
- Managed over 40 staff with accountability for the decisions taken by the team – including those made during inspections, international meetings and conferences.
- Influenced at both a national and international level with regard to medicines regulations and inspection issues.
- Undertook high profile presentations on behalf of the Agency and Inspectorate.
- Chaired and participated in project groups involving UK and International Governments, regulators and industry stakeholders.
- Drafted briefings for Ministers and other regulatory bodies, to allow them to make informed decisions.
- Managed non-compliant manufacturers and distributors and the associated risk to public health.

Expert GMDP Inspector
Medicine and Healthcare Products Regulatory Agency Dec 12 – Jul 14

- Conducted high profile and sensitive projects nationally and internationally in order to establish an authoritative and definitive MHRA position
- Developed technical international inspectorate policy, in order to harmonise and improve standards.

- Monitored and evaluated global developments to identify opportunities and threats that could impinge on public health and the business of the MHRA.
- Drafted briefings for Ministers and other regulatory bodies, to allow them to make informed decisions.
- Maintained and developed systems across the Inspectorate Group to ensure that a uniform approach to technical activities was applied.
- Established, developed and motivated small teams of Inspectors to deliver assigned projects.
- Conducted inspections of drug substance and drug product manufacturers and wholesale distributors, particularly those of a complex or sensitive nature, to ensure regulatory compliance.
- Managed non-compliant manufacturers and distributors and the associated risk to public health.

Operations Manager / Senior GMP Inspector
Medicine and Healthcare Products Regulatory Agency Jul 04 – Nov 12

- Managed and supervised a team of GMP/GDP Inspectors in accordance with MHRA policies and procedures.
- Produced, agreed and delivered the annual inspection plans for the GDP and GMP Inspectorates.
- Planned and led recruitment campaigns and assessment centres to identify and employ new inspectors.
- Actively participated in the general management of the GMP/GDP Inspectorate including the management and monitoring of financial performance.
- Senior GMP Inspector responsibilities as below

Senior GMP Inspector
Medicine and Healthcare Products Regulatory Agency

- Planned, and conducted inspections of drug substance and drug product manufacturers and wholesale distributors, particularly those of a complex or sensitive nature, to ensure regulatory compliance.
- Provided considered technical and regulatory advice to stakeholders on behalf of the Inspectorate/Division, in response to more complex issues.
- Utilised inspection related skills, knowledge and experience to identify and evaluate potential risks to public health
- Provided training/mentoring/coaching to develop other Inspectors.
- Reviewed and developed Inspectorate policies/procedures and guidelines to improve processes.
- Reviewed the work of specified staff to ensure consistent and required standards were met.
- Represented the Agency at National and International levels to ensure that the Agencies policies/guidance were promulgated

GMP Inspector
Medicines Control Agency Oct 01 – Jul 04

- Planned, conducted and reported on assigned inspections.

- Provided appropriate technical and regulatory information and guidance to stakeholders to enable them to make informed decisions.
- Assessed technical information and enquiries received and provided stakeholders with a considered decision.
- Trained, supported and assessed new inspectors in specific tasks to enable them to meet the required standards.

Product Manager
BASF Plc Cramlington Division Jan 00 - Oct 01

- Built and led multi-functional product focused teams, co ordinating their work to achieve key strategic milestones.
- Developed and delivered defined product plans, giving clear direction to the Production Team as to priorities and customer requirements.
- Worked with other Product Managers and Production Management to optimise production activities in order to deliver the divisional strategy.
- Promoted a culture of continuous improvement and ensured that the Product Teams operate within the company quality, health, safety, and environmental management systems.
- Provided the key link to the divisions customers.
- Took full financial responsibility for the products in my portfolio.

Shift Production Manager
Knoll Pharmaceuticals Jun 98 - Dec 99

- Developed and agreed the weekly production plan.
- Identified and allocated resource to ensure achievement of the production plan.
- Undertook training needs analyses to identify skills gaps, arranging training as required.
- Conducted performance appraisals, highlighting and pursuing development opportunities.
- Resolved conflicts, driving change and improvements in line with business needs.
- Developed common systems and policies across the shift teams.

Quality Improvement Officer
Knoll Pharmaceuticals Mar 94 - May 98

- Prepared and managed the company internal audit schedule.
- Developed an internal auditor training course and trained 35 people.
- Conducted internal and external process and procedural audits.
- Managed and facilitated the resolution of all customer complaints, and non-conformances.
- Managed the company document control system.
- Assisted with the management of audits from customers, and external bodies.

Senior Product / Laboratory Supervisor
Boots Chemicals Jan 91 - Feb 94

- Provided technical and laboratory support to the bulk pharmaceutical production plants.

- Investigated production difficulties, advising and implementing remedial action.
- Analysed production data and prepared performance summaries and reports.
- Introduced process changes to optimise plant efficiency and throughput.
- Produced operating procedures, batch records, and cleaning procedures.
- Trained and supervised junior members of staff.
- Scheduled work within the development laboratory, making best use of available equipment and resource.

Laboratory Technician
Boots Chemicals Aug 84 - Dec 90

- Conducted laboratory, pilot plant and production scale studies, utilising factorial experimental design.

Qualifications

Masters Degree	Quality Management and Improvement
BSc Degree	Applied Chemistry (Final year not completed)
BTEC HNC	Chemistry
BTEC ONC	Chemistry