CURRICULUM VITAE

Alan Moon

BSc(Hons), CBiol MRSB
Pharmaceutical Industry Consultant

Recognised Areas of Expertise

An experienced quality professional with expertise in Good Manufacturing Practice (GMP) environments for multiple dosage forms. Experience gained from working both as a Lead Senior GMP Inspector with the Medicines and Healthcare products Regulatory Agency (MHRA) and in a variety of industry roles, primarily related to sterile and investigational medicinal products (IMPs), but also non-sterile dosage forms and unlicensed medicines. Conducted approximately 200 inspections both nationally and internationally while working at MHRA, including multiple overseas inspections of behalf of the European Medicines Agency (EMA). Supported legislation and guidance updates, most recently as a core member of the global working group for the revision to EU & PIC/S GMP Annex 1 for the manufacture of sterile medicinal products, and preparation and publication of UK guidance for the IMP import oversight process following the UK's exit from the EU. Excellent communication and organisational skills, with a passion for education; a self-motivated individual, ensuring knowledge and skills are maintained to current standards.

Involvement with Professional Associations/Societies

- Since 1999 – Royal Society of Biology – Member, Chartered Biologist

Current Employment

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

- Director of independent GMP consultancy from March 2023, providing services for multiple pharmaceutical companies

Career History

Mar 2023 – current
AM GMP Limited -Director

- Providing independent GMP consultancy to the pharmaceutical industry.

Jul 2013 – Mar 2023
MHRA-Lead Senior Inspector (from May 2022), Senior Inspector (from Jul 2017), GMDP Inspector (initially)

Lead Senior Inspector:

- Lead for the MHRA Compliance Management Team.
- Additional responsibility for technical training of Inspectors.

Senior Inspector:

- Technical lead for both sterile products and IMPs within the GMP Inspectorate.
- Principal UK representative on the global working group for the revision to EU & PIC/S GMP Annex 1 for the manufacture of sterile medicinal products.
- Member of the European working group for the revision to EU GMP Annex 13 for IMPs.
- Prepared UK guidance for industry and the framework for the oversight process for import of IMPs to Great Britain from approved countries following the UK's exit from the EU.
- Member of the working group for the review of UK legislation for clinical trials, including participation in industry stakeholder engagement meetings.
- Member of the Compliance Management Team.
- Regular participant in the Innovation Office advisory team.

Inspector:

- Conduct of GMDP inspections for UK and international manufacturing sites, including third country inspections on behalf of the European Medicines Agency (EMA).
- Accredited to inspect manufacturers of sterile and non-sterile products, IMP sites and manufacturers of unlicensed medicines.
- Supported and trained junior inspectors as a designated mentor.
- Technical lead for IMPs within the GMP Inspectorate.
- Member of MHRA GMP Inspectorate technical subgroups for sterile products and packaging.
- Presented at multiple conferences, including MHRA GMP symposia.

May 2008 – Jun 2013
Almac Clinical Services-Quality Compliance Manager

- Responsible for ensuring that finished Investigational Medicinal Products were suitable for QP certification and release to the Sponsor for use in clinical trials.
- Significant interaction with Sponsor companies to ensure compliance with CTA submissions for the supply chain and associated GMP history.
- Audits of global facilities against EU and international regulatory standards for the manufacture, packaging, and testing of medicinal products in support of import and QP certification.

Jan 2007 – Apr 2008
Patheon UK Limited-Product Quality Manager (Cephalosporins)

- Responsible for a cross-functional team incorporating batch record review and approval, deviation investigation / closeout and QP certification for release, 'line QA', QC analysis and environmental monitoring for aseptic powder filling and lyophilisation facilities producing commercial products.
- Reviewed and approved technical documentation including site SOPs, master batch records, Quality Agreements and both validation protocols and reports.
- Routine participation in cross-functional quality forums to monitor site compliance and improvement.

May 2005 – Jan 2007
Patheon UK Limited-Validation Manager (Requalification) and QA Project Support

- Ownership of both the site Validation Master Plan and Policy.
- Provision of advice and technical support across the site including both commercial and clinical trial manufacture.
- Site subject matter expert in relation to sterilisation and aseptic processing supporting Site Management and QPs.

May 2003 – May 2005
Patheon UK Limited-Assistant Manufacturing QA Manager

- Hosting and participation in regulatory inspections and client audits of the site and auditing of suppliers from both a microbiological control and validation perspective.
- Preparation and delivery of training courses on subjects such as "Validation of Aseptic Processes Using Media Simulations" and "Aseptic Manufacturing and Associated Good Manufacturing Practices" plus general GMP / Quality Systems.
- Significant involvement in the validation of new processes and products during introduction onto the site by the organisation's formulation and development function. This included process development, design of sterilisation cycles and aseptic process simulation design.

Oct 2001 – May 2003
Patheon UK Limited-Validation Section Head (Requalification)

- Managing a team of five to achieve validation compliance of all equipment and processes associated with aseptic product manufacture on site.
- Responsible for coordinating validation activities for eight cleanroom facilities incorporating twenty-one aseptic filling lines.
- Reclassification of cleanroom facilities. Particle monitoring, HEPA integrity testing (DOP); air flow velocity measurement; testing of sterile gas & air supplies for both viable and non-viable contamination.
- Steam sterilisation processes. Design and validation of specific loading patterns for [e.g.] aseptic filling line product contact parts, stoppers, terminal sterilisation of finished products.
- Dry heat sterilisation / depyrogenation processes. Validation of the different finished product container formats (ampoules/vials of different sizes) by thermal mapping and endotoxin destruction testing.
- Aseptic filling processes – media fill design and execution.

Jan 1999 – Oct 2001
Hoechst Marion Roussel / Patheon UK Limited-Manufacturing Quality Assurance Officer

- Auditing of aseptic and terminal sterilisation manufacturing facilities and processes including microbiology QC.
- Validation of equipment and processes including steam sterilisers, dry heat sterilisers and aseptic filling of sterile drug products.
- Daily review and approval of sterility assurance data including: autoclave and dry heat sterilisation cycles, filter integrity test data, physical monitoring data (particles, pressure, temperature and humidity) from aseptic and terminal sterilisation cleanrooms.
- Training of personnel working in cleanrooms (including but not limited to: general GMP / Quality Systems, basic Microbiology; procedures for aseptic gowning; cleanroom comportment).

Sep 1997 – Jan 1999
Hoechst Marion Roussel-Leading Process Technician

- Responsible for a team of three process technicians.
- Aseptic product manufacture, set-up and optimisation of aseptic filling lines (vial, ampoule, syringe and eye drop presentations – manufacturing and filling a wide range of sterile aqueous and suspension drug products).

Feb 1994 – Sep 1997
Hoechst Marion Roussel-Microbiology QC Technician to Senior Technician to Technical Officer

- Environmental monitoring of cleanrooms and water systems.
- Identification of organisms isolated from monitoring.
- Microbiological assays of antibiotic content of drug products.
- Endotoxin assays using gel clot and kinetic turbidimetric methods.

Education

1996 – 1999

- University of the West of England (part time study)
  BSc(Hons) Applied Biological Sciences

2003 – 2005

- Qualified Person training (David Begg Associates, all modules)