GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Jon Halling

BSc (Hons)
Senior Consultant, GxPAssure

Recognised Areas of Expertise:

- Over 30 years' experience in Pharmaceutical Quality Assurance across biologics, vaccines and ATMP modalities, including monoclonal antibodies, hormones, therapeutic proteins, live attenuated influenza viruses, and autologous/allogeneic/viral-vector therapies.
- Experience spans biologics including monoclonal antibodies, hormones, and therapeutic proteins, vaccine products including live attenuated monovalent influenza viruses, and ATMP modalities (autologous, allogeneic, viral-vector)
- Extensive background in both low-bioburden and aseptic GMP manufacturing within innovative in-house development and contract manufacturing organisations.
- Extensive Quality Assurance expertise including regulatory interactions with MHRA, FDA, PMDA, TGA and ANVISA.
- Background includes Quality Control, Analytical Development, Validation and Qualification of processes, utilities, cleanrooms, and equipment.
- Experienced in GMP training and capability development.
- Recognised for integrity, tenacity, honesty, empathy, and collaborative approach.
- Thrives in environments of complexity, novelty, and ambiguity, leading and empowering teams through unprecedented challenges.
- Confident communicator and regular ISPE conference speaker; passionate about sharing ideas, driving innovation, and problem-solving.
- Credible and effective at all organisational levels, known for solution-focused thinking and resourcefulness.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Managing Director of Quality working for Cell & Gene Therapy Catapult

Career History:

- **April 2022 - present: for Cell & Gene Therapy Catapult, Stevenage & Braintree site, UK – Managing Director of Quality**

  Role expanded to provide strategic management to both the Stevenage and Braintree Manufacturing and Innovation Centres, responsible for ~100 personnel across Quality Assurance, Quality Control, Skills & Training and Validation. Member of the Executive Management Committee for the organisation, reporting to the Chief Manufacturing Officer.

  - Developed & deployed from first principles, a unique (at the time) Quality Management System underpinning GMP compliance for a novel multi-modal, multi-tenant ATMP manufacturing centre. Achieved MHRA licensure (MIA & MIA(IMP)) within 22m of the facility build commencing.
  - Supported Business Development in onboarding a total of 9 ATMP therapy developers into the facility. Four were supported to independent licensure by MHRA (MIA(IMP)) while resident in the facility. One went on to offboard to their own local purpose-built facility and recently achieved BLA approval & US commercial launch.
  - Provided quality leadership & strategy in transitioning the Braintree Manufacturing Centre from an underinvested aging animal vaccine manufacturing site to an MHRA licensed Human ATMP Manufacturing and Innovation entre, achieving the MIA(IMP) in 18m with just a single 'Other' deficiency noted at inspection.
  - Personally hosted 15 MHRA inspections and the two Manufacturing & Innovation Centres since April 2016.

- **April 2016 – March 2022: for Cell & Gene Therapy Catapult, Stevenage & Braintree site, UK – Director of Quality**
  - Direct report to the Chief Manufacturing Officer and member of the Executive Management Team.
  - Working within a multi-disciplinary team to lead, design and oversee the quality aspects of a new Phase III/Commercial aseptic GMP manufacturing facility for cell and gene therapy.
  - Managing client interactions and secure new business.
  - Leading on regulatory agency and client inspections during the design/build/ validation phases plus operational phases of the centre.
  - Ensuring the QMS is fit for purpose for a multi-purpose, multi-client facility.
  - Leading on the integration of client assay and process documentation into the facility QMS as part of the Technology Transfer team.

- Ensuring quality aspects of the End-to-End Supply Chain are appropriate for supply of material from 'patient back to patient' Includes starting material procurement, supplier, logistics and storage audits.
- Providing general quality leadership for the facility operations (and entire Cell Therapy Catapult.).
- Ensuring the purchase, validation and operation of the facility systems and equipment meets regulatory requirements.
- Providing compliance support by giving advice and facilitating the escalation of compliance issues through the appropriate routes.
- Ensuring company inspection readiness and leading regulatory agency and client inspections.
- Key member of the Manufacturing Centre senior management team and major participant in delivering its commercial success and sustainability through business support, project ownership and strategic planning.

- **January 2011 – March 2016: MedImmune UK Ltd (A wholly owned subsidiary of AstraZeneca) – Director, Quality Assurance**
  - Overall responsibility for all QA activities on site.
  - Membership of the Site Leadership Team.
  - Defining and driving the strategic direction of the QA organisation and ensuring the correct alignment is maintained to support the ever-changing regulatory environment.
  - Ensuring changes to the site QA direction and function are driven through all parts of the business – The focus being that quality assurance is a key business process engaging all areas of the organisation and not a department.
  - Responsibility for the dissemination and subsequent implementation of any regulatory driven changes.
  - Responsibility for engendering the appropriate quality culture across the organisation (Quality @ Source, Quality on the Floor).
  - Responsibility for governance and oversight of the tactical management of separate Quality Assurance Departments:
  - Quality Systems
  - Quality Operations
  - QA Documentation
  - Line management responsibility for departmental managers and QPs.
  - Responsibility for managing the departmental budget
  - Membership of a global QA team responsible for driving cross-site harmonisation of quality management systems across the MedImmune/AZ enterprise
  - Ensuring the site is maintained in a state of perpetual inspection readiness.
  - Responsibility for lead hosting inspections from worldwide regulatory bodies (including FDA & MHRA).
  - Responsible for the final decision on all escalated quality issues.

- **March 2007 – December 2010: Lonza Biologics, Slough, UK – Head of Quality Assurance (Sept 2007-Dec 2010), Acting Head of Quality Assurance (Mar 2007-Sept 2007)**
    - Overall responsibility for all QA activities on site.
    - Membership of the Slough Site Leadership Team.
    - Defining and driving the strategic direction of the QA organisation
    - Responsibility for the dissemination and subsequent implementation of any regulatory driven changes.
    - Responsibility for engendering the appropriate quality culture across the organisation.
    - Responsibility for governance and oversight of the tactical management of seven separate Quality Assurance Departments:
        - QA Batch Review & Disposition
        - QA Documentation
        - QA Operations Compliance
        - QA Development Audit
        - QA Regulatory Affairs
        - QA Customer Support
        - QA Operational Excellence & Continuous Improvement
    - Line management responsibility for 11 direct reports including departmental managers, Principal QA Associates (QA technical experts) and QPs.
    - Responsibility for managing a departmental budget of >£3m.
    - Responsibility for chairing the site Quality Council
    - Membership of a global QA team responsible for driving cross-site harmonisation of quality management systems between facilities located in the UK, US, Spain, Switzerland and Singapore.
    - Customer facing responsibilities (Lonza's client base covers the spectrum from instantly familiar global organisations to small start-ups and everything in between):
        - Hosting client GMP & due diligence inspections supporting both existing and prospective clients
        - Hosting/supporting initial meetings with prospective new clients at a senior management level
        - Hosting/supporting client technical meetings providing QA and Regulatory input
        - Negotiation of Service Agreements and Quality Agreements
    - Ensuring the site is maintained in a state of perpetual inspection readiness.
    - Responsibility for lead hosting inspections from worldwide regulatory bodies (two successful MHRA pre-approval inspections Q2 2006 and a Japanese PMDA inspection Q4 2007. A successful US FDA pre-approval inspection Q1 2009 and two MHRA biennial inspections also Q1 2009).
    - Responsible for the final decision on all escalated quality issues.

- **July 2005 – March 2007: Lonza Biologics, Slough, UK – Quality Assurance Compliance Manager**
    - Departmental management responsibilities for the QA Compliance group (team of 12).
    - Responsibility for management of departmental budget.
    - Responsible for establishing and maintaining site key quality systems:
        - Deviation management
        - Change control management
        - Self-inspection management
        - Regulatory inspection preparation (lead project resulting in two successful MHRA inspections in 2006)
        - Vendor qualification
    - Responsible for provision of front-line support for Operations with a strong focus of 'in facility' support for manufacturing staff.
    - Generation, trending and reporting of key quality metrics.
    - Lead project to implement an electronic Quality Management System (QMS) for deviation, change control and audit management (TrackWise).
    - Responsible for establishing first QA operational excellence initiatives on site (6Sigma Green Belt trained).
    - Responsible for acting as a Lot Disposition Specialist for clinical and commercial APIs.
    - Responsible for managing the project that achieved site MHRA accreditation and the provision of the 1st MIA licence/GMP certification to be granted to the site.

- **May 2003 – July 2005: Lonza Biologics, Slough, UK – Senior Quality Assurance Associate**
- Responsibility for the provision of QA subject matter expertise in a variety of areas:
    - Lot review and lot disposition of commercial and clinical material
    - Deviation management and approval (chair of site Management Review Board responsible for oversight, governance and approval of all significant deviations)
    - Troubleshooting manufacturing issues
    - Change control management and approval (chair of site change control committee)
    - Vendor auditing
    - Negotiating client Quality Agreements
    - Approval of GMP documentation
    - Review and approve of CMC modules for regulatory dossiers
    - Representing QA/Regulatory for interdepartmental projects/meetings, customer projects/meetings, customer audits, regulatory audits and conferences/seminars.

- **August 2002 - May 2003: Lonza Biologics, Slough, UK – QA Lot Review Manager**
    - Departmental management responsibilities for the QA Lot Review group (team of 14).
    - Responsibility for management of departmental budget.
    - Responsibility for the co-ordination of all Lot review and disposition activities performed on site.

- Responsible for acting as a Lot Disposition Specialist for clinical and commercial APIs.

- **March 2001 – August 2002: Genzyme Diagnostics - Senior Quality Control Manager**

- **February 2000 – March 2001: Genzyme Diagnostics - Quality Control Laboratory Manager**

- **October 1998 – February 2000: Genzyme Diagnostics - Quality Control Supervisor, Diagnostic Intermediates**

- **July 1996 – June 1998: Hoechst Marrion Roussel - Scientific Officer, Finished Products, Quality Control**

- **October 1991 – June 1996: Pall Europe Ltd - Technical Support Engineer**

Education:

1990 – BSc (Hons) Applied Chemistry, Coventry University

2001 – Chartered Quality Institute Membership (Full CQI), Mid Kent College

2011 – Qualified Person Training (All Modules) RSSL, Reading