



GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Ian Ramsay

BSc (Hons)
Executive Consultant
Owner & Director, GxPAssure



Recognised Areas of Expertise:

- 8+ years experience as an independent consultant supporting pharmaceutical companies worldwide
- Supported multiple company EMA and US-FDA pre-approval readiness as well as SARS-CoV-2 vaccine readiness
- Expertise in regulatory inspection preparation, management and follow up
- Expertise in designing, supporting and overseeing remediation programmes following compliance/regulatory inspection
- Expert advice on current EU regulatory expectations and requirements
- Expertise in ATMPs (Cell & Gene) , Biosimilars, Vaccines and Sterile Manufacturing
- Able to offer technical and operational support to:
 - Inspection preparation (mock inspections & consulting)
 - Inspection remediation (responses, CAPA & independent oversight)
 - Training & Capability Building (specific quality, compliance & technical support and training)
 - Quality System & Quality improvement (systems designed to meet current expectations)
 - Microbiology & Sterility Assurance topics
 - Data Integrity controls, expectations and remediation
- Provided EU and US-FDA compliance support throughout his career:
 - Helped to host and coach FDA inspections in the UK, Belgium, Germany and Canada.
 - Supported routine FDA inspection prep and coaching for Influenza manufacture (yearly inspection at the time) and supported site readiness for 4 routine and 2 PAI inspections by FDA.
 - Experience in helping companies prepare for initial FDA pre-approval inspection worldwide.



- Experience in the following dose forms:
 - Sterile API manufacture for 1 year whilst in industry prior to MHRA
 - Oral Solid Dose (OSD) manufacture for 4 years whilst in industry prior to MHRA
 - Metered Dose, Dry Power Inhalers for 3 years whilst in industry prior to MHRA
 - Topical products (creams and ointments) for 1 year in industry prior to MHRA
 - Sterile vaccine and adjuvant manufacture for 2 years whilst in industry prior to MHRA
 - Combination products (pre-filled syringes) for 2 years whilst in industry prior to MHRA
 - Extensive experience in OSD, Topicals, Steriles and Biologics at MHRA for 4 years. Including Biosimilars, ATMPs and Unlicensed Specials.
 - Extensive experience in Biosimilars, ATMPs, Sterile Manufacturing and Cell & Gene Therapy
- LMLS Green Belt accredited and able to offer pragmatic, risk-based and efficient solutions to real-life quality and compliance issues.

Current Employment:

- June 2016 to Date
- Owner & Director of GxPAssure Ltd.
- Owner & Director of RamsayPharma Ltd.
- Independent GMP & GDP Quality consultant providing a range of services
- Supported multiple companies in improving quality & compliance across a wide range of areas including:
 - Proactive consultation & continuous improvement
 - Inspection Readiness
 - Remediation following regulatory action
 - Third Party auditing & supply chain management

Career History:

- **June 2012 – June 2016: Medicines & Healthcare Products Regulatory Agency (MHRA) – GMP & GDP Inspector**
 - Provide regulatory oversight to multiple companies worldwide
 - Lead complex regulatory inspections of manufacturing sites to assess quality & compliance status across a range of dose forms (non-sterile, sterile, biologic, ATMP & unlicensed)
 - Over 100 inspections led worldwide with a strong emphasis on third countries

- Plan, prepare, execute & manage on-site inspections- including follow up & reporting
 - Provide leadership and direction to the management of significant non-compliant sites- including liaison with international bodies (EMA, CHMP, IWG, DoH etc).
 - Led the management of several serious non-compliance cases through regulatory action
 - Contributed to active legal proceedings (court cases & enforcement action) and make recommendations to the Secretary of State regarding provisions of licence & supply.
 - Provide guidance and training for junior inspectors- including coaching, mentoring and structured training.
 - Provide guidance and direction to manufacturing sites under regulatory censure. Review and evaluate effectiveness of significant site remediation plans.
 - Contributed to the revision of EU-GMP guidance documents including Annex 16 and Annex 1.
 - Contributed to the creation & revision of non-statutory guidance documents including UK MHRA guide to unlicensed specials manufacture and associated Q&A documents.
 - Contributed to the MHRA strategy on Data Integrity. Trained as key subject matter expert in Data Integrity and inputted on the MHRA guidance and approach.
 - Act as subject matter expert within inspectorate team for serious non-compliance cases & microbiology. • Significant travel worldwide- approx. 50-60%
- **November 2010 – June 2012: GlaxoSmithKline Biologics (Belgium) – Senior Specialist Compliance Support- Global Quality Assurance**
 - Provide global quality support & oversight to multiple sites
 - Focus on flu vaccine franchise- Canada & Germany working directly with VP QA North America
 - Provide Inspection readiness support- including on-site coaching and mentoring during inspection and post inspection response & CAPA support.
 - Lead & direct regional strategy for quality system improvement in collaboration with regional VP. Identify strengths, weaknesses & opportunities and design and execute improvement plans.
 - Contribute to the development of global quality standards and policies.
 - Significant travel worldwide- approx. 40-50%

- **September 2007 – November 2010: GlaxoSmithKline UK – Quality Manager**
 - Provide front line QA support to multi-dose form commercial & new product introduction facility
 - Execution of delegated QP duties (including QA oversight of deviations, CAPA, Change control etc)
 - Undertook & completed study-guide training towards QP eligibility (viva not undertaken)
 - Management of complex quality incidents in support of QA Director.
 - Coaching, mentoring & training of junior QA staff and operations

- **September 2005 – September 2007: GlaxoSmithKline UK – Graduate Development Program**
 - Fast-track GSK Graduate Talent development program intended to give broad experience to future talent.
 - 1 Year at Ulverston supporting Bulk, Sterile API in microbiology
 - 1 year at Crawley supporting non-sterile oral solid dose and topical products in microbiology
 - Extensive training, development and skills development

Education:

2001 - 2004

- University of Manchester BSc(Hons) Microbiology