# CURRICULUM VITAE

## Ian Ramsay

**BSc (Hons)**

**Pharmaceutical Industry Consultant**

**Recognised Areas of Expertise**

- 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 prior to MHRA.
    - 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 adjutant 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 Unlicenced Specials.
- LMLS Green Belt accredited and able to offer pragmatic, risk-based and efficient solutions to real-life quality and compliance issues.

**Current Employment**

- Independent Consultant working on behalf of ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry
- Independent GMP & GDP Quality consultant providing a range of services from late May 2016
- Supported multiple companies in improving quality & compliance across a wide range of areas including:
    - Proactive consultation & continuous improvement
    - Remediation following regulatory action
    - Third Party auditing & supply chain management

**Career History**

- June 2012 – June 2016: Medicines & Healthcare Products Regulatory Agency – 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