CURRICULUM VITAE

Ian Ramsay

BSc (Hons)
Pharmaceutical Industry Consultant

Ian Ramsay is an independent pharmaceutical consultant with experience in the industry and as an MHRA inspector. He worked as a GMP and GDP inspector for the MHRA from 2012 to 2016 leading over 100 inspections worldwide with emphasis on third countries. He has experience in a range of dose forms (non-sterile, sterile, biologic, ATMP and unlicensed).
He 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.

Ian has significant experience in Quality Assurance and compliance.

Ian is LMLS Green Belt accredited and able to offer pragmatic, risk-based and efficient solutions to real-life quality and compliance issues.

Ian is eligible to act as an MHRA Compliance Monitor.

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

Qualifications

Degree in Biology
Member of the Royal Society of Biology