CURRICULUM VITAE

Darren Jones

BSc (Hons), CBiol, MRSB
Pharmaceutical Industry Consultant

Recognised Areas of Expertise

- Sterile and Aseptic manufacture
- Mock MHRA inspection readiness audits
- MHRA/EMA Inspection preparation and issue resolution
- Deemed eligible by MHRA to act as a Compliance Monitor in the MHRA Pilot
- Worldwide audits of sterile, aseptic and non-sterile (liquid and solid) dosage form manufacturing operations for both commercial and clinical trial use.
- Quality Management Systems
- Eligible Qualified Person
- Sterile products and auditor training

Current Employment

- Director of ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry

Involvement with Professional Associations/Societies

- Chartered Member of the Royal Society of Biology.
- IRCA Principal Auditor

Career History

- Dec 2014 to date: Director of Ex Pharmaceutical Inspectors Consortium Limited; a company specialising in the provision of former regulatory inspectors (GxP) to provide audits and consultancy tailored to the client's needs.
- Sept 2012 to date: Director of Pharmassure International Limited.
- 2008 – 2012: GMP Inspector, MHRA. Performing manufacturing, testing and importation site inspections of varied dosage forms in the UK and around the World.

- Accredited by MHRT to inspect: sterile, non-sterile, radiopharmaceutical, specials, importation, PLPI and Investigational Medicinal Products sites.
- Lectures presented to the PHSS and at the MHRA GMP symposium.

- 1990 -2008: AstraZeneca - a variety of roles including:
  - Global External sourcing QA Executive responsible for auditing, selecting and managing contract manufacturers of sterile, aseptic and non-sterile products throughout Europe; responsible for approving product to be placed on the market.
  - QA Associate: providing incident support for a large site manufacturing API, non-sterile solids and liquids, aseptic product. Primary contact / risk assessor for manufacturing and testing issues. 'High risk' investigations lead author. Eligible QP performing product release activities.
  - Global R&D QA Associate and QP (qualified under the transitional arrangements of the Clinical Trials Directive). Providing QA oversight of an IMP sterile and aseptic manufacturing unit and a non-sterile solid dose manufacturing unit. QP certification of clinical trials products including randomised and blinded materials.
  - QA Officer on various API plants (small scale automated, traditional manual plant, lab. scale API for a parenteral product). Product release disposition.
  - QA Officer of aseptic facilities manufacturing a complex, lyophilised, sustained release implant. Recommending batch disposition to the QPs, supplier auditing, deviation and complaint investigation and steriliser qualification assessment and approval.
  - Environmental Control Manager responsible for viable and non-viable monitoring programmes on aseptic manufacturing plants. Staff management, Water system (Purified and Water for Injection) owner. Aseptic practice observation and improvement, disinfection regime management.
  - QC Microbiology technician performing a range of microbial recovery, isolation and identification methods. Environmental monitoring, water testing, establishment of a satellite Laboratory within an Aseptic manufacturing plant