CURRICULUM VITAE

Darren Jones

BSc (Hons), CBiol, MRSB
Pharmaceutical Industry Consultant

Recognised Areas of Expertise

- Sterile and Aseptic manufacture
- MHRA Inspection preparation and issue resolution
- 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
- Audits of EU importation sites including 'virtual companies'.
- Eligible EU Qualified Person

Current Employment

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

Involvement with Professional Associations/Societies

- Member of the Society of Biology.

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 and Associate of NSF DBA.
- 2008 – 2012: GMP Inspector, MHRA. Performing manufacturing, testing and importation site inspections of varied dosage forms in the UK and around the World.
  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
- 1990 – 1990 Microbiological Laboratory Technician, Fisons Pharmaceuticals, performing media preparation, sterilisation and isolate identification activities