EPiC Auditors
ExPharmaceutical
Inspectors Consortium
Limited

CURRICULUM VITAE

Nicola Jones
BSc (Hons), MRSC
Pharmaceutical Industry Consultant

Recognised Areas of Expertise

- Eligible QP in accordance with Article 49 of 2001/83/EC
- Quality Assurance expert for Aseptic manufacture
- Experienced QA/QC Manager
- Extensive regulatory inspection preparation experience (MHRA/FDA)
- Pharmaceutical Quality System processes

Current Employment

- Quality Consultant and Operations Manager at EPIC Auditors Ltd.

Involvement with Professional Associations/Societies

- Member of the Royal Society of Chemistry

Career History

- Qualified person under the permanent provisions
- Previously at AstraZeneca (1985 – 2018) in a variety of roles including:
    - Global R&D Lead QA Advisor and QP: Providing QA oversight of Phase I/II&III IMP manufacture and testing on site and at global CMO's. QP certification of clinical trials products including randomised and blinded materials. QA Business Partner for Early Phase Chemical Development - primary QA contact for compliance related issues and quality improvement programmes using quality risk management principles.
    - Lead Auditor for Internal and External Audits: Area of expertise Laboratory Compliance and Pharmaceutical Quality Systems.
    - Quality Facilitator and Quality Assurance Officer for commercial aseptic facilities manufacturing a complex lyophilised sustained release implant: Batch review and recommendation of batch disposition to the QP's, primary QA contact for compliance issues and improvements, deviations and complaint approval using root cause tools

and quality risk management principles, sterilizer qualification review and approval, review and approval of Process Simulation Trials and environmental assessments.
- Business process owner for the Out of Specification process, Commercial Stability Programme and Product Quality Complaint process.
- QC Manager for finished product and API testing laboratories.
- Chemical analysis of raw materials, intermediates and finished products.