



DARREN JONES

NSF Independent Consultant

BSc (Hons), CBIol, MRSB

AREAS OF EXPERTISE

TRAINING

Investigational Medicinal Products
Quality Risk Management
Manufacturing Sterile/Aseptic Products
Audits and Self Inspections
GMP

AUDITING

Steriles - Aseptic and Terminal
Non-steriles
IMPs
'Virtual' Operations
Mock Regulatory Inspections
IRCA Principal Auditor

CONSULTANCY

Inspection Preparation and Remediation
Quality Systems Assessment and Improvement
Risk Management
Facility Design

KEY KNOWLEDGE AREAS

Product Experience
Oral Solid Dose
Sterile Products
Radiopharmaceuticals
Topicals
Non-sterile liquids
Specials
Primary and Secondary Packaging
Clinical Trials
APIs
Packaging Materials
Distributors

CONTACT

EMAIL:
darrenjones@nsf.org

EXPERIENCE

- > Worked as an MHRA GMP inspector for four years, inspecting a wide range of sites, including parallel importation and virtual sites
- > Worldwide audits/inspections of medicinal product dose forms and investigational medicinal products forms, approximately 500 performed
- > IRCA Principal Auditor
- > Experience of working as Global External Sourcing QA responsible for auditing, selecting and managing contract manufacturers of sterile, aseptic and non-sterile products throughout Europe
- > A transitional clinical trials QP, also eligible under the permanent provisions to act as a commercial QP
- > Extensive QA and production experience with sterile dosage forms including complex, lyophilised aseptics
- > Experienced in APIs and solid dosage forms
- > A microbiologist by training

KEY JOB ROLES

- > NSF Consultant since 2012
- > MHRA GMP inspector, 2008-2012
- > Astra Zeneca, 1990-2008
 - o Global External Sourcing QA Executive
 - o Global R&D QA Associate and QP
 - o QA Site support (API, aseptic manufacturing, non-sterile solids and liquids)
 - o QA Officer on API site
 - o QA Officer, aseptically manufactured lyophilisation
 - o Environmental Control Manager
 - o QC Microbiology Technician

EDUCATION

- > BSc (Hons) in Microbiology
- > Chartered Biologist
- > Member of the Royal Society of Biology
- > Eligible as a QP under the EU's permanent provisions

NSF INTERNATIONAL | PHARMACEUTICAL SERVICES

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF
T +44 (0) 1751 432 999 | E pharmamail@nsf.org | www.nsfpharma.org