RACHEL CARMICHAEL

NSF Executive Director

AREAS OF EXPERTISE

TRAINING

Data Integrity

EU Law and GMP Guidance

Pharmaceutical Quality System

Focus on Deviations, Change control, Document control

Good Inspection Management (GxP)

Quality Risk Management

IRCA Auditor and Self Inspection

AUDITING

Audits/mock inspections of medicinal product manufacturers, distributors

Pharmaceutical quality systems

Independent oversight of regulatory inspection CAPA, written responses and effectiveness checks

CONSULTANCY

Regulatory inspection management, from preparation to remediation programs

Development of quality systems

Company wide gap assessments

CONTACT

PHONE:
+44 1751 432999

WEBSITE:
www.nsfpharma.org

EMAIL:
rcarmichael@nsf.org

EXPERIENCE

- Ex-MHRA GMDP Inspector. Wide range of accreditations: Non-sterile production, importation, assembly – parallel importation, specials including NHS aseptic units, radiopharmacy, investigational medicinal products, Gamma irradiation, blood establishments, hospital blood banks, overseas plasma sites, Good Distribution Practice
- Experience of responding to regulatory inspections and tracking actions to completion. This has included responding to Inspection Action Group letters/non-conformance reports from EMA inspections
- In industry various responsibilities in Technical Support and subsequently Quality Assurance including:
  - Quality systems strategy and sustainability, corporate procedure compliance, deviations system, document control and site quality plan
  - Trainer for new production and inventory control system (SAP)
  - Dry products GMP compliance – tablets and capsules. Responsible for identification, analysis and resolution of issues impacting on quality and production and batch documentation improvements

KEY JOB ROLES

- NSF Director October 2015-present
- GMDP Inspector, MHRA, Dec 2004 – Sep 2015
- Various roles Eli Lilly and Co Ltd, Basingstoke, Jun 1996 – Dec 2004
  - Sep 2002 – Dec 2004 Project Leader, Quality Systems,
  - May 1999 – Sep 2002 Product Quality Specialist, Manufacturing and Packaging (QA)
  - Dec 1997 – May 1999 Continuous Improvement, Packaging
  - Jun 1996 – Dec 1997 Technical Specialist, Prozac
- Graduate trainee, Babcock King-Wilkinson (BK-W), Crawley May 1994 – Jun 1996

EDUCATION

- BSc (Hons) Biochemistry, 1988–1992 University of Dundee
  - 1989 to 1990, University of Illinois, Champagne-Urbana, Illinois, USA
- Masters degrees:
  - 1992–1993, Marketing, University of Strathclyde
  - 1999–2002, Industrial Pharmaceutical Studies, University of Brighton
- Eligible as an EU Qualified Person