Rachel Susan Carmichael

BSc, MSc, MRSB

Recognised Areas of Expertise

- Former MHRA GMDP Inspector
- Eligible to act as a Qualified Person under provisions of Directives 2001/83/EC and 2001/82/EC
- Qualified ISO 9000 Lead Auditor
- Manufacture and control of oral solid dosage forms

Current Employment

- NSF Health Sciences, Pharma Biotech Consulting

Involvement with Professional Associations/Societies

- Member of the Royal Society of Biology

Career History

Dec 2004 – Sep 2015 **Medicines and Healthcare Products Regulatory Agency – MHRA Centre GMP Inspector – GMDP Inspector**

- Inspections of pharmaceutical manufacturing and distribution organisations for compliance with the EU GMP/GDP requirements and associated quality standards for medicines and blood establishments in the UK and abroad

Jun 1996 – Dec 2004 **Eli Lilly and Co Ltd, Basingstoke**

Sep 2002 – Dec 2004 **Project Leader, Quality Systems, QA/Compliance Team**

- Responsible for the quality systems strategy and sustainability, corporate procedures, deviations, document control and site quality plan

May 1999 – Sep 2002 **Product Quality Specialist, Manufacturing and Packaging**

- Responsible for dry products GMP compliance – tablets and capsules
- Trainer for new production and inventory control system (SAP)
- Capacity planner for Quality team

Dec 1997 – May 1999 **Continuous Improvement, Packaging**

- Responsible for identification, analysis and resolution of issues impacting on quality and production

Jun 1996 – Dec 1997 **Technical Specialist, Prozac Production**

- Responsible for capsule production, quality and batch documentation issues

May 1994 – Jun 1996 **Babcock King-Wilkinson (BK-W), Crawley**
Company Trainee, Marketing, Fine Chemicals and Pharmaceuticals Team

- Formal training programme in process engineering including:
  - Civils, C&I, electrical, expediting, process, project planning, project management, purchasing, sales and marketing

Including placements at:

- Eli Lilly, Basingstoke, Glaxo Wellcome, Dartford and Glaxo, Ware
  [The latter two now known as GSK]

MHRA Additional Information

Accreditations:

- Good Distribution Practice
- Good Manufacturing Practice:

- Importation
- Non-sterile production
- Assembly – parallel importation
- Specials including NHS aseptic units
- Radiopharmacy
- Investigational medicinal products
- Gamma irradiation
- Blood establishments
- Hospital blood banks
- Overseas plasma sites

Major Presentations

2008 Multiple venues, UK

- Introduction to GMP for Hospital Blood Banks

2010 FDA/Xavier University, USA, Global Outsourcing Conference

- Global Outsourcing Compliance expectations and Initiatives

2014 Goa Pharmaceuticals Manufacturer's Association and Indian Pharmaceutical Association

Goa State Branch organised seminar, Hotel Mandovi, Panaji, Goa

- Data Integrity Issues - Understanding and Resolution

Head of Supplier Quality Shared Services, GSK, (2007 – 2010)

- Development of the GSK supplier quality management system
- Responsible for auditing and quality development of suppliers
- Management of critical issues, e.g. GMP certificate and EDQM certificate suspensions

Global Quality Director, Quality Strategy, UCB (2006 – 2007)

- Development of the UCB global quality policies and quality system
- Led quality culture programme for all levels of staff
- Responsible for regulatory intelligence and converting intelligence into action

Head of Inspectorate and Licensing, MHRA (2004 – 2006)

- Leadership of the GMP. GDP, GCP, GLP and PV Inspectorates
- Part of the IAG (Inspection Action Group) for GMP, GDP, GCP and PV
- Responsible for the management of Manufacturing Authorisations, e.g. granting, modifying and suspending
- Working with companies to bring them into compliance
- Participation in EU/global working parties, e.g. Inspectors Working Party, PIC/S
- Working with other inspectorates, e.g. US FDA on risk-based inspection process

Quality Director, GSK Crawley site (2002 – 2004)

- Leadership of the Quality function at a site manufacturing topicals, solid dose and parenteral products
- Management of regulatory inspections, e.g. MHRA, US FDA, ANVISA etc.

Earlier Career Roles (1978 – 2001)

- 10 years' experience in laboratory roles at a site manufacturing a broad range of products, e.g. solid dose, topicals, parenterals, APIs
- 10 years working as a QP and Head of QA for a manufacturing stream manufacturing solid dose and parenteral products
- 5 years' experience of management of supplier quality assurance, i.e. suppliers of materials to GSK sites and contract manufacturers supplying a wide-range of products
- Management of the GSK UK internal audit programme
- Management of GSK UK GMP training programme