GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Neil Raw

BSc (Hons), Msc, MBiol
Senior Consultant

Recognised Areas of Expertise:

- Expertise in MHRA and ISO 13485 inspection preparation, management and follow up
- Trained by MHRA to conduct GMP/GDP inspections of:
  - Sterile and non-sterile manufacturing sites.
  - IMP manufacturers
  - Commercial and NHS specials manufacturing units including radio pharmacies
  - Parallel importers
  - Contract laboratories.
  - Wholesale Dealers/Storage and distribution sites.
  - Blood banks and plasma collection sites.
- Expert advice on current EU/UK regulatory expectations and requirements
- Clinical trial manufacture/packaging and QP release
- Sterile, Aseptic, Biological and ATMP manufacture
- Combination Products and Medical Device GMP (ISO 13485 & 21 CFR part 820)
- Eligible EU Qualified Person – experience in certification for release of sterile and oral solid dose, marketed and clinical trials product
- Adept at presenting information and training to personnel in formal and informal settings.
- Over 25 years' experience in commercial/IMP pharmaceutical manufacturing with hands on experience in sterile liquids (aseptic/terminally sterilised), biologicals, tablets, capsules, dry powder inhalers, blow fill seal, liquids and medical devices

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Director of independent GMP consultancy providing services for multiple pharmaceutical companies

Career History:

- **Jan 2018 to Present Director of Raw Quality Associates – Pharmaceutical & Medical Device Quality Consultancy**
  - Performing supply chain/vendor audits of API, intermediate, ATMP and biological intermediates, finished product, QC labs and other service providers in the UK, Europe and US
  - Supporting preparation for regulatory audits through mock inspections, training and coaching.
  - Remediation of significant compliance issues resulting from regulatory audits.
  - Contract QP
  - Interim Head of Quality

- **Nov 2013 to Jan 2018 Vice President of Quality, VECTURA LTD**
  - Company specializing in the development and manufacture of small molecule and biological treatments, and delivery devices for respiratory diseases.
  - Responsible for the development and maintenance of the company's Quality Management System and all associated documentation, ensuring ongoing compliance with cGMP, GCP and relevant medical device requirements, (including ISO 13485, MDD/MDR), and all appropriate regulatory requirements.
  - Company expert to ensure awareness of emerging trends in quality and regulatory matters pertaining to quality.

- **Mar 2006 to Oct 2013 Medicines & Healthcare Products Regulatory Agency (MHRA), GMP Inspector**
  - Inspection of UK and third country manufacturing and importation sites to confirm compliance to EU GMP. Technical areas included steriles, non-sterile, investigational medicinal products, blood banks, plasma collection, specials, irradiation facilities, wholesale dealers & parallel imports.
  - Primary inspectorate representative in the Risk Based Inspection IT Project.
  - Lead inspector in a number of inspections for the EMA

- **Aug 2002 to Mar 2006 Quality Group Leader & QP, Eli Lilly**
  - Manager of a group of 10 QPs and quality specialists responsible for maintaining GMP compliance in a large secondary packaging department
  - Review and certification of >80 finished product batches/week (oral solid dose formulations).

- **Apr 1998 to Jul 2002 Microbiology QC/GMP Compliance Manager, Boehringer Ingelheim**
    - Manager of the Microbiology QC team of 5 microbiologists and then manager of a group of 12 quality specialists supporting manufacturing & packaging of sterile solutions for nebulisation.

- **Sep 1996 to Mar 1998 QA Associate, PPL Therapeutics**
    - Small biotechnology manufacturing site for phase I/II supplies – protein purification of transgenic ovine milk to recover AAT.
    - Primary QA resource on site, review of batch manufacturing and analytical records.

- **Oct 1994 to Sep 1996 Microbiologist, Rhone Poulenc Rorer**
    - Bench microbiologist performing routine environmental monitoring, bioburden analysis and sterility testing.

Education:

Sep 1989 – Jun 1993

- University of Nottingham BSc(Hons) Agriculture and Food Science with European Studies Specializing in Human Nutrition

Sep 1993 – Sep 1994

- University of Bradford MSc(Hons) Biomedical Sciences Specializing in Microbiology