GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

John Clarke

BSc (Hons), CChem, MRSC
Senior Consultant

Recognised Areas of Expertise:

- Over 35 years' experience in pharmaceutical manufacturing with experience in sterile liquids/powders, solid dose, metered dose inhalers, powder inhalers, creams/ointments, oral liquids, sterile APIs.
- Expert at performing GMP inspections across a wide variety of organisations in the UK and over overseas. Also, with inspectors from other EU regulatory agencies, US FDA, TGA and Chinese, Indian and Turkish authorities.
- Trained by MHRA to conduct GMP inspections in UK and Overseas of:
    - Sterile and Non-Sterile manufacturing sites.
    - IMP manufacturers
    - Sterile API manufacturers
    - Parallel importers
    - Contract laboratories.
    - Gamma Irradiations sites
    - ETO facilities
    - Commercial and NHS 'Specials' manufacturing units including Radiopharmacies
    - Storage and distribution sites.
- Eligible EU Qualified Person
- EU Expert Inspector

Current Employment:

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

Career History:

- **Aug 2017 to Present Director, Independent Pharmaceutical Consultant, Clarke Pharma Consulting**
    - Providing Quality & Compliance support to multiple companies worldwide

- **2003 to 2017 Medicines & Healthcare Products Regulatory Agency (MHRA), Senior GMP Inspector**
    - Lead GMP inspector for Steriles, Non-Sterile and 'Specials' manufacturing.
    - Setting inspectorate expectations and policy on Sterile and 'Specials' manufacture.
    - Co-author of 'Specials' Q&A document.
    - Represented MHRA at several symposia and training events e.g. MHRA GMP, ISPE, RQA and symposia in Goa India speaking on a variety of topics.
    - Trained GMP inspectors both "on the job" and in training sessions particularly on Sterile and 'Specials' product manufacture.

- **2001 to 2003 Medicines & Healthcare Products Regulatory Agency (MHRA), GMP Inspector**
    - Performed regulatory inspections of a great variety of licensed factories, contract laboratories, hospital manufacturing units, and warehouses.
    - Inspected a wide range of premises, equipment, processes and quality systems against the requirements of EU Rules and Guidance, and assessed any risk to the patient.
    - Inspection findings and their implications being routinely informed to senior management. Where necessary, serious findings were communicated to senior MHRA staff and recommendations made for formal regulatory action.

- **1986 to 2001 GlaxoSmithKline – a wide variety of roles including:**
    - Global Supply Dose Form Leader
    - Part of the corporate team responsible for the world-wide realignment of the global supply for sterile and non-sterile Cephalosporins.
    - QA manager Cephalosporins (sterile and non-sterile) and QP-QA manager responsible for a team of quality staff, including QPs, to assure the manufacture and release of sterile and non-sterile cephalosporins was in accordance with the requirements of the licences, EU GMP and internal quality policies, and then certified for release.
    - Operations Manager-QA Analytical Laboratories-responsible for managing the product release analytical laboratories for the Barnard Castle site covering sterile powders, sterile liquids, clean liquids, tablets, granules, creams and ointments

- Quality Compliance Audit Manager UK-responsible for a team of auditors routinely inspecting UK dose form facilities (sterile powders, sterile liquids, clean liquids, tablets, capsules, MDPIs, aerosols, suspensions, granules, micronized APIs, creams and ointments)
- Quality Compliance Auditor UK-inspection of UK dose form facilities
- Supplier Auditor UK-inspection of a range of primary and secondary packaging suppliers

- **1980 to 1986 Technical Executive, Drayton Castle Autoclaves**
  - Technical executive in the sale of autoclaves to the pharmaceutical and healthcare industries

Education:

1975 - 1978

- University of Salford BSc(Hons) Biochemistry

- MRSC
- CChem