CURRICULUM VITAE

John Clarke

BSc(Hons) CCHEM, MRSC
Pharmaceutical Industry Consultant

Recognised Areas of Expertise

- 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
        - Commercial and NHS 'Specials' manufacturing units including Radiopharmacies
        - Sterile API manufacturers
        - Parallel importers
        - Contract laboratories.
        - Gamma Irradiations sites
        - ETO facilities
        - Storage and distribution sites.
- Eligible EU Qualified Person
- EU Expert Inspector
- 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.

Current Employment

- Director of own pharmaceutical consultancy firm
- Consultant for ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry

Involvement with Professional Associations/Societies

- Member of the Royal Society of Chemistry.

Career history

- 2003 – 2017: Senior GMP Inspector, MHRA - As GMP Inspector (below) but also:
    - 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 – 2003: GMP Inspector, MHRA - performed regulatory inspections of a great variety of licenced 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 – 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

- 1980/82 – 1984/86: Drayton Castle Autoclaves - Technical executive in the sale of autoclaves to the pharmaceutical and healthcare industries