# CURRICULUM VITAE

## Richard Funnell

**MA, MRSC**
**Pharmaceutical Consultant**

**Recognised Areas of Expertise**

- Expert at performing GMP inspections and audits with experience of a wide variety of organisations across over 250 different sites in the UK and over thirty other countries. Also, with inspectors from other EU regulatory bodies and the US FDA.
    - Trained by MHRA to conduct GMP inspections of:
        - Sterile and non-sterile manufacturing sites.
        - IMP manufacturers
        - Hospital type specials manufacturing units including radio pharmacies and PET sites
        - Sterile API manufacturers
        - Parallel importers
        - Contract laboratories.
        - Storage and distribution sites.
        - Blood banks and plasma collection sites.

- Able to audit biologicals sites as well as traditional pharmaceutical operations; drug substance and drug product manufacturers.
- Effective at feeding back the results of audits and inspections and any implications to senior managers in verbal and written form.
- Adept at presenting information and training personnel in formal and informal settings.
- A reference point for other quality professionals particularly in the areas of GMP for IMP manufacture, steriles production, and also the role and responsibilities of QPs. Knowledge in these and other areas has been built up over many years addressing queries from within and without the MHRA.
- Accurate and consistent in the giving of advice and information in response to specific queries; bearing in mind relevant legislation, guidance and regulatory expectations.

- A background in the production and QA of sterile products, tablets and oral liquids.
- Qualified QP since 2002

**Current Employment**

- Consultant for ExPharmaceutical Inspectors Consortium Limited
- October 2014 to date: Independent Consultant providing quality and GMP related consultancy services to the sector both within the UK and overseas; particularly in the areas of:
    - Mock Pre and post inspection support
    - Quality system reviews
    - GMP training
    - Supplier selection.
    - Data integrity issues.

  Contracted by WHO to perform regulatory inspections.

**Career History**

**MHRA, Buckingham Palace Rd, London**
***Senior GMP Inspector*** ***2006 – 2014***
As GMP Inspector (below) but also:

- Setting inspectorate expectations and policy on QP issues, importation and steriles manufacture.
- Lead GMP inspector for IMP manufacture liaising with GCP and CT assessors and answering numerous queries.
- Represented MHRA at EMA and worked with EU colleagues (including work on the drafting group for the revised version of Annex 16).
- Represented MHRA at a wide variety of symposia and training events speaking on a variety of topics. (These included MHRA GMP and GCP symposia, RQA, DBA, QP Association, Pharmaceutical Quality Group; and a QbD webinar for de Montfort University.)
- Trained GMP and GCP colleagues both “on the job” and in training sessions particularly on sterile product manufacture, IMPs and QP related topics. (Held internal workshops including on interpretation of new Annex 16 and “QP discretion”.)

***GMP Inspector*** ***2003 - 2006***
Performed regulatory inspections of a great variety of licenced factories, contract laboratories, hospital manufacturing units, and warehouses. Compared a huge range of premises, equipment, processes and quality systems against the requirements of EU Rules and Guidance, and assessed any risk to patient. Fed back findings and their implications to senior management. Where necessary fed back serious findings to senior MHRA staff and made recommendations for formal regulatory action.

**Glaxo Smith Kline, Dartford**
***Sterile Products, Operational Quality Manager 2001 – 2003***

- Led a team of quality professionals including QPs which:
    - Assured that sterile products had been manufactured in accordance with the requirements of the licences, GMP and internal quality policies, and certified them for release
    - Promoted quality and compliance within the sterile product stream
    - Worked with other groups to investigate deviations and identify and implement corrective and preventive action
- Key participant in the setting of quality policy at the site level
- Acted as the prime QA management representative for the steriles stream

***Analytical Labs Operations Manage*** ***2000 – 2001***
Headed the analytical QC testing laboratories, responsible for a budget of £2.2M and 73 staff

***Non-Manufacturing QA Manager*** ***1999 – 2000***
Quality responsibility for all manufacturing and supply activities on site other than those in the immediate production areas, for instance warehousing and distribution, engineering, pack management, customer services, and IT. Main activities were the introduction of quality systems compliant with increasing regulatory expectations, and the making of recommendations on required standards of facilities, services and documentation.

**Glaxo Wellcome, Stockley Park**
***International Quality Executive*** ***1995 – 1999***
Part of a small team which:

- Set the Group Quality Policy standards required for facilities and manufacturing operations; provided guidance on meeting those standards; and audited GW manufacturing sites, contractors and suppliers across the world against them
- Held and presented international workshops on GMP, ISO9000 and Continuous Improvement
- Performed technical due diligence on potential acquisitions

**The Wellcome Foundation, Dartford**
***Compliance Auditor*** ***1993 – 1995***
Provided independent audits and made recommendations on acceptable processes, facilities and systems for factories across the world making Wellcome products and supplying raw materials. Acted as a focus for technical queries from overseas units and provided on-site technical support as required.

***Senior Production Technologist*** ***1991 – 1993***

Headed a team of four technologists in the Sterile Products Dept. Responsible for process improvements, resolution of technical difficulties, application of Total Quality and carrying out steriliser revalidation.

**Newfoundland, Canada**
***Voluntary Work*** ***1990 – 1991***
Whilst resident in Canada I carried out voluntary work in the local high school conducting science experiments and running a computing course.

**The Wellcome Foundation, Dartford**
***Production*** ***1985 – 1990***
A number of supervisory and technical support roles within tablets and liquids manufacturing