CURRICULUM VITAE

Ian Harwood

BSc (Hons), MRSB
Pharmaceutical Industry Consultant

Recognised Areas of Expertise

Ian Harwood is an independent pharmaceutical consultant with over 35 years experience of pharmaceutical manufacturing and GMP regulatory inspections. He has extensive experience in a wide range of pharmaceutical dosage forms and manufacturing processes including Terminal Sterilization and Aseptic manufacture (both large and small scale), lyophilization, biologicals and non-sterile manufacture of tablets, capsules creams and ointments.

As a Senior Inspector at the MHRA Ian was the lead for Unlicensed medicines. As part of this role he represented the Agency at industry and NHS groups including the NHS QA Committee and UK Radiopharmaceutical Group. He also gained significant experience of working with companies with complex compliance issues that had been referred to the Inspection Action Group and Compliance Management Teams.

Ian is eligible to act as an MHRA Compliance Monitor.

Ian also has significant experience of Senior QA management roles, including 14 years as a Qualified Person, gained in various pharmaceutical companies ranging from large multinational companies to small startups.

Involvement with Professional Associations/Societies

- Represented the MHRA at industry and NHS groups including the NHS QA Committee and UK Radiopharmaceutical Group.

Current Employment

- Independent Consultant working on behalf of ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry

- Director of Independent GMP Consultancy from March 2022, providing consultancy services for multiple pharmaceutical companies.

Career History

July 2014 to Feb 2022
GMP Inspector with Medicines and Healthcare products Regulatory Agency (MHRA).
Promoted to Senior Inspector May 2019.

May 2013 to June 2014
QA Operations Manager - BTG Ltd.

- Helping to introduce GMP compliant systems to obtain MIA and MS licences and FDA approval for a unique combination drug / device delivery system.

Nov 2009 to April 2013
Senior QA Manager / Lead Qualified Person - Patheon Ltd

- Releasing QP on the manufacturing and clinical trials licences. The site produced aseptically filled, terminally sterilized and non-sterile products for commercial release and clinical trials.

Oct 2001 to Oct 2009
Lead Qualified Person / Product Release Manager - Catalent Pharma Solutions.

- Named on MIA and MIA(IMP) licences in a site producing freeze dried tablets and soft gel capsules.

April1998 to Sep 2001
QA Manager - G&A Printers.

- A pharmaceutical printing firm which was working to GMP standards. Customers were major pharmaceutical companies worldwide.

Oct 1985 to March 1999
Wyeth Manufacturing Ltd - various roles in QA departments in a large multi-product company.

Qualifications

- BSc Hons Microbiology - Liverpool University (1985)
- PGDip Industrial Pharmaceutical Science - University of Brighton (1996)
- Eligible for Nomination as a Qualified Person under Permanent Provisions of EC Directive 2001/83 (2000)