CURRICULUM VITAE

Stephen Grayson

MSc,
Pharmaceutical Industry Consultant

An experienced GMP quality professional with a wide range of experience in the inspection and auditing of pharmaceutical and blood facilities.

Stephen has over 43 year's pharmaceutical industry experience in manufacture, packaging, auditing and inspection. He has completed more than 500 UK inspections and over 300 third country inspections. These have been completed solo, with MHRA colleagues, and with EU inspectors, USFDA, Health Canada, TGA and WHO including multi-Agency inspections with several sites having critical GMP failures which have been of international concern and been subject to regulatory action.

He has been regularly observed for development purposes by inspectors from the USA, Canada, Australia, India and China.

Stephen is MHRA trained and accredited in the following inspection categories:

- Collection, processing, testing and distribution of blood and blood components.
- Sterile and non-Sterile manufacturing sites (all dosage forms).
- NHS and commercial "Specials" manufacture, including sterile product.
- Sterilisation processes including irradiation, ethylene oxide, moist heat and dry heat.
- Sterile API manufacture
- Wholesale dealers (storage and distribution)
- EU Expert Inspector
- Eligible to be named as a MHRA Compliance Monitor

He has also conducted regulatory inspections and commercial corporate level audits of biological product manufacture, contract manufacturers, contract laboratories and suppliers.

Current Employment

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

Career History

2022 to date **Grayson Pharma Consultants Ltd.**

Independent consultant providing quality and GMP related consultancy services both in the UK and overseas. Principal areas:

Mock regulatory inspections; Pre and post regulatory inspection support; Inspection deficiency remediation support and oversight; Quality compliance and technical capability building; Third Party auditing.

Employer **Medicines and Healthcare Products Regulatory Agency (MHRA)**
2015 to 2022 Senior Medicines Inspector GMDP

Regulatory inspection of manufacturing and testing facilities within the UK and worldwide to assess compliance with UK and EU legislation. MHRA accredited in the inspection of Sterile, Non-Sterile, Unlicensed Medicines (Specials), Blood Components and Wholesale Dealers.
I have completed over 800 regulatory inspections, both in the UK and overseas including leading joint inspections with other EU competent authorities and other principal worldwide medicines inspectorates. In addition, I have periodically been observed on inspections for development purposes by inspectors from TGA, Chinese FDA, Health Canada, Indian FDA, USFDA.
Areas of responsibility held:

- MHRA Inspectorate lead for blood regulation; Blood Forum developer and administrator; Lead for Blood Compliance Reporting; Lead for EMA Inspectors Working Group on risk-based blood inspections; Haemovilgilance Expert Panel Member; Blood Consultative Committee Secretary; UK representative Council of Europe Competent Authorities for Blood
- MHRA Compliance Management Team (CMT) member
- MHRA GxP data integrity reference team member and core contributor to MHRA Data Integrity guidance
- MHRA Inspectorate lead for computerised systems; ISPE-GAMP EU Steering Committee Member and regulatory authority reviewer on several ISPE guidelines, including Data Integrity topics.

Employer **Blood Quality Consultants Ltd.**
2015 Owner / Director

Providing consultancy services and auditing of blood establishments and hospital blood banks.

Employer **AstraZeneca PLC**
2014 to 2015 Associate Director, Worldwide Audit Group

Corporate level auditing of AstraZeneca owned and Contract Manufacturing Organisation sites, including Biological, Sterile, Non-Sterile and API manufactures and suppliers.

Employer **Medicines and Healthcare Products Regulatory Agency (MHRA)**
2007 to 2014 Medicines Inspector, GMPD

One of a small team of inspectors with responsibility for inspecting and assuring compliance of pharmaceutical product manufacture, blood and blood component manufacture and testing facilities both within the UK and overseas.

Employer	**Bio Products Laboratory, Elstree, Hertfordshire**
2002 to 2007	Technical Services Manager: Process improvement and rectification.
1983 to 2002	Night Shift Manager; Packaging Manager; Production Manager; Supervisor

Education and Training

1998 to 2003	**M.Sc. Bioprocessing (**Distinction**):**	University College London
1995	**M.Inst.Pack (Dip):**	Thames Valley University
1980 to 1982	**B.Sc. Biological Sciences:**	The Polytechnic, Wolverhampton
1978 to 1980	**HND Applied Biology:**	The Polytechnic, Wolverhampton.