GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Ian Thrussell

MA Hons (Chemistry)
Senior Consultant

Recognised Areas of Expertise:

Highly experienced GMP inspector with specialist expertise in sterile product manufacturing, including biologics, vaccines, and the development of regulatory guidance. Since 2017, he has provided extensive consultancy support in GMP implementation and inspection, as well as regulatory systems strengthening working with National Medicines Regulatory Agencies, WHO, PATH, and the Gates Foundation. From October 2020 to April 2022, Ian was based in China during the pandemic, delivering GMP and regulatory consultancy to organisations involved in the manufacture and global supply of COVID-19 vaccines, monoclonal antibodies, and selected other vaccines. He is currently based in the UK, Geneva and Shanghai, continuing to support NGOs, WHO, PATH, and Gates projects with biologics manufacturers through both remote and on-site engagement. A passionate advocate for assuring “Quality medicines for all’.

Key skills;

- Good Manufacturing Practice (GMP)
- Regulatory affairs
- Head of inspections for Pre-qualification of essential medicines and Vaccines at WHO, based in Geneva.
- Expert GMP inspector with U.K. MHRA.
- UK(Human) representative for MHRA UK GMP Inspectorate at EMEA
- Member of ICH Q10 EWG for the European Commission team.
- Specialties: Sterile and Biologics Product GMP advice, gap assessment and Inspections.
- Languages: native English and professional working French

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Independent advisor to the Gates Foundation and PATH
- Independent advisor to the World Health Organisation (WHO)

Career History:

- **December 2016 – Present: Park Pharma Compliance Solutions - Regulatory and GMP Consultant**
  - Established Park Pharma Compliance Solutions providing independent GMP and Regulatory Science Consulting
  - As a former staff member of WHO Prequalification, continuing to support WHO PQT as an independent self-employed consultant, temporary advisor, and external inspector. Conducting regular inspections internationally, with particular focus on China and India.
  - Support for WHO RSS Regulatory Strengthening assessments and regional WHO/Country Office initiatives and trainings primarily with Chinese NMPA/CFDI and Provincial FDAs, India CDSCO, Egyptian Medicines Authority and in several Sub- Saharan counties including Nigeria, Kenya, Botswana, Uganda and Tanzania.
  - Appointed as an external GMP inspector and trainer and advisor to the Maltese Medicines Authority. Providing Consultant and Temporary Advisor basis for sterile products inspections and training support.
  - Working with Bill and Melinda Gates Foundation project in China, on Provincial and National GMP System Gap Finding and National System Strengthening.
  - External Expert and GMP course trainer for IPEM, Peking University in Beijing and Shanghai.

- **October 2011 – November 2016: World Health Organisation Prequalification Group – Inspections Team**

- **March 2015 – DECEMBER Head of Inspections – All sectors**
  - Head of Inspections for APIs, Medicines, Vaccines, Medical Devices and Diagnostics and Vector PQ programmes. Fixed term position with WHO.
  - Management of international risk based inspection programme, staff and budget.
  - Negotiation and reporting on key performance indicators to key doners e.g. Gates Foundation
  - GMP expert inspector for WHO Prequalification
  - Representation of PQT interests at WHO Expert committees for the elaboration of international guidance for pharmaceuticals and biological products.
  - Advocated successfully for WHO co-operation in Sterile Annex Revision.
  - Representation of WHO at PIC/s Committee of Officials.

- **January 2014 – November 2015: World Health Organisation – Expert Inspector and GMP Technical lead – Consolidated PQT team.**
    - Fixed term position with WHO as Expert Inspector and GMP Lead with in the newly restructured and consolidated Prequalification Team (Previously Vaccines and Devices and Diagnostics. Were in different WHO Directorates).
    - GMP expert inspector for WHO Prequalification
    - Representation of PQT interests at WHO Expert committees for the elaboration of international guidance for pharmaceuticals and biological products.
    - Representation of WHO at PIC/s Committee of Officials.
    - Identification and assessment of rotational Inspector fellowship posts from WHO member states
    - Lead for GMP and Inspection at annual WHO stakeholders meeting in Copenhagen.

- **January 2014 – November 2015: World Health Organisation – Expert Inspector and GMP Technical lead – Consolidated PQT team.**
    - Appointed to fixed term position with WHO as Expert Inspector with in the newly restructured Prequalification Team
    - GMP expert inspector for WHO Prequalification
    - Review and approval of inspection reports of staff inspectors
    - Representation of PQT interests at WHO Expert committees for the elaboration of international guidance for pharmaceuticals and biological products.
    - Representation of WHO at PIC/s Committee of Officials.
    - Leading on the most complex of inspections
    - Training staff and co-inspectors on WHO inspections especially for sterile products.
    - Representation of WHO GMP matters at international meetings and member state trainings
    - Identification and assessment of rotational Inspector fellowship posts from WHO member states
    - Liaison with collaborating international NGOs including UNICEF, UNFPA, Gobal Fund, ICRC, MSF.
    - Leading trainings for Member State GMP Inspectorates
    - Audit of staff inspectors

- **October 2011 – December 2013 World Health Organisation Prequalification Group Head of Inspections – Pharmaceuticals Inspections Team**
    - Fixed term temporary position with WHO as Head of Inspections Prequalification Team Pharmaceuticals Inspections Team (At this time inspections of Vaccines was managed in a different unit.
    - WHO Staff position (On secondment from MHRA) for two years on a Temporary appointment as Head of Inspections.

- Management of international risk-based inspection programme, staff and budget.
- Leading on the most complex of inspections and handling of appeals and complaints
- Training staff and co-inspectors on WHO inspections especially for sterile products.
- Representation of WHO GMP matters at international meetings and member state trainings GMP Inspection lead on digitalisation of WHO work flows and document management of new software to manage the assessment and management of all WHO dossiers. And inspections.

- **December 2006 – October 2011: MHRA – UK Human Expert at EMEA GMP GDP IWG**
  - UK (Human) representative at EMEA GMP GDP Inspectors Working Group(June 2006 – 2010) Inspectorate representative on the Chemistry and Pharmacy Sub-committee of UK CSM
  - EU Regulatory Expert appointed by European Commission to the ICH Q10 EWG (2006 – 2008).
  - Very experienced GMP inspector with specialist knowledge of sterile products manufacture.
  - Performance of the most complex and sensitive of MHRA inspections e.g. Chiron Vaccines
  - Member of the Inspection Action Group recommending regulatory actions against inspected companies and licence holders.
  - Support to WHO on selected projects as a temporary advisor.
  - Training review of new inspectors and audit of staff inspectors.
  - Rapporteur for the assessment of Badam POM, Indonesian GMP Inspectorate for PICs Membership.

- **April 1994 – October 2011: MHRA – Expert GMP Inspector**
  - Very experienced GMP inspector with specialist knowledge of sterile products manufacture.
  - Over 14 years with MCA/MHRA has over 1500 days on GMP inspections on a wide range of sites in the UK and overseas.
  - Over 120 weeks of overseas inspection experience in Puerto Rico, Japan, India, USA, China, Poland, Romania, Australia, Italy, the majority as lead inspector.
  - Co-rapporteur (with Sweden) for the audit of the GMP Inspectorates Lithuanian Human and Veterinary Agencies for implementation EU GMP and Licensing legislation.
  - GMP Trainer for Maltese and Latvian Agencies prior to accession to the EU. Lead Auditor ISO 9000 – 2000.

- **1989 – 1994: Fresenius Kabi – Quality Manager**
  - Responsible for the Quality and site Regulatory Compliance for all operations of the Group in the UK.
  - Qualified Person and Quality Manager for manufacturing of LVP products

- **1984 – 1988: Boots – Sterile Products TDG Manager**
  - Process development, trouble shooting and validation of large and small volume parenteral products at the Boots Beeston site.
  - Technical transfer and validation of LVP operations to the Basingstoke site.

- **1977 – 1984: Boots Healthcare International – Senior Developer**
  - Process development, trouble shooting and validation of new and upgraded OSD operations

Education:

- 1973 - 1977: Exeter College, Oxford – Master of Arts (MA) Chemistry
- 1973 – 1977: University of Oxford – MA Hons, Chemistry
- 2005: Royal Society of Chemistry – Fellow and Chartered Chemist, Pharmaceutical Sciences