GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Ewan Norton

BSc (Hons)
Senior Consultant, GxPAssure

Recognised Areas of Expertise:

- 31 years' experience within the pharmaceutical industry
- MHRA GMDP inspector for over twelve (12) years
- Held position of Lead Senior Inspector for approximately 5 years
- MHRA accredited inspector for:
  - Non-Steriles
  - APIs
  - Unlicensed Medicines (Specials)
  - Importation
  - Parallel Importation (PLPI)
  - Investigational Medicinal Product (IMP) manufacturers
  - Blood Banks
  - Blood Establishments
  - Herbals (including cannabis sites)
  - Good Distribution Practices (GDP)
- Regulatory Inspection experience:
  - Carried out over 350 regulatory inspections
  - Led MHRA inspections with up to four accredited inspectors and enforcement staff
  - Led EMA inspections
  - Led joint inspections with other regulatory authorities (WHO and USFDA)
  - Specialised in the inspection of sites with serious compliance issues
  - Whilst in industry was main host for regulatory inspections (MHRA and USFDA)
- Key MHRA Roles:
  - GMP representative on MHRA Inspection Action Group (IAG) which determines if any regulatory action to be taken on companies with serious compliance issues
  - Development and oversight of the 'Compliance Monitoring' process
  - Creation of the MHRA 'Remote inspection' process
  - Member of the EMA Continuous Manufacturing team (PAT) prior to Brexit

    - On the PIC/S drafting group for issued 'Remote Assessment' guideline
    - Developed and trained all GMP inspectors on PQS data analysis process
    - Mentored several GMDP inspectors
- Widely regarded as an excellent presenter and has presented on behalf of the MHRA frequently in the UK, Europe, India, and China
- Nineteen (19) years' pharmaceutical industry experience prior to joining the MHRA:
    - Worked in both large and small pharma companies
    - Managed a Quality Unit of over 35 people
    - Hands-on manufacturing experience of APIs, Cytotoxic products, and Biologic intermediate products (Antibody-Drug Conjugates (ADCs)
    - Main host for FDA and MHRA regulatory inspections

Current Employment:

- **Sep 2025 to Date**
    - Senior Consultant, GxPAssure Ltd.
    - Owner & Director of NortonGMP Ltd.
    - Independent GMP & GDP Quality consultant providing a range of services
    - Supported multiple companies in improving quality & compliance across a wide range of areas including:
        - Proactive consultation & continuous improvement
        - Inspection Readiness
        - Remediation following regulatory action
        - Third Party auditing & supply chain management

Career History:

- **Jan 2013 – Sep 2025: Medicines & Healthcare Products Regulatory Agency (MHRA) – Lead Senior GMDP Inspector**
    - Carried out regulatory inspections in the UK, and overseas, on behalf of the MHRA
        - Lead Senior Inspector since November 2020, specialising in inspections of sites with poor compliance histories
        - Technical lead at various points for APIs, Non-Steriles, Starting Materials, Herbals (including cannabis), and Continuous Manufacturing
        - Accredited MHRA inspector for; API, Non-Steriles, Importation, Parallel Importation (PLPI), Investigational Medicinal Products (IMPs), Blood Banks, Blood Establishments, Herbals, and Good Distribution Practice (GDP)
        - Previously led, and been part of, European Medicines Agency (EMA) inspection teams
    - Lead GMP representative on the Inspection Action Group (IAG) for three years
        - IAG is the formal MHRA body making decisions on the requirement for regulatory action against companies

    - Designed and implemented the MHRA 'Compliance Monitoring' process, then trained all fifty Compliance Monitors
    - Developed the MHRA remote inspection process in response to the Covid pandemic and trained all inspectors on the process
    - Presented at seven (7) MHRA Symposia, receiving 'excellent' feedback ratings from approximately 90% of delegates
    - Presented on behalf of the MHRA at conferences in the UK, India, China, and across Europe
        - Conferences in India and China were in collaboration with National and International regulatory authorities
    - Authored MHRA blogs on a range of subjects including API supply chains, Cannabis inspection process, & Compliance Monitoring process
    - On the PIC/S drafting group that authored Guidance and Aide Memoire documents on 'Remote Assessments' (PI 056-1 and PI 057-1)
    - GMP representative on the EMA Continuous Manufacturing team (PAT team)
    - Generated training materials and delivered training to MHRA and EMA GMDP inspectors on a range of topics, including supply chain risks, PQS data analysis, how to write inspection deficiencies, inspection of herbals, and continuous manufacturing
- **September 2002 – December 2012: Various Positions including Quality Unit (QU) Manager, Piramal Healthcare (formerly Avecia), Grangemouth**
    - Managed the QA, QMS, and QC departments (~35 employees)
    - Responsibility for all aspects of cGMP compliance at the site
    - Site lead host for three MHRA and two USFDA inspections (including a Pre-Approval Inspection (PAI) for the first Antibody Drug Conjugate (ADC) to be launched in the US)
    - Member of Corporate Quality Assurance (CQA) auditing team
    - QA released batches of APIs and ADCs
    - Generated, reviewed, and executed equipment qualification documentation
- **January 2001 – August 2002: Regulatory Compliance Executive, GlaxoSmithKline, Montrose**
    - Regulatory responsibility for a portfolio of seven APIs
    - Generated submissions for Certificates of Suitability of the European Pharmacopoeia (CEP)
    - Managed the elaboration of an EP monograph for an API
- **January 1999 – January 2001: New Product Introduction Team Manager, GlaxoWellcome, Montrose**
    - Responsible for team of manufacturing chemists introducing new APIs to site, including feasibility studies, generation of manufacturing batch records and hazard studies
    - Managed and mentored ten members of staff

- **April 1996 – January 1999: New Product Introduction Development Chemist, GlaxoWellcome, Montrose**
    - Oversaw scale-up and validation batch manufacture of a range of APIs
    - Worked on a project to outsource all seven stages of an API to a third-party site
    - Seconded to the GlaxoWellcome Dartford site for eight months to gain experience of the process and introduce improvements
    - Oversaw the technical, cGMP, and regulatory aspects of manufacture whilst based at the third-party receiving site
- **August 1994 – March 1996: Research and Development Chemist, Wellcome Foundation, Beckenham, Kent**
    - Research chemist working on the development of new drug substances using combinatorial chemistry

Education:

- 1990-94 BSc Hons. (2:1) in Chemistry, Edinburgh University
- 2013-23 MHRA Symposia (wrote and presented sessions at seven symposia)
- 2013 Tabletting Technology, Royal Pharmaceutical Society
- 2014 Data Integrity Training, Monica Cahilly, Green Mountain QA
- 2015 APIC/CEFIC API European Conference, Amsterdam (wrote/delivered session)
- 2016 Inspectorates of the Future, Manchester UK, PIC/S training
- 2016 A-Z of Sterile Products Manufacturing, NSF
- 2017 USFDA Continuous Manufacturing Training
- 2017 EMA New Inspector's Training (wrote and delivered two sessions)
- 2018 Health Based Exposure Limit (HBEL) EMA Training
- 2019 Data Integrity Training, Peter Baker
- 2023 NSF Quality Control Testing QP Module Training
- 2023 Data Integrity Training 'The Future', Peter Baker
- 2021-24 MHRA Inspector Academy training modules: Sterile Products, Unlicensed Medicines, Non-Sterile dosage forms, API (wrote/presented), Herbals (wrote/presented), Unlicensed medicines, Investigational Medicinal Products (
- 2025 Artificial Intelligence (AI) in Pharma Course, Martin Lush
  Investigational Medicinal Products, QP Module (Remote), NSF
  PIC/S Continuous Manufacturing training for inspectors (led by Health Canada)
  NSF GMP for Clinical Trials Manufacture and Supply