GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Dearbhla Byrne

BSc (Hons)
Senior Consultant, GxPAssure

Recognised Areas of Expertise:

- Over 20 years of experience in Pharma/Biopharma across Quality Assurance, QC and Validation.
- Former GMP Inspector with Ireland's HPRA, leading international inspections for HPRA and EMA as a registered biotechnology expert.
- Extensive facility inspection expertise: sterile/non-sterile, biotechnology, IMPs, ATMPs and contract laboratories, including;
    - Inspection readiness
    - Inspection support
    - Compliance risk reduction
    - Licence applications
    - Auditing
    - Contamination control strategies
    - Quality system development
    - QP batch disposition
    - Validation of process, equipment and facilities, QC activities
- Holds a BSc (Hons) in Biochemistry, an H. Dip in Biotechnology, and an H. Dip in Pharmaceutical Manufacturing Technology (QP eligible in the EU).

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Principle Consultant, Owner/Director – Outside The Box cGxP Consulting Ltd

Career History:

- **May 2019 – Present: Outside The Box cGxP Consulting Ltd - Principle Consultant, Owner/Director**
    - GMP/GxP Consultant to the Pharmaceutical/Biopharmaceutical and Advance Therapy Medicinal Products industries.
    - Consulting services provided:
        - Inspection readiness – conducting mock inspections of facilities and screening of personnel
        - Inspection support and remediation
        - Development, implementation and enhancement of quality risk management systems
        - Compilation and implementation of contamination control strategies
        - Preparation and review of manufacturing licence applications and variations
        - Development/enhancement of robust Quality Systems management processes
        - Conduction of internal and external audits
        - Configuration and implementation of supply chain strategies
        - Contract QP
        - GMP training on a wide range of topics e.g. Data integrity, QRM, Quality Systems

- **January 2016 – May 2019: Health Products Regulatory Authority, Dublin 2 - GMP Inspector**
    - GMP Inspector for the biotechnology, ATMP and sterile manufacturing sectors. Responsibilities included:
        - Planning and execution of regulatory inspections of sterile pharmaceutical, biotechnology and ATMP facilities nationally, and internationally on behalf of the EMA.
        - Review and approval of variations to manufacturing licenses for human, veterinary and investigational medicinal products.
        - Responding to technical queries from companies as they arose.
        - Collaborating with colleagues on development of industry guidance.
        - Providing updates to industry and academic stakeholders via presentations, workshops and communications.

- **May 2015 – December 2015: Fannin Compounding Ltd., 18 - QA Consultant**
    - Responsibilities included:
        - QP disposition of sterile compounded products for same day nationwide distribution.

        - Alignment of quality systems to fit the compounding manufacturing business model.

- **August 2014 – April 2015: Sona Nutrition Ltd., Unit 3 Westgate Business Park, Dublin 24 - QA Manager/QP**
    - Part-time position managing the Quality Assurance systems and Regulatory Affairs requirements for both Food Supplement and Traditional Herbal Medicinal products.

- **September 2012 – July 2014: Amgen Ireland Ltd., Co. Dublin - Quality Systems**
    - Responsibilities included management of four direct reports, coordination of site quality systems teams, integration of Amgen Dun Laoghaire into the global networks for each of the Quality Systems and alignment with Amgen corporate standards.

- **October 2008 – August 2012: Helsinn Birex Pharmaceuticals Ltd., Dublin 15 - Qualified Person**

- **April 2008 – October 2008: Helsinn Birex Pharmaceuticals Ltd., Dublin 15 - QC Manager (maternity cover)/Trainee QP**

- **June 2007 – March 2008: Career break – taken to care for daughter at home and to complete the QP course.**

- **March 2004 – June 2007: Schering Plough (Bray) Ltd., Co. Wicklow - Senior Validation Scientist**

- **July 2000 – February 2004: Organon Ireland Ltd., Co. Dublin - Validation Chemist**

- **August 1998 – July 2000: Glaxo Wellcome, Montrose, Scotland - Laboratory Analyst**

- **April 1998 – August 1998: Organon Ireland Ltd., Co. Dublin - Laboratory Analyst**

- **July 1997 – December 1997: - The Netherlands Institute for Dairy Research (NIZO), The Netherlands - Research associate**

Education:

- 2005 – 2007: Trinity College Dublin – P. Grad. Dip. Pharmaceutical Manufacturing Technology (QP Qualification)
- 2001 – 2002: DIT Bolton Street – S.M.E. Certification in Manufacturing Engineering
- 1996 – 1997: University College Cork - Postgraduate Diploma in Biotechnology
- 1992 – 1996: University College Dublin – BSc (Hons) Biochemistry