GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Nina Bjork

MSc
Senior Consultant, GxPAssure

Recognised Areas of Expertise:

Experienced executive in the regulated product industry, specializing in startup and turnaround operations across Manufacturing, Quality, Supply Chain, Production, and Compliance. Proficient in problem-solving, organizational development, effective communication, and leadership, with a focus on aligning multi-site operations with organizational goals to enhance value.

Native Icelandic speaker with professional working proficiency in English, and limited working proficiency in Danish, Swedish, and Norwegian.

- Quality expert in biotechnology (MABs, Peptides, ATMPs), pharmaceutical, and medical device
- GMP- phase appropriate compliance programs establishment (Commercial QMS, Sponsor CTR / GCP QMS), including, Process Verification / Validation, IPC, Stability strategy, Material controls, Container closure controls, Contamination Control strategy, Environmental monitoring, Facility management, calibration, maintenance, etc.
- Quality System overhaul – System Maturity Model (Deviation, CAPA, Change Control, Training, Self-inspections, Recall, etc.)
- An expert at Pre-approval / Mock Inspection for inspection readiness
- GxP compliance audits for commercial / clinical manufacturing sites, packaging material suppliers, raw material suppliers, and contract laboratories
- Regulatory Application support and review (Dossier, BLA, IND, IMPD, etc.)
- CMC support and Pivotal readiness program
- MIA / WDA applications
- New product lunch
- Change Agent
- EU QP product release / disposition (IMPs / Commercial)

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- VP of Quality and QP, Founder and Owner of INGUZPHARMA B.V.

Career History:

- **2019 - Present: INGUZPharma B.V. – VP of Quality and QP, Founder and Owner**
  - Quality Consulting in EU/US GMP, Quality System set-up, license support and applications, QP release, audits, inspection preparation (PAI), remediations.
  - Provide GMP, QMS, and RA consulting to the pharmaceutical, biological, and medical device industries (scale-up, ballroom concept, development issues, Quality System overhaul, etc.)
  - EU QP product release (Biologics, ATMPs, small molecules)
  - License applications with Health Authorities, MIA, API registration, WDA, etc.
  - Mock Inspection / Pre-Approval Inspection and routine Regulatory Authority inspections (FDA, EU authorities, PDMA, Brazil, Turkey, Canada etc.).
  - Performing audits / evaluation for:
    - Drug Substance – Active Pharmaceutical Ingredient (Chemical and biologics)
    - Drug Product – Sterile, aseptic, lyophilized filling, non-sterile
    - Packaging Facilities - primary and secondary
    - Contract Laboratories (chem and microbiology)
    - Warehouses / LSP
    - Medical device Quality System Regulation audits
    - Sponsor site - QMS and responsibilities
    - Investigator site - IB, AE reporting, protocol adherence, etc.
  - Regulatory Application support / review (Dossier, BLA, IND, IMPD, etc.)
  - Supply chain strategy and troubleshooting, incl. launch of products worldwide

- **2023 – 2024: Galapagos B.V - Head of Quality Assurance Cell Therapy a.i.**
  - Biological company focused on groundbreaking research capabilities and a decentralized manufacturing platform for CAR-T.
  - Re-organization of the Quality department
  - Quality system overhaul (SOPs, overdue -reduction, tiered governance, etc.)
  - Manufacturing and Importation application (MIA) and preparation for inspection (IGJ)
  - CMC support, pivotal readiness plan
  - IND writing and submission / regulatory support
  - IMPD writing and submissions

- **2022 – 2023: Alvotech - VP, Head of Quality Operations a.i**

- Monoclonal antibody Biosimilar Company, targeting cancers and arthritic pain.DS-USP/DSP single-use technology, DP-Filling lines for pre-filled syringes and Medical Device.
- Lead, build up and develop talented site Quality team (appr. 70 employees)
- Participate in the transition of the site from clinical to commercial manufacturing of DS and DP
  - Implementing Quality on the Floor
  - Establishing Investigational Review Board
  - Quality System overhaul to meet the commercial demand.
- Batch Disposition acceleration project through Lean processes and online review of batch documents
  - Supporting SAP and LIMS implementation
- FDA PAI (Pre-Approval Inspection) preparation, strategy and execution, remediation of observations
- Led Communication with Health Authorities regarding license expansions / changes
- Regulatory filing support e.g. review and approval (Dossier / BLA / IND / IMPD)
- Capital Quality Projects lead
- Member of the Quality Leadership Team, deputizing the CQO (Chief Quality Officer)

- **2021 – 2022: Bluebird Bio – Quality Expert**
  - Biotech company (ATMP) with focus on delivering new therapies for severe
  - genetic diseases.
  - Establishing EU Tissue Establishment license for Bluebird Bio
  - Establishing Quality System and other relevant procedures (Traceability, transport, import, export,
  - returns, destruction, etc.) for the BBB Europe subsidiary to support the license application
  - Evaluation tissue suppliers (hospitals, clinics)
  - Batch documentation review to support release of the ATMP

- **2019 – 2022: Paion AG – VP, Head of Quality a.i / QP**
  - Biotechnology company with focus on innovative drugs to be used in hospital based sedation, anaesthesia and critical care services.
  - Lead, build up and develop the talented Global Quality Team
  - Qualified Person batch certification (IMP and finished product)
  - Quality System overhaul to meet the clinical and commercial demand and Health Authorities expectations.
  - Company lead for Health Authorities Inspections and Clients audits incl., license management
  - External Manufacturing Management (DS and DP sterile filling)

- Supply chain strategy and troubleshooting, incl. launch of products worldwide
- Member of the PAION Leadership Board, led by the CEO to support the company growth and current and future pipeline.

- **2017 – 2019: Patheon part of Thermo Fisher Scientific – Quality Director and QP**
  - Biotechnology Contract Manufacturing Organization, Groningen, Netherlands.
  - Site Head of Quality leading a team of app 100 employees (QA and QC)
  - QP release of clinical and commercial batches
  - Build up a Quality Department to take the site from clinical to commercial manufacturing
  - Drive the establishment and full implementation of the Pre- approval inspection logistic system.
  - Leading the System Maturity Model to mature the site Quality System to a stable and efficient state
  - Leading the accelerated batch disposition project
  - Lead the site through inspection preparation to inspection readiness with successful outcome from
    - FDA, EU – Dutch authorities (IGJ), PMDA, ANVISA, Turkey, Health Canada, etc.
  - Establishing the Quality Management culture and key performance indicators
  - Co-lead the Accelerated drug substance manufacturing project to maximize the capacity of the site
  - Accelerated drug substance manufacturing project to maximize the capacity of the site

- **2013 – 2017: Alvotech – Director of Organisational Development, Director of Training and Qualifications, Director of Quality Compliance**
  - Monoclonal antibody Biosimilar Company, targeting cancers and arthritic pain. DS-USP/DSP single-use technology and DP-Filling lines for pre-filled syringes.
  - Director of Organisational Development
    - Dynamic role working with the CEO to build the Alvotech organization from the beginning, involved in selection of key personnel and set up department structure, goals and business development
    - Developing an integrated project plan to enable successful start-up using a multidiscipline team
    - Support to Alvotech Departments in structure and process design.
    - Establishing the Quality Management culture and key performance indicators
  - Director of Training and Qualifications
    - Engaging with local Universities to collaborate in setting up teaching programs for future growth

        - Drive the establishment and full implementation of the Company Training System and Program
        - Generating the Corporate Training Program to run for all Alvotech sites across Europe
    - Director of Quality Compliance
        - Leading the Inspection Readiness Program to establish a manufacturing license for the site
        - Setting up the supplier qualification system (audits and agreements), technical/supplier agreements and performing audits
        - Quality Risk management (QRM) procedure implementation and performance of Risk Assessments.

- **2008 – 2013: Portfarma (now Alvogen Iceland) – Sr. Director of Quality and Technical Affairs, QP**
    - Pharmaceutical company marketing products in Iceland, Denmark, Latvia, Lithuania and Estonia.
    - Acquiring a Manufacturing License (MIA) for the site and implemented a sustainable effective Quality System
    - Managing Quality Assurance (QA) Department of Portfarma
    - Batch QP Release for EU markets
    - Business Development support, including supply agreements and negotiating with contracted companies
    - Overall quality support to other departments of Portfarma, training of employees and evaluation of suppliers
    - Member of the General Management Board of Portfarma along with the CEO and CFO, participating in major decision making for Portfarma and managing employees

- **2002 – 2008: Icelandic Medicine Agency (IMA) – Inspector**
    - **I**ndependent regulatory authority, which appertains to the Ministry of Welfare of Iceland.
    - GxP inspections, evaluation of license applications and collaboration with other EU regulatory authorities in harmonizing understanding and of application of EU-guidelines and regulations.
    - Good Manufacturing Practice (GMP), Good Laboratory Parcice (GLP) and Good Distribution Practice (GDP) inspections of manufacturing sites in Iceland Joint inspection with other EU inspectors in international inspections.
    - Good Clinical Practice (GCP) and Pharmacovigilance (PhV) inspections mainly focusing on Investigators and Sponsors of clinical trials.
    - Member of the GCP and PhV Inspection Working Group at the European Medicine Agency (EMA) that focused on harmonization and co-ordination of GCP

and PhV related activities at Community level, participated in quarterly meetings at the EMA.

- **2001 - 2002: Company details to be inserted pls – Regulatory Affair Specialist**
    - General review and approval of applications for marketing authorization for EU.

Education:

Pharmacist

- M.Sc. Pharmacy, University of Iceland, 2001.
- Bachelor of Pharmacy, University of Iceland, 1999

Courses & Conferences

- GDP training – ECA 2024
- Toyota Lean Academy, 4-day workshop – Alvotech 2022
- FDA Inspection, laws, and regulations – Alvotech 2022
- Deviation and CAPA Masterclass – Paion August 2021
- Issues in Manufacturing and problem solving (Annual Quality Meeting) -Thermo Fisher, February 2019
- Deviation and CAPA Masterclass – Thermo Fisher October 2018
- Patheon Advantage Academy – McKinsey Capability Centre, April 2018
- GMP and Data Integrity NSF, June 2017
- Aseptic filling – Biotech Training Facility, December 2016
- GAMP 5 – ISPE, November 2016
- Quality Risk Management – Key 2 Compliance, May 2016
- GMP for Biological and Biotechnology products – NSF, May 2015
- A-Z sterile products manufacture – NSF, April 2015
- EU GMP, Annex 16 (new version) course – Web-based QP Association, October 2013
- Role of the QP in the Supply chain – QP Association, July 2012
- Qualified Person Education Course - QP Association, September 2011,
- User training course – Eudravigilance and Electronic Transmission of Individual Case Safety Reports (ICSRs), European Medicines Agency, June 2011
- User training course – Eudravigilance Medicinal Product Dictionary (EVMPD) - European Medicines Agency, June 2011
- Batch releasing training, Pharmathen, September 2010
- QP training at manufacturing site, Parmethen, August-September 2010
- Quality manual set up and ISO standards, Focal, October 2009
- Manufacturing and Regulatory training, November 2008
- European Pharmaceutical Legislation course at University of Reykjavik, January 2009

- Pharmacovigilance inspections seminar held by MHRA in Edenborough, March 2007
- Good Clinical Practice (GCP) inspections seminar held by GCP inspectors group at EMEA, in Athens, October 2007
- Good Clinical Practice (GCP) inspections seminar held by GCP inspectors group at EMEA, in Vienna, October 2006