GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Edit Szocs

MSc Chemical Engineer
Senior Consultant

Recognised Areas of Expertise:

Senior pharmaceutical quality professional with 35 years of experience across industry, health authority, and global auditing roles. Combines deep manufacturing and testing knowledge, European regulatory authority insight, and extensive GMP/GDP audit delivery worldwide. Trusted for risk-based audits, pragmatic compliance solutions, and executive-level training.

Proven ability to deliver auditing, training, and advisory projects in partnership with consulting firms and client organisations.

- Regulatory inspections and interaction with regulators;
  - Conducted over 100 GMP/GDP inspections
  - Assumed the role of Co-Inspector for over 20 WHO inspections for the prequalification of medicines
  - Delivered presentations to FDA Inspectors on behalf of PIC/S; and delivered presentations to Swissmedic Inspectors as part of their annual training on the topics of Data Integrity and 'GMP for APIs'.
  - Former member of the PIC/S Risk Assessment Expert Circle, and member of Advisory Board of the European QP Association (2011-2015)
  - Hosted and supported over 50 Health Authority inspections of which 25 FDA inspections
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- Immediate credibility with clients, inspectors, and senior management;
    - Strong delivery of audits, training workshops, and advisory engagements for
    - Quality Management Systems including CAPA
    - Data Integrity and Risk Management
    - Supplier and Distribution Chain Compliance
    - GxP Training and Knowledge Transfer
- Highest technical expertise by product types;
    - Pharmaceutical products (sterile and non-sterile)
    - Investigational Medicinal Products (IMPs)
    - Biotechnology products
    - Active Pharmaceutical Ingredients (APIs):
        - Small-molecule APIs
        - Biologics, including monoclonal antibodies (mAbs) and antibody–drug conjugates (ADCs)
- Highest technical expertise by operations;
    - Solid and liquid pharmaceutical products covering end-to-end operations
    - Sterile fill-and-finish (F&F) operations covering vials, syringes, lyophilized- and combination products
    - Synthetic APIs from process development to commercial production
    - Biotechnology products manufactured by large scale fermentation
    - QC testing utilizing classical chemistry and instrumental analysis such as UHPLC, GC, MS, NMR.
- Extensive language skills;
    - English - Fluent
    - Hungarian, Romanian – Fluent
    - French, German, Italian, Spanish – Professional working comprehension

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited

Career History:

- **2016 - 2026: Ares Trading (Merck Switzerland) - Senior GMP / GDP Auditor and Consultant**
    - Performed global GMP and GDP audits across manufacturing, warehousing, and distribution
    - Delivered clear, defensible, and timely audit reports aligned with EU, CH, US FDA and other (local) expectations.
    - Supported clients with CAPA remediation, inspection readiness, and compliance strategy
    - Frequently selected for high-risk audits and complex consulting projects requiring senior judgment

- **2011 - 2016: European Health Authority – Senior Expert**
    - GMP Inspector role with active collaboration involving WHO, PIC/S, EMA (IWG), and member of the Advisory Board of the European QP Association
    - Contributed to inspection programs, GMP interpretation, and regulatory harmonisation
    - Provided authority-level insight into inspection expectations and compliance pitfalls.

- **1990 - 2011: Pharmaceutical Manufacturing, Canada - Senior Leadership – Quality & Production**
    - Held management roles in Quality Assurance and Production
    - Oversaw GMP operations for multiple dosage forms
    - Led quality systems, inspection support, and continuous improvement initiatives

Education:

- 1990 - 2011: Polytechnical Institute 'Traian Vuia', Timisoara, Romania – MSc Chemical Engineering