

Best Technology Talent For Companies Around The World



Andrii

CSV / CSA Validation Engineer

Summary

CSV / CSA Validation Engineer with solid experience in regulated pharmaceutical environments. Strong background in Quality Management Systems, Change and Deviation Control, CAPA, and Computer System Validation (CSV). Hands-on experience validating GxP systems, authoring and executing validation documentation, and supporting audits and inspections. Comfortable working in Agile and cross-functional teams, with a strong focus on compliance, risk-based validation (CSA), and process digitalization.

TECHNICAL SKILLS:

- Quality & Compliance: GxP, QMS, CSV, CSA, Change Control, Deviation Management, CAPA, APQR, SOPs
- Validation & Systems: TrackWise QMS, Jira, URS, OQ, UAT, Data Integrity
- Standards & Regulations: GAMP 5, 21 CFR Part 11, EU Annex 11, ISO, HACCP
- Other: Audits & Inspections, Risk Assessment, Process Digitalization, Staff Training

Professional Career

Corporate Quality Assurance Specialist

Feb 2025 – Present | Ukraine, Kyiv

Project Info:

Enterprise-level pharmaceutical environment focused on harmonization and digitalization of Quality Management Systems across multiple sites

Responsibilities:

- Collaborated with global stakeholders to harmonize QMS processes across sites.
- Designed and implemented digital workflows for Change Control, Deviations, and CAPA
- Executed Operational Qualification (OQ) activities and maintained full CSV documentation lifecycle
- Participated in regulatory inspections and internal audits
- Conducted training sessions for end users and quality staff

Quality Specialist

Aug 2024 – Jan 2025 | Ukraine, Kyiv

Project Info:

Quality system assessment and digital transformation initiative within a regulated pharmaceutical environment

Responsibilities:

- Analyzed existing QMS and defined a roadmap for digital transformation
- Acted as Process Owner for Change Control, Deviations, CAPA, and APQR processes
- Coordinated with international suppliers to ensure compliance with regulatory requirements
- Performed audits and self-inspections

Leading Engineer for Change and Deviation Control

Jan 2024 – Aug 2024 | Ukraine, Kyiv

Project Info:

Enterprise QMS operations using TrackWise and Jira to support GxP-compliant system changes

Responsibilities:

- Managed full lifecycle of Change and Deviation processes in TrackWise
- Authored, reviewed, and approved quality and validation documentation
- Maintained and optimized SOPs related to quality and validation activities

- Acted as SME for TrackWise and Jira, including URS validation and UAT execution
- Delivered training sessions for users involved in quality processes

Engineer / Senior Engineer of Standardization and Quality

Oct 2020 – Dec 2023 | Ukraine, Kyiv

Project Info:

Ongoing support and development of Quality Management Systems in pharmaceutical manufacturing

Responsibilities:

- Ensured continuous operation and compliance of QMS processes
- Developed and updated HACCP prerequisite programs
- Prepared documentation for regulatory inspections and audits
- Tracked implementation of Changes, Deviations, and CAPAs
- Evaluated equipment and systems for data integrity compliance
- Conducted staff training and onboarding

Technologist

Jun 2017 – Oct 2020 | Ukraine, Kyiv

Project Info:

Pharmaceutical manufacturing and production documentation support

Responsibilities:

- Developed and updated production and registration documentation
- Supported installation, qualification, and setup of new equipment
- Conducted periodic training for production staff

Education

Kyiv National University of Technologies and Design
Master's Degree in Industrial Pharmacy

Kyiv National University of Technologies and Design
Bachelor's Degree in Pharmaceutical Production Technician-Technologist

Foreign Languages Skills

English: Upper-Intermediate

Ukrainian: Native