

Anette Hentschel

SENIOR COMPUTER SYSTEM VALIDATION (CSV) EXPERT

CSV / CSA + GxP IT Compliance + Digital Transformation + Global Audits +
more than 20 years of experience + open to part-time and temporary roles +



What I do

- ✓ Design risk-based CSV strategies and life-cycle documentation (e.g., URS, Risk Assessment, IQ/OQ/PQ/UAT, testing, traceability, reporting, archiving)
- ✓ Validate systems to ensure GxP compliance, including cloud, robotics, and AI-enabled solutions
- ✓ Oversee large-scale, cross-functional validation programs and manage global teams
- ✓ Establish scalable release and change management processes
- ✓ Act as a representative during audits/inspections and contribute to PV System Master File content
- ✓ Develop Standard Operating Procedures (SOPs) for CSV
- ✓ Provide expertise in regulatory and industry standards (e.g. FDA, EMA, MHRA, PMDA and GAMP®)
- ✓ Mentor teams to enhance their understanding and acceptance of CSV practices

Selected References

CSV / CSA + PROJECT MANAGEMENT

- **Oracle Argus Safety** – workflow management system for adverse events management in drug safety (*over 1,200 global users*)
- **Documentum** - document management system
- **TrackWise** - quality management system
- **PMX** - production management system for the production and tracking of investigational drugs

SYSTEM AUDITS + SUPPLIER AUDITS

- Pharma processes: Medical Affairs, Commercial Operations
- IT processes: Computer System Validation
- Supplier audits: Quality Management System, IT Quality

SOME CLIENTS

- Bayer Pharmaceuticals (*since 2015 employed*)
- Bayer Business Services GmbH
- Evonik Technochemie GmbH
- Syncwork AG
- IABG mbH
- ARGUS Consult GmbH

Qualification

Master of Business Administration and Engineering, 2002, HTW Berlin - University of Applied Sciences

Diploma (Master) of Geography, 1991, University of Göttingen

Geography (exchange student, 1987/1991) University of California, Los Angeles (UCLA)

My Toolsets and Systems

- Oracle Argus Safety
- Reportum (MyMeds&Me)
- Genpact PVAI
- Veeva Vault
- TrackWise
- ValGenesis
- Generis CARA
- Jira
- Microsoft 365
- SharePoint
- Clarivate Cortellis Regulatory Intelligence

LANGUAGES

GERMAN (Native/C2)
ENGLISH (Business fluent/C2)
SPANISH (Advanced/B2)
ITALIAN (Advanced/B2)
JAPANESE (Basic-Intermediate/A2)

ANETTE HENTSCHEL

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