Aurore TILLIER

Computer System Validation (CSV) Specialist

Medical devices · FDA 21 CFR Part 11 & 820 · CE marking · GAMP 5 (risk-based approach)

French native · English fluent · Spanish professional · Chinese intermediate

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Paris, remote · Planned relocation: Tours or Angers (2027) · Hybrid or fully remote



CSV since
2022
medical devices

10+
systems validated
EDMS, R&D, production, clinical

Team management
CSV team of 3 · up to 6 testers

0
major nonconformities
in audits (internal, DEKRA notified body)

PROFILE

As a CSV specialist in medical devices, I lead **end-to-end validation projects**, from URS to final report, in accordance with **21 CFR Part 11 & 820** and a risk-based approach (GAMP 5). A developer and then Test Lead before moving into validation (in IT since 2017), I am **equally at ease with regulatory and technical topics**. I set up and managed a validation team, and I act as the link between Quality Assurance / Regulatory Affairs (QA/RA), IT and business teams.

EXPERIENCE

Computer System Validation Specialist — 2022 – present

Science (August 2024 – present) · Pixium Vision (2022 – 2024) · Permanent contract · Paris, remote

- **10+ systems validated** under Part 11 & 820: 2 electronic document management systems (EDMS), including a customized Confluence EDMS (electronic signature, versioning, approval workflows), R&D, production and clinical trial software, Jira (CAPA), Git/GitHub
- **End-to-end deliverables**: URS/FRS/SRS, validation plans (including migrations), risk analyses using failure mode and effects analysis (FMEA), IQ/OQ/PQ protocols, 50+ test scripts, traceability matrices, reports, user acceptance testing (UAT)
- **Electronic device history records (DHR)** (21 CFR 820.184, pre-QMSR): management of the project to move them into the EDMS, validation, work instruction
- **Method**: sprint-based qualifications, regression testing scope adjusted after defects, approval of OQ/PQ scripts, 21 CFR Part 11 coverage in URSs
- **Audits with no major nonconformity**: systems presented during internal audits and the DEKRA notified body audit (CE marking)
- **Projects led independently**: Squash TM validation, EDMS enhancements for production, retrospective specification of the EDMS to fix legacy defects; retrospective specification of the Jira FMEA configuration; configuration of validation project workflows (Confluence and Jira)
- **Day-to-day quality**: change control (impact assessment), validation discrepancies, deviations and nonconformities (root cause, criticality, re-execution) through to closure, procedure (SOP) updates; scripted testing complemented by exploratory testing upon receipt of deliverables

EXPERTISE

CSV · **21 CFR Part 11** · **21 CFR 820** · **IQ / OQ / PQ** · **GAMP 5 (risk-based)** · **CE marking** · **ISO 13485 (basic knowledge)** · **URS / FRS / SRS** · **Risk analysis** · **Traceability** · **Change control** · **Deviations / CAPA** · **UAT** · **Project management** · **Data integrity (ALCOA+)** · **Audit trail review** · **FMEA**

Science / Pixium Vision (continued) — 2022 – present

Computer System Validation Specialist

- **Management and cross-functional work**: CSV team of 3 (recruitment with job descriptions and case studies, supervision, training); management of the website project for CE marking (requirements, IQ/OQ/PQ acceptance testing, coordination of the various disciplines involved; MDR 2017/745, electronic instructions for use (e-IFU), ANSM (French medicines agency) and GDPR requirements applied); task allocation to the IT infrastructure service provider; administration of tools (Confluence, Jira, Squash TM, Dolibarr) and training of user teams (including quarterly EDMS sessions, knowledge assessment, traceability of user authorizations) (R&D, production, clinical, QA/RA), materials in French and English
- **IT managed services**: requirements specification, periodic operational reviews: access, backups, security, business continuity plan (BCP); qualification of a server migration; monitoring of service delivery
- **Maintaining the validated state**: data integrity (ALCOA+), audit trails, periodic reviews, checks of Squash TM reports; supplier assessment and qualification (including a web service provider) with QA/RA; document templates; co-approval with R&D of deployments with no product impact
- **Documentation rigor**: retrospective record reviews, versioning and traceability rules

PREVIOUS EXPERIENCE

Software Quality Engineer – Test Lead — 2020 – 2022

IAD · Permanent contract · Seine-et-Marne · hybrid

- **Test Lead**: remote management of 4 to 6 testers in Morocco (offshore team of about ten people), across 2 projects
- **Test strategy** and methodology of the Quality team; Squash TM repository, defect analysis (Jira), execution reports
- **Methodology**: wrote a Squash TM guide (repository, reusable test cases, campaigns) and trained the testers
- **Acceptance testing**: effort estimation, test data sets, integration scenarios, functional documentation
- **Test automation**, self-taught (Katalon Studio, TestComplete)

PHP/Symfony Web Developer — 2017 – 2019

ACENSI · Permanent contract · Hauts-de-Seine · on-site

- Online appointment booking application for doctors (MVC, database, responsive); business-side project support for a client: product backlog and detailed specifications written with the project manager, acceptance test strategy and scenarios, functional and regression testing, test reports

Tourism, events and teaching — 2010 – 2016

Stade de France · Château de Blandy-les-Tours · Fontainebleau and Milly-la-Forêt Tourist Offices · on-site

- Project management
- Coordination of staff at trade shows and pitchside (hospitality staff, security staff, caterers): instructions, run of show, compliance with safety rules
- Trilingual guided tours: standard, technical and themed (theatrical) tours
- French language assistant in the United Kingdom (Oakgrove School, Milton Keynes, 2010 – 2011)

EDUCATION & TRAINING

- **Computer System Validation — Boot Camp** · Compliance Trainings · 2022
- **Jira — administration** · ADN · 2022
- **Les clés du management de projet** (Key Principles of Project Management) · Cegos, Paris · 2023
- **PHP/Symfony Web Developer** · Wild Code School (career change) · 2017
- **BTS Animation et Gestion Touristiques Locales** (French 2-year higher national diploma, EQF level 5) · ETS Paris · 2013
- **Licence LEA Affaires et Commerce** (bachelor's degree, EQF level 6; English/Chinese) · Paris III · 2010

TOOLS

Confluence · **Jira** · **Squash TM** · **Git · GitHub · Gitea** · **Katalon** · **TestComplete** · **PHP / Symfony** · **MySQL** · **Dolibarr**

LANGUAGES

French native · English fluent · Spanish professional · Chinese intermediate

GENERATIVE AI

Personal use: proficient with coding agents (Claude Code, Codex, Antigravity) — written instructions, cross-review, version tracking; test case review, writing, web development.

SOFT SKILLS

Documentation rigor · Teaching and facilitation · Explaining technical topics in plain language · Diplomacy · Ability to synthesize · Autonomy · Curiosity and ability to learn · Managing parallel projects, with dedicated teams per project · Writing skills · Analytical mindset

INTERESTS

Facilitator of peer co-development (action learning) groups · Hiking · Photography · Gardening · Creative handicrafts: watercolor, drawing, clay modeling… · Meditation · Ice skating