Baptiste Calin

Freelancer

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Quality Expert

With more than 15 years of experience in quality management and software engineering, I bring a strong understanding of processes in healthcare companies and deep expertise in ISO standards and regulatory compliance. I specialize in building, optimizing, and certifying QMS frameworks aligned with ISO 13485, MDR, and ISO 14971, ensuring safe and compliant medical device software.

I help organizations structure and digitalize their quality processes while aligning regulatory requirements with technical delivery. My expertise combines hands-on regulatory compliance with practical implementation of digital tools that streamline quality operations.

- Regulatory Compliance & Standards: ISO 13485, MDR, ISO 14971, ISO 12207, GDPR, ITIL 4
- Quality Management Systems: Design, optimization, certification, and integration with business processes
- Healthcare & SaMD: Medical device regulations, risk management, authority & notified body communication
- Tools & Automation: Jira, Confluence, GitLab, Jenkins, SonarQube, Docker, PowerBI, Bizzmine eQMS

My value lies in bridging healthcare compliance and technical realities, enabling companies to meet regulatory demands while accelerating innovation and delivering safe, high-quality solutions.

Soft Skills

- Leadership / Ownership
- Team coordinator / leader
- Trainer & Coach
- Proactive
- Result oriented
- Innovation thinking
- Positive and invested

Profile skills

Processes	QMS, ITIL 4 practices, Agile / Scrum methodology, BPMN
Management	KPI, Personal Development Plan, Recruitment, PRRC
Tools	Jira, Confluence, PowerBI, GitLab, Jenkins, SonarQube, Docker, Microsoft Office Suite, Miro, Snyk, Bizzmine (eQMS), IntelliJ, Postman, Eclipse
Standards	ISO 12207, ISO 9001, ISO 13485, MDR, ISO 27001, ISO 9126, ISO 82304, ISO 62304
Platform	AWS, CI/CD, JBoss, Tomcat, Linux
Development	Java/J2EE, XML/XSLT, HTML/JS/CSS
Frameworks	JUnit / TestNG, Angular, Selenium, RESTful APIs, Spring, Hibernate / JDBC, DHTMLX, JQuery
Databases	PostgreSQL, SQL Server, Oracle, H2

Work Experience

Quality Expert

SPW - Freelance | Apr 2023 - Sept 2025 | Namur (2 yrs 6 mos)

Quality Management System (QMS) with ISO 9001 and Application Lifecycle Management (ALM) with ISO 12207 - Analysis of the standard and identification of actions to be implemented - Project: Participation in setting up a development factory and CI/CD chain implementation at the SPW - SonarQube: Implementation of the tool in conjunction with the MoE project's DevSecOps team and developers teams

Skills used:

- **Processes:** QMS, ITIL 4 practices, Agile / Scrum methodology, BPMN
- **Management:** KPI
- **Tools:** Jira, Confluence, PowerBI, GitLab, Jenkins, SonarQube, Docker, Microsoft Office Suite, Miro, Snyk
- **Standards:** ISO 12207, ISO 9001
- **Platform:** AWS, CI/CD

Quality Expert

ZORGI | Jun 2019 - Apr 2023 | Heverlee (3 yrs 11 mos)

Medical Device Project management - Quality Management System implementation under Medical Device Directive (93/42/EEC) and Medical Device Regulatory (EU) 2017/745 - SaMD: Technical files consolidation - Certification ISO 13485 - Training Management - Records management - Authority and Notify body communication - ISO 13485 Quality Management System connection with ISO9001 and ISO27001 - Quality Management System connection with ITIL 4 practices - GDPR Project management + GDPR connection with ISO27001

Skills used:

- **Processes:** QMS, ITIL 4 practices, Agile / Scrum methodology, BPMN
- **Management:** KPI, Personal Development Plan, Recruitment, PRRC
- **Tools:** Jira, Confluence, PowerBI, Bizzmine (eQMS), Microsoft Office Suite, Miro
- **Standards:** ISO 13485, MDR, ISO 27001, ISO 9001
- **Platform:** CI/CD

Test & Release Manager

Xperthis group | Jun 2020 - Jun 2021 | Nivelles (1 yr 1 mo)

Release software management - Deployment planning - Test automation strategy and implementation - Quality Software management (Quality Assurance, Control, Managemnet) - Downtime management of IT System - Team management

Skills used:

- **Processes:** ITIL 4 practices, Agile / Scrum methodology
- **Management:** KPI, Personal Development Plan, Recruitment
- **Development:** Java/J2EE, XML/XSLT
- **Frameworks:** JUnit / TestNG, Angular, Selenium, RESTful APIs
- **Tools:** Jira, Confluence, PowerBI, Jenkins, IntelliJ, Microsoft Office Suite, Postman
- **Standards:** ISO 9126
- **Platform:** CI/CD

Solution Architect - Software Engineer

Xperthis group | Mar 2006 - Jun 2019 | Nivelles (13 yrs 4 mos)

Product management & Architect for a web-based healthcare application: Electronic Patient Record (EPR) - Saas Solution for Portail Patient Application - Set of teams coordinator and Team management - Incident consultant and helpdesk management

Skills used:

- **Processes:** ITIL 4 practices, Agile / Scrum methodology, BPMN
- **Management:** KPI, Personal Development Plan, Recruitment
- **Development:** Java/J2EE, HTML/JS/CSS, XML/XSLT
- **Frameworks:** Spring, Hibernate / JDBC, DHTMLX, JQuery, RESTful APIs
- **Databases:** PostgreSQL, SQL Server, Oracle, H2
- **Tools:** Jira, Confluence, Jenkins, IntelliJ, Eclipse, Microsoft Office Suite
- **Standards:** ISO 12207, ISO 82304, ISO 62304
- **Platform:** JBoss, Tomcat, Linux, CI/CD

Education & Certifications

- AWS Cloud Practitioner essentials (2023)
- Certified ScrumMaster - CSM (2023)
- Person Responsible for Regulatory Compliance (2021)
- Coach and Manage a team (2021)
- ITIL 4 Foundation (2020)
- ISO 13485/2016 and CE Mark (2019)
- PostgreSQL DBA (2015)
- Bachelor's in Informatics – H.E.P.M.B.C (2005)

Communication skills

- English : Limited working proficiency
- French : Native