



## Baptiste Calin

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## Quality Expert

With more than 15 years of experience in software engineering and quality management, I combine a solid technical background with strong expertise in regulated environments, particularly in the medical device industry.

I started my career as a software developer and architect (Java, Node.js, React, Spring Boot) before specializing as a Quality Expert in projects requiring strict compliance (ISO 13485, MDR, ISO 14971, ITIL, GDPR).

This hybrid journey enables me to act as a strategic partner for organizations seeking to structure, optimize, and digitalize their quality processes, or to develop applications in a regulated environment.

- Quality & Compliance: Implementation and optimization of QMS aligned with ISO 13485, MDR, ISO 12207, ITIL, GDPR
- Software Engineering: Java, Spring Boot, Node.js, React, SQL, CI/CD, DevSecOps
- Leadership & Change: Team coordination, training, coaching, change management, KPI-driven improvement
- Tools & Automation: Jira, Confluence, GitLab, Jenkins, SonarQube, Docker, PowerBI

I stand out by my ability to bridge the gap between regulatory requirements and technical realities, ensuring projects that are compliant, efficient, and innovative. My goal: enable companies to deliver safe, high-quality, and sustainable digital solutions.

## Soft Skills

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

## Profile skills

<b>Processes</b>	QMS, ITIL 4 practices, Agile / Scrum methodology, BPMN, Change Management
<b>Standards</b>	ISO 9001, MDR, ISO 13485, ISO 27001, ISO 9126, ISO 82304, ISO 62304
<b>Tools</b>	Microsoft Office Suite, Jira, Confluence, PowerBI, SonarQube, Miro, Snyk, Bizzmine (eQMS), IntelliJ
<b>Management</b>	KPI, Personal Development Plan, Recruitment, PRRC
<b>Platform</b>	AWS, Linux
<b>Development</b>	Java/J2EE
<b>Frameworks</b>	JUnit / TestNG, Selenium

## Work Experience

### Quality Expert

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

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
- **Standards:** ISO 9001
- **Tools:** Microsoft Office Suite, Jira, Confluence, PowerBI, SonarQube, Miro, Snyk
- **Management:** KPI
- **Platform:** AWS

### 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:** Personal Development Plan, Recruitment, KPI, PRRC
- **Tools:** Jira, Confluence, PowerBI, Microsoft Office Suite, Bizzmine (eQMS), Miro
- **Standards:** MDR, ISO 13485, ISO 9001, ISO 27001

## Test & Release Manager

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

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

### Skills used:

- **Processes:** Change Management, ITIL 4 practices, Agile / Scrum methodology
- **Tools:** IntelliJ, Jira, Confluence, IntelliJ, PowerBI, Microsoft Office Suite
- **Management:** Personal Development Plan, Recruitment, KPI
- **Development:** Java/J2EE
- **Platform:** Linux
- **Frameworks:** JUnit / TestNG, Selenium
- **Standards:** ISO 9126

## 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:** Change Management, ITIL 4 practices, Agile / Scrum methodology
- **Standards:** ISO 82304, ISO 62304, ISO 9126
- **Tools:** Jira, Confluence, Microsoft Office Suite, IntelliJ
- **Management:** Personal Development Plan, Recruitment, KPI
- **Development:** Java/J2EE
- **Platform:** Linux
- **Frameworks:** JUnit / TestNG, Selenium

## 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