

JOHAN ROCHER

Consultant · Medical Software · Regulatory Compliance · Product Cybersecurity

Saint-Prex, Vaud · +41 78 336 10 15 · johan.rocher.pro@gmail.com · caducia.ch · linkedin.com/in/johan-r-1b77ba71



PROFILE

Senior embedded software engineer, more than ten years in connected medical devices at **EMS** and **bioMérieux**, most recently as **Principal Engineer & Cybersecurity Officer**. I now work with manufacturers as an independent consultant, from critical embedded development to defending the software file in audits. Both sides of the table: I write the code, and I answer the auditor.

WHAT I BRING

End-to-end product cybersecurity

Threat modeling, secure boot, code signing, OTA, cybersecurity files for MDR and FDA registrations.

Complete IEC 62304 software file

Architecture, SOUP, traceability, ISO 14971 risk analysis. Ready for the notified body.

Production embedded platforms

Yocto/Linux on NXP i.MX, Zephyr and FreeRTOS on STM32/ESP32, from kernel driver to Qt interface.

Senior reinforcement, operational from day one

Audit, documentation remediation, or a few days per month within your teams. On site or remote.

EXPERIENCE

Co-founder & CTO · **Alsensia SA**, EPFL Innovation Park, Lausanne

Since 2025

VR biofeedback device with proprietary physiological sensor (patent pending): product, architecture, industrialization.

Principal Engineer & Cybersecurity Officer · **EMS Electro Medical Systems, Nyon**

2023 · 2026

- Software architecture across the whole medical device range, from kernel drivers to the user interface.
- Cybersecurity strategy for MDR and FDA registrations: threat modeling, risk analysis, full documentation.
- Secure boot chain, code signing and OTA updates for field-deployed clinical devices.
- Yocto embedded Linux platforms on NXP i.MX (Toradex): layers, BSP, kernel drivers, device tree.
- Firmware lead for the new dental prophylaxis devices: ESP32/Zephyr, NXP LPC/FreeRTOS, STM32.
- GitLab and Jenkins CI/CD pipelines: Yocto builds, release process, automated testing.

Embedded software engineer · **EMS Electro Medical Systems, Nyon**

2019 · 2023

- Urology: evolution of the Trilogy user interface (Qt on embedded Linux, NXP i.MX6) and Yocto build maintenance.
- Pain therapy: firmware and GUI for the new DolorClast generation (STM32, Kinetis), with complete IEC 62304 and ISO 13485 documentation.
- Feasibility phase for a new high-end device: hardware and software architecture.
- Connected machine log analysis tool (Python, Qt, Microsoft Azure).

R&D software engineer · bioMérieux, Lyon

2014 · 2019

- Firmware for in vitro diagnostics devices (STM32, CAN bus).
- Device connectivity solutions with cloud-based monitoring.
- Management of offshore development teams (India, UK, US) with regulatory compliance responsibility.
- Contribution to verification and validation processes (V&V planning, technical support).

Engineering intern · Thales Avionics, Valence

2013

Firmware for a next-generation avionics power-supply card (TMS320), Python test automation, real-time data visualization (Python, Qt).

Engineering intern · KRHONE, Romans-sur-Isère

2012

Generic communication interface (GSM, Wi-Fi, Zigbee, Ethernet), Microchip PIC24F firmware and PCB prototyping.

WAYS OF WORKING TOGETHER

Software file audit

2 to 3 days

Assessment of the software file against IEC 62304: gaps, risks, prioritized action plan.

Design control remediation

5 to 10 days

Bringing documentation up to standard: plans, SOUP, traceability, risk analysis, cybersecurity.

Recurring role

2 to 6 days per month

Software and regulatory lead within your team, without hiring.

EXPERTISE

Regulatory & quality

IEC 62304 (class A to C) · ISO 13485 · design control · MDR 2017/745 · FDA · ISO 14971 · technical documentation · audit preparation

Product cybersecurity

Threat modeling · secure boot · code signing · dm-verity · secure OTA · MDR & FDA premarket requirements · encryption · secure protocols

Software engineering

Yocto · embedded Linux · Zephyr · FreeRTOS · STM32 · NXP i.MX · ESP32 · C · C++ · Python · Rust · Qt · BLE · Wi-Fi · Azure · GitLab CI · Jenkins · Docker

Education: Master of Engineering, embedded systems & automation · Grenoble INP Esisar · 2013

Languages: French (native) · English (fluent) · German (basics)