



MATHIS BOUTER

QARA Engineer – AI-based Medical Device Software (SaMD)

PROFESSIONAL EXPERIENCE

September 2024 – September 2026

QARA Engineer (Apprenticeship) - DESKi, Bordeaux (33)

- Contributed to the technical documentation that led to CE marking (MDR) and FDA Clearance
- Management of the Quality Management System (ISO 13485): drafting of procedures, change control, document control, training of new staff
- Led risk management activities (ISO 14971) covering patient, AI/ML and cybersecurity risks
- Autonomous execution of internal QMS audits
- CAPA process management: identification of non-conformities, root cause analysis, verification of effectiveness
- Post-Market Surveillance (PMS) and compliance with IEC 62304 / IEC 62366
- Supplier evaluation and qualification
- Software validation and requirements traceability

March – August 2024

Quality & Regulatory Affairs Intern - DESKi, Bordeaux (33)

- Preparation of regulatory files for CE and FDA certifications
- Participation in the Quality department activities and software validation (Cherkin test cases)

May – August 2023

Pharmaceutical Production Intern / Temporary Staff - Eurofins, Martillac (33)

- Development of a stock management software (VBA) and reorganisation of the internal storage area
- Drafting of Quality documents

April 2021 – March 2024

Order Picker - Chronodrive, Pessac (33)

Permanent contract, 15h/week alongside studies

EDUCATION

April - July 2026 - Harvard Medical School

- AI in Health Care: From Strategies to Implementation

2024–2026 - University of Bordeaux

- Master's TECSAN - Health Technologies

2022–2024 - University of Bordeaux

- Bachelor's TECSAN - Health Technologies

2021–2022 - University of Bordeaux

- First year of Life Sciences degree

2020–2021 - University of Bordeaux

- First Year Common to Health Studies (PACES)



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24 years old



Driving licence (own car)



[LinkedIn Profile - Mathis Bouter](#)

LANGUAGES

- French (Native)
- English (Professional working proficiency)

SKILLS

Regulatory & Quality

- QMS – ISO 13485
- SaMD – IEC 62304 / 62366
- Risk management – ISO 14971
- Medical device cybersecurity
- CE (MDR) & FDA submissions
- Post-Market Surveillance (PMS)
- CAPA & internal audit
- AI Act (EU 2024/1689)

Testing & Tools

- Test cases, Cherkin, traceability
- Jira, Confluence, XRay
- VBA, Microsoft Office

INTERESTS

- Football
- Travel
- Cooking
- Rugby