

Systems Engineer Risks and Safety Standards

m/f/d,

For Roche Diagnostics, we are looking for an experienced **Systems Engineer** with a strong background in **risk management, safety engineering, and medical device compliance**. This role is ideal for professionals with proven experience in regulated product development environments and deep knowledge of critical industry standards such as **ISO 14971, IEC 60601-1, IEC 61508, and IEC 62304**.

Hard Facts

- * **Start Date:** 01.10.2026 latest 01.01.2027
- * **Duration:** 12 months
- * **Extension:** Very likely
- * **Workload:** 100%
- * **Location:** Rotkreuz, Switzerland & Mannheim, Germany
- * **Home Office:** Hybrid, minimum 50% onsite presence required
- * **Travel:** Up to 20% to Mannheim, Germany
- * **Work Model:** Hybrid

Responsibilities

- * Lead and facilitate Failure Mode and Effects Analysis (FMEA) workshops with cross-functional engineering teams
- * Identify hazards and evaluate risks within the product risk management process
- * Review and update hardware and software safety and reliability concepts, including functional safety aspects
- * Oversee test execution and documentation required for certification board (CB) reports
- * Maintain and update technical documentation in accordance with internal and external standards
- * Plan, coordinate, and report work packages and project activities to stakeholders

Must-Have Qualifications

Job profile

-  IT - Quality Management
-  Contracting
-  Full Time
-  01.10.2026 - 31.09.2027
-  Product development, GMP, Design Controls

Job benefits

-  Company laptop
-  Coopers Care
-  Further education
-  Home Office
-  Modern workspace



Sounds interesting?

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- * Degree in Electrical Engineering, Mechanical Engineering, Software Engineering, Physics, or a related field
- * More than 3 years of experience in product development
- * Experience in GMP-regulated environments, including:
 - * Design Controls
 - * Good Documentation Practice (GDP)
 - * Design Transfer
 - * Risk Management
 - * Quality Process Compliance
- * Fluent English communication skills

Nice-to-Have

- * German language skills

Ideal Candidate Profile

The ideal candidate brings hands-on experience across the complete systems engineering lifecycle, including requirements engineering, system architecture, integration, usability engineering, and verification & validation (V&V). A strong track record in medical devices or IVD products, combined with expertise in risk management, safety/reliability engineering, and regulatory compliance, will be key to success in this role.

Sounds like a great job?

Then we look forward to receiving your complete application documents through our online application form.

When applying by email, the sender agrees that his or her data will be used in accordance with our data privacy policy.

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