

icometrix – Lead System Designer

Lead System Designer - AI-Enabled SaMD & Platform Integration

The Lead System Designer (LSD) owns the end-to-end system design of cloud native AI-based Software-as-a-Medical-Device (SaMD) — from requirements definition through verification, validation, and regulatory clearance.

This role sits at the intersection of deep learning product development and regulated design controls, translating clinical and engineering needs into architecture, requirements, risk-managed designs, and release-ready evidence.

The LSD leads cross-functional and cross-border teams — Engineering, QA/RA, Program Management, and partner organizations across the US, Europe, China, and India — drives M&A SaMD integration into the GE HealthCare QMS, and applies AI / GenAI tooling to accelerate engineering and regulatory workflows.

Key Responsibilities

- Own the end-to-end design scope, architecture, and integration plan for AI SaMD with on-prem and cloud offering, including requirements for baselining and the compliance roadmap.
- Drive the design controls of “API as a product” and define the critical quality strategy, risk, usability and design transfer and deployment for “build once and deploy anywhere SaMD”.
- Participate in design decisions of AI model training, testing and integration to the host systems.
- Author and define requirements, lead the RAC / CMT traceability, and design-change plans, defining “ready” criteria for release gates and migrating artifacts into approved QMS tools.
- Plan and execute verification & validation for SaMD, including cloud-based V&V, software reliability testing, DICOM conformance, and validation-cycle execution against user requirement specifications.
- Lead risk management artifacts — FMEAs, ISO 14971 risk files, and AI model design controls (IEC 62304 Class C) — and drive CSV reduction and GxP assessment.
- Serve as the technical focal point for regulatory strategy across global markets (FDA 510(k), EU MDR / TÜV, Korea MFDS / DMPA, NMPA), resolving SaMD-specific questions including EU AI Act, PCCP, AI Conformance Statements, and gap assessments.
- Drive M&A systems integration of acquired companies into the GE HealthCare QMS —retrospective reviews, DHF / technical-file remediation, and D&D process harmonization.
- Collaborate with partner-team members, guiding them through GE HealthCare SDLC, V&V, and QMS processes.
- Represent the program in core team and executive forums, delivering milestone status, QA/RA recovery plans, and design reviews.

What do we expect from you?

Qualifications and Requirements

- Master’s degree in engineering, computer science, biomedical engineering, or related technical field (Ph.D. preferred).
- 5+ years of medical-device or regulated software experience, including leading NPI programs end-to-end.

- Demonstrated expertise in deep learning / AI product development (CNNs, LLM / RAG) and the AI SDLC.
- Strong command of Design Controls, requirements / traceability, V&V, and Quality Management Systems for SaMD (IEC 62304, ISO 14971).
- Experience with regulatory submissions (510(k), EU MDR / TÜV) and SaMD-specific regulatory frameworks.
- Proven cross-functional and cross-border leadership across Engineering, QA/RA, and Program Management.

Desired Expertise

- Hands-on GenAI tooling (Copilot Studio, RAG pipelines) applied to regulated documentation and automation.
- M&A / third-party integration into a regulated QMS.
- DICOM / medical-imaging workflows and cloud-based V&V architecture.
- Systems-thinking approach with the ability to model workflows and identify AI leverage points.

Success Measures

- On-time delivery of milestone-critical SaMD releases (FDR gates) with zero gating action items.
- Regulatory submissions cleared / approved with high package quality.
- Reduction in verification / documentation cycle time through AI-enabled automation.
- Successful QMS integration of acquired products with no silent recalls and audit readiness.
- Standardized, reusable design / verification artifacts adopted across NPI teams.

What do we offer you?

- Lots of learning opportunities, especially regarding cloud computing
- A lot of freedom and collaboration with a diverse set of nice colleagues.
- Hybrid work possible
- A market conform wage
- A job advancing healthcare and technology
- A job in an innovative, growing company with a worldwide impact

Applicants must be currently authorized to work in Belgium. Visa sponsorship is not available for this position.

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