



Life Sciences Architecture.

From molecule to market, architecturally secured.

Scientific innovation demands architectural discipline

Life sciences operates at the intersection of science, regulation and commerce. W69 implements AI architecture for pharmaceutical companies, biotech and medical devices where validation and traceability are core. R&D cycles shorten, regulatory requirements tighten, and the competition for first-to-market intensifies. Without architectural discipline, your innovation speed becomes your greatest risk.

“You don’t merely develop a molecule; you safeguard the scientific integrity for the next generation of your patients.”

We don’t build for today’s trial, but for tomorrow’s therapy. Your innovation deserves an architecture that stands the test of time.

Research Governance

Strict guardrails for scientific integrity and data governance.

Validation Logic

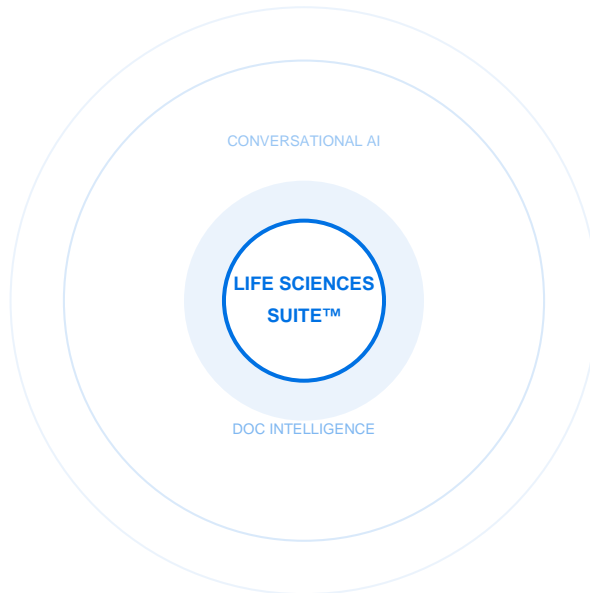
Automated validation of research results and process control.

GxP-by-Design

Seamless integration with GxP requirements and regulatory frameworks.

The Life Sciences Suite™

How W69 connects AI components into one scientific architecture.



- **Research Engine**

Intelligent support for drug discovery, target identification and literature analysis.

- **Regulatory Compliance**

Automated review against GxP, FDA/EMA guidelines and clinical trial requirements.

- **Clinical Trial AI**

Optimization of trial design, patient selection and data monitoring.

- **Reporting**

Automated reports for regulatory submissions, safety reports and board presentations.

- **Audit Trail**

Full traceability compliant with 21 CFR Part 11 and EU Annex 11 for GxP accountability.

Cross-cutting capabilities: Document Intelligence and Conversational AI are integrated across all components of the Life Sciences Suite™.

From scientific documents to regulatory insight

AI that understands, analyzes and transforms your scientific document flow into actionable regulatory insights.

1 Clinical Study Report Analysis

Automatic extraction of endpoints, adverse events and statistical results from clinical study reports and IBs.

2 Regulatory Submission Screening

Real-time screening of dossiers against EMA/FDA requirements with gap analysis and compliance reporting.

3 Pharmacovigilance Reporting

Generation of PSURs, safety updates and signal detection reports based on source data.

Intelligent interaction for life sciences

AI-driven conversations that support researchers, accelerate regulatory processes and foster knowledge sharing.

1 Medical Information Assistant

Automated answering of medical-scientific questions from HCPs with source references to SmPC and clinical data.

2 Regulatory Intelligence Bot

AI assistant providing regulatory affairs professionals with direct access to current guidelines, guidances and precedents.

3 R&D Knowledge Platform

Search complex scientific literature, patent databases and internal research data via a conversational interface.

From passive tools to autonomous intelligence

Static AI models wait for a prompt. **Agentic Systems** by W69 take the initiative. We design architectures in which AI agents autonomously plan tasks, consult sources, orchestrate tools and validate results.

1 Reasoning Engines

Chain-of-Thought protocols for scientific analysis. From target validation to regulatory strategy, step by step and validated.

2 Tool Augmentation

Integration with your research ecosystem. Whether it involves LIMS, CTMS or electronic lab notebooks.

3 Human-in-the-Loop

For scientific and regulatory decisions, the system escalates to your experts. No autonomy without scientific accountability.

4 Continuous Learning

The architecture evolves with scientific insights and regulatory developments. Feedback loops refine the models within GxP guardrails.

Your AI Readiness Score

The Navigator™ Assessment provides an initial indication of your organization's AI maturity. Scores range from 10 to 50, divided across three maturity levels.

Exploration

10 – 20

AI is in an early experimental phase. Individual experiments, few organization-wide guidelines, fragmented tools.

Integration

20 – 35

AI is already applied in specific workflows. Concrete use cases, partial integration, growing adoption by teams, governance in development.

Strategic AI

35 – 50

AI is a structural part of the organization. Organization-wide adoption, integrated AI architecture, clear governance, AI-supported decision making.

Start your Navigator™ Assessment

Discover your organization's AI maturity in 5 minutes.

www.w69.ai/sectors/life-sciences.html

W69 PROOF™



Every system delivered by W69 carries the W69 Proof™ seal — your guarantee for architecture, governance and compliance.

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W69 AI Consultancy

Life Sciences Architecture · Governance · Transformation

www.w69.ai · Amsterdam