KVALITO

Capabilities Overview

Company Overview

KVALITO is a trusted consulting partner for quality, compliance and digital transformation. We empower Life Sciences, Healthcare and other regulated industries to achieve operational excellence and regulatory confidence. Founded in Switzerland in 2013, we have a strong footprint across Europe and APAC, bridging compliance needs with emerging technologies. From AI, ML, AR/VR, Blockchain, and Big Data to Cloud and Robotics — we help future-proof businesses through smart, scalable innovation.

At A Glance

Actively supporting many of the TOP tier pharma companies globally

+300 Successful Client Engagements since 2013

+100 Talent from over 20 countries

8 Global Locations

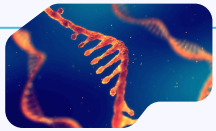
Core Services - Optimized Compliance. Minimal Disruption. Maximized Efficiency.

IT & Digital Transformation

- Digital Strategy & Roadmapping
- Enterprise Systems Integration (ERP, QMS, LIMS, RIMS, DMS platforms)
- Validated & Compliant IT Systems
- Risk-based validation (CSV), ISRM, regulatory compliance across platforms
- Data Integrity & Governance
- Supply Chain & Manufacturing IT Solutions
- Prompt Engineering & Business Intelligence

M&A Process Integration

- IT Systems & Infrastructure Integration
- Business Process Harmonization
- Quality & Compliance Alignment
- Change & Stakeholder Management
- Integration Governance & Synergy Management



Innovative Therapies

- Advanced Modalities: Cell & Gene Therapy, Radioligands, Biologics, Small Molecules
- Personalized & Precision Medicine
- Next-Gen Manufacturing Models (decentralized, modular)
- Digital Clinical Supply Chain
- Data-Driven R&D Enablement
- Modality-Aligned Process Automation

QA & Compliance Excellence

- **Audits & Assessments** (GxP, vendor audits, gap analysis, readiness)
- **Regulatory Compliance** (FDA, EMA, ISO, MDR, and GxP)
- **Data Integrity & 21CFR Part 11** (ALCOA+, audit trails, e-records compliance
- **Computerized System Validation (CSV)** (risk-based, GAMP 5, SaaS/cloud)
- **Commissioning, Qualification & Validation (CQV)**
- **Quality Managament Systems (QMS)** (global frameworks, digital enablement)

People, Processes, Tools

Key Roles	Core Processes	Industry Standards & Tools
Quality & Compliance Managers	CSV, CQV, Data Integrity, QMS	GxP, GAMP 5, 21 CFR Part 11, ALCOA+
Project & Program Managers	M&A Integration, Change Management, Roadmapping	PMI, Agile, V-model, ISO 9001
Digital & IT Consultants	ERP/QMS Integration, MES, Supply Chain IT, AI/ML Development, Automation Engineering	SAP, Oracle, TrackWise, MasterControl, Veeva Vault
R&D and Manufacturing Experts	Precision Medicine, Smart Manufacturing	ICH Guidelines, EU MDR, ISA-95, LIMS, RIMS, CTMS

Pushing Boundaries in Regulated Industries

Rooted in Values. Driven by Impact.
Purpose-Driven & People-Centric: Values-led culture rooted in equity and expertise, delivering impactful solutions.

Leading Change Confidently
Excellence in Compliance & Transformation: Driving future-ready operations through quality, regulatory, and digital integration.

Investing in a Sustainable Future
On our ESG journey, we help our clients achieve their goals responsibly. We are committed to ethical practices, recognized frameworks and ongoing improvement of our environmental and social impact.

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View selected **KVALITO Case Studies**