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When the Regulations Change, We Help You Stay Ready

Quality & Compliance Support for Life Sciences

How Theoris Can Help

Regulations are complex. Deadlines are tight. If you're launching a product, reacting to new regulatory changes, or updating outdated systems, Theoris creates the clarity and support you need to keep moving forward.

With deep, hands-on experience across the life sciences, our team has supported FDA submissions, CE marking, ISO certifications, and QMS overhauls for medical device, pharmaceutical, and biotech companies.

We collaborate with your team to build reliable systems and processes that meet regulatory requirements and keep daily operations running smoothly.

Our Life Sciences Q&C Expertise

Regulatory Compliance & Strategy

- Global regulatory strategies (FDA, EU MDR, international)
- Compliance audits, gap analyses, & FDA/CE readiness
- Remediation of warning letters & technical files
- Facilities & operations reviews

Quality Management Systems

- ISO, cGMP, ICH, and MDSAP readiness & audits
- CAPA process improvement & supplier/vendor oversight
- QMS outsourcing & due diligence for M&A
- Certification support (ISO 9001, 13485, 17025, 22000)

Regulatory Affairs

- U.S. Class II/III & EU MDR submissions
- Product registrations, complaint handling & recalls
- Regulatory authority interactions & reporting
- Guidance for product development teams

Validation Services

- Validation master planning
- Process, product, equipment, & computer systems validation
- Test methods & special processes validation