



9000 Keystone Crossing, Ste. 230
Indianapolis, IN 46240
1-866-843-6747
www.theoris.com

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 If you're launching a product, reacting to new regulatory changes, or updating outdated systems, Theoris creates the clarity and support you need to keep moving forward.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

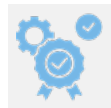
We collaborate with your team to build reliable systems and processes that meet regulatory requirements and keep daily operations running smoothly.

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