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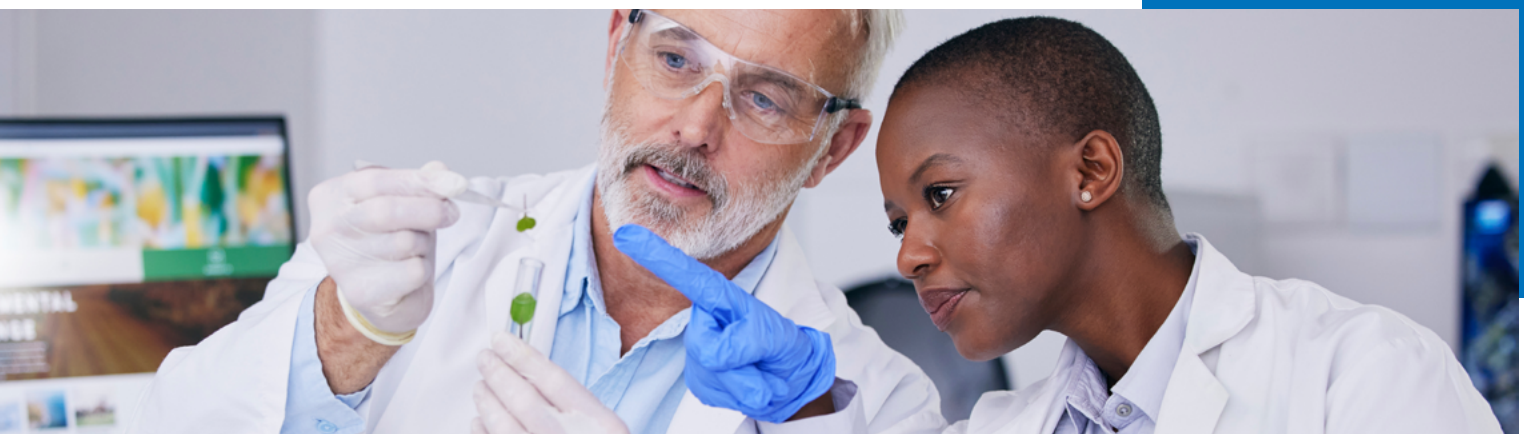
Helping You Achieve Your Business Objectives

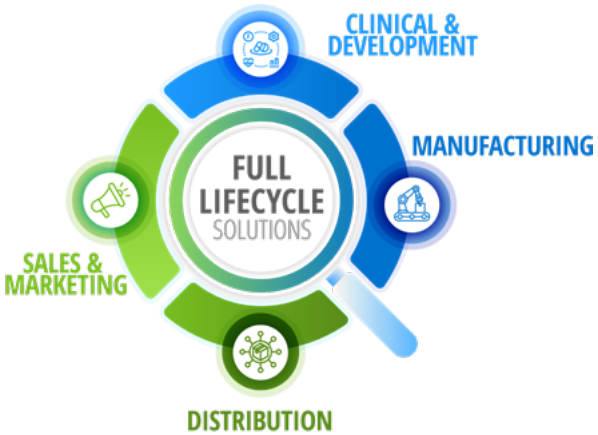
Quality & Compliance Solutions for Life Sciences



How Theoris Can Help

For over 40 years, Theoris has been the trusted partner of life science companies, including those in the medical device, pharmaceutical, and biotechnology sectors, to help them achieve their short and long-term project and resourcing needs. We understand the challenges you face in finding the right talent to succeed in this highly regulated industry. That's why we've developed a flexible model, allowing you to scale your workforce effortlessly, ensuring the right people are available when and where they are needed.

Our expertise spans the entire product life cycle—from clinical and development to manufacturing, distribution, and sales and marketing—providing comprehensive support for your business.



Our Life Science Talent Expertise

Regulatory Compliance

- Global regulatory strategies (FDA/EU)
- Compliance audits & gap analyses
- Mock inspections
- CE Mark
- FDA warning letter responses & remediation
- Facilities operations review

Quality Management Systems

- Quality systems auditing
- Pre-certification auditing
- ISO certification readiness
- Batch records/DMR/DHR
- CAPA services
- Vendor/supplier audits

Regulatory Affairs

- US Class III medical device submissions; EU Class III MDD submissions (change amendments, design dossiers)
- Technical file remediation
- Independent regulatory guidance to product development teams
- Complaint handling & recalls

Validation

- Validation master plan
- Process & product validation
- Computer systems validation
- Equipment validation
- Special processes & procedures
- Test method validation