



# *STRATEGIC COMPLIANCE AND RISK MANAGEMENT*

**At PAREXEL Consulting, we believe that compliance and quality should be managed as any other critical business issue, and that by doing so, companies can reap the benefit of substantial ROI. The business benefits of proper quality management and maintaining a state of regulatory compliance will result in a reduction of direct costs such as reducing rejects to more indirect but substantial benefits such as eliminating adverse events and recalls.**

Through our fusion of scientific, regulatory and business expertise, PAREXEL Consulting has developed a number of integrated expert services to help you align GxP compliance in a fashion that supports your business strategies and goals. Our consultants, including former regulatory authority investigators, experienced in the compliance and business challenges our clients face, develop practical, tailored plans that align global quality capabilities with business strategy. Our experts bring to bear PAREXEL Consulting's broad capabilities, close relationships with regulatory agencies, and credible experience to maximize business performance. Our services are based on the premise that the most cost-effective solution is a plan of action, not a reaction.

## **WHAT WE DO**

- Conduct audits to assess GxP compliance and regulatory risk
- Help clients prepare for and manage FDA inspections, including pre-approval inspections (PAIs)
- Assist with privileged legal issues, data-integrity investigations and litigation-related issues
- Develop and help execute corrective action plans following FDA sanctions such as FDA-483 responses, warning letters and consent decrees
- Assist and represent clients in FDA communications and during inspections
- Provide training in GxP compliance and topical issues for executive management
- Help clients to improve credibility and trust with FDA and other regulators

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- Evaluate and simplify quality and compliance programs
- Perform compliance due diligence of potential product in-licensing or acquisitions
- Process optimization, documentation and compliance

## YOUR ADVANTAGE

- Maintain, or return to, regulatory compliance and minimize downtime
- Understand regulatory challenges, unimpeded by internal barriers to information flow
- Shorten time-to-market and improve asset value
- Align compliance strategy with business strategy
- Optimize business performance through proactive strategies to mitigate compliance exposure
- Maintain effective, reputable relationships with authorities
- Create and maintain a culture of compliance and continuous improvement
- Have correct regulatory data and documentation up to date and compliant, with processes to keep it that way
- Have a risk-management plan in place to proactively manage compliance, including a crisis-management plan
- Work effectively across functions for overall corporate compliance

**Contact us today, so we can introduce you to our Strategic Compliance and Risk-Management experts.**

Our regional leads are always available for a conversation.

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**PAREXEL®**  
*YOUR JOURNEY. OUR MISSION.™*

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