

REGULATORY COMPLIANCE SERVICES FOR LARGE COMPANIES

OUR SERVICES

Regulatory Compliance and Risk Mitigation

- **Auditing:** General GxP audits, Good Distribution Practices, Quality Systems, Management Controls, FDA-type Mock PAIs and Inspections, Verification Audits and Effectiveness Checks, Gap Analyses
- **Data Integrity:** Directed audits and analysis, subject matter training, procedure development, interviews of staff, internal investigations, fraud evaluation, coordinating efforts with legal counsel
- **Strategic Advisement:** Healthcare authority communications/meetings, Consent Decree remediation and verification activities, Warning Letter/483 responses, preparation for or attendance at FDA meetings
- **Inspection Support:** Hosting, front/back room support, mock interviews, readiness assessments, Application conformance reviews, review hosting process and site presentations, tour routes

PAREXEL's Risk Mitigation and Compliance Management experts work seamlessly with colleagues representing biopharmaceutical companies and law firms to form a cohesive team that proactively reduces compliance risk when the trust of regulatory agencies needs to be established or regained.

For more than 35 years, our practical interpretation and implementation of regulatory agency and health authority requirements have been second to none in the industry.

PAREXEL can help you transition to a more proactive, compliance minded organization and away from a state of reactionary crisis management caused by poor systems and individuals failing to execute. These global services are a true differentiator as manufacturing and drug supply become more global.

REDUCE DOWNTIME AND PROTECT REVENUE

In the event of a compliance issue, PAREXEL's established team of experts will deliver the depth and breadth of expertise needed to provide fast, effective responses, rebuild trust with regulators and get operations quickly back on-track.

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RECEIVE RELIABLE GUIDANCE FROM THE MOST EXPERIENCED EXPERTS

Our experts have broad capabilities, close relationships with regulatory agencies, and credible experience to maximize business performance.

PAREXEL consultants, many of whom are former regulatory authority officials and experienced industry representatives, have the experience needed to understand complex regulatory challenges and develop practical, tailored plans that align quality and business strategy.

MITIGATE RISK PROACTIVELY

Our experts offer best-in-class risk-mitigation strategies to mitigate compliance exposure. We can also help optimize business performance through proactive strategies and improve asset value.

GET CROSS-FUNCTIONAL SUPPORT

We help clients work effectively across corporate functions for a holistic culture of compliance.

- **Training:** General GxP topics, data integrity, FDA interaction/prep for FDA inspections, 1:1 mock interviews
- **3rd Party Batch Record Reviews:** Identify records and documents to be reviewed, determine critical elements, implement additional controls, certification (if needed)
- **Deviation Investigations & CAPA:** Conduct investigations, problem identification and resolution, report writing
- **Technical Writing:** SOPs, Validation Protocols and Reports, Annual Product Reviews, FDA correspondence, audit responses, strategic plans, other technical reports.
- **Data Trend Analysis:** Collection, review, analysis and summary reporting

CORPORATE HEADQUARTERS

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