

# REGULATORY COMPLIANCE SERVICES FOR SMALL TO MID-SIZED 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
- **Inspection Support:** Hosting, front/back room support, mock interviews, readiness assessments, Application conformance reviews, review hosting process and site presentations, tour routes
- **Training:** General GxP topics, data integrity, FDA interaction/prep for FDA inspections, 1:1 mock interviews

PAREXEL's Risk Mitigation and Compliance Management team provides a complete solution to support GXP compliance – helping your organization align quality with strategy, mitigate compliance risk, develop a compliance culture and build trust with regulators.

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. 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 has the established team of experts needed to provide the fastest, most effective, response to rebuild trust with regulators and get operations quickly back on-track.

## 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 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.

- **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
- **Strategic Advisement:** Healthcare authority communications/meetings, Consent Decree remediation and verification activities, Warning Letter/483 responses, preparation for or attendance at FDA meetings

## CORPORATE HEADQUARTERS

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