PPD®
Part of Thermo Fisher Scientific

HELPING DELIVER LIFE-CHANGING THERAPIES

PPD® FUNCTIONAL SERVICE PARTNERSHIP (FSP) SOLUTIONS

QUALITY ASSURANCE

DISCOVER THE RIGHT SOLUTION TO ENSURE THE SAFETY AND INTEGRITY OF YOUR CLINICAL TRIAL

To ensure the safety and integrity of your clinical trials, it's imperative to adhere to protocols, comply with international regulatory guidelines, and protect the rights and welfare of study participants. You also need a Quality Assurance (QA) partner with extensive local knowledge and know-how to help you navigate the nuances of country-specific rules and regulations, mitigate risks, drive compliance, and — most importantly — keep patients safe.

PPD Functional Service Partnership (FSP) Quality Assurance Solutions provides the strategic and operational expertise biotech, biopharmaceutical, and medical device organizations need to ensure the integrity and safety of their clinical trials. Whether you need specialized functional support or highly skilled staff to complement your existing capabilities, we draw from the people and best practices of a proven quality management system (QMS) to deliver bespoke solutions tailored to your unique needs — while providing much needed resource flexibility, reliability, and continuity.

Proven track record

- **30+ years** of QA experience
- **More than 2,500 contracted audits** across nearly 70 countries
- **Approximately 400 Clinical Supplies QA awards** for almost 200 customers since 2012
- **More than 600 Good Practice (GxP) quality experts** in every region around the world

COMPREHENSIVE QUALITY ASSURANCE (QA) SOLUTIONS TO ENSURE CLINICAL TRIAL INTEGRITY

PPD FSP QA Solutions helps ensure the reliability and integrity of your clinical trials with a proven track record of delivering comprehensive solutions. Our breadth and depth of strategic and operational expertise helps keep your studies on schedule by rigorously assessing your clinical trial programs and systems to ensure that they meet ethical, regulatory, and legal requirements and protect study participants.

Our QA solutions include:

Study-Specific Quality Support

Act as a dedicated QA point of contact to assist customer and study teams with all quality aspects of the trial

Inspection Readiness

Support the preparation, hosting, response management, and follow-up of inspections of regulated operations

Supply Chain Quality Management

Support oversight of product manufacturing, clinical packaging and labeling, and distribution to sites

Government Consulting

Provide QA services specific to the requirements of government-funded studies

Information Systems Quality Assurance Consulting

Assess quality management systems, including gap analysis, risk assessment, and procedural development; consultancy and training for validation and data integrity

Auditing

Provide audits of regulated operations to support clinical trial submission, including:

- Clinical investigator sites
- Processes
- Vendors
- Files
- Databases
- Pharmacovigilance
- Computer systems and validation
- Electronic records and signatures
- Data integrity
- Suspected misconduct
- Qualified Persons (QP)

LEVERAGE LOCAL KNOWLEDGE AND GLOBAL EXPERTISE TO MITIGATE RISK, DRIVE COMPLIANCE, AND PROTECT PATIENTS

For each engagement, PPD FSP QA Solutions employs dedicated teams of quality assurance experts selected for their customer-first problem-solving mindset, extensive risk assessment skills, and local experience and expertise. Located throughout the world, our team members provide in-depth knowledge and know-how of their home country's rules and regulations to help you better navigate the nuances of local regulatory requirements.

Dedicated team of QA experts

- Customer-first problem-solving mindset
- Adherence to tight timelines
- Extensive risk assessment skills
- In-depth knowledge of local rules and regulations
- Strong collaboration skills
- Keen understanding of study execution and performance

Strong culture of training and accountability

- Embrace techniques from industry-standard quality programs:
  - Six Sigma
  - Lean Sigma
  - Total Quality Management
  - ISO 9001
- Conduct regular reviews of training needs
- Perform semi-annual performance reviews
- Assign role-specific trainings within the learning management system (LMS)

BESPOKE SOLUTIONS TAILORED TO MEET YOUR UNIQUE NEEDS

Our extensive QA expertise allows us to quickly identify the best engagement model for your needs. Using best practices and lessons learned from our decades of experience, our QA solutions support a customizable mix of systems, processes, and oversight — yours or ours — and provide the flexibility to either embed staff within your workforce using your existing infrastructure, SOPs, and processes or take the business fully in-house using PPD's SOPs, processes, and systems.

Quality management system (QMS)

Whichever level of engagement you choose, our QA solutions draw from a proven QMS that helps keep your clinical trial in compliance with all applicable laws, regulations, and institutional policies through the systematic use and application of:

- Well-established QA best practices
- Key performance indicators
- Key quality indicators
- Data analytics
- Audit and quality event (QE) outcomes
- Corrective and preventive actions (CAPA)
- Executive management review

Flexible pricing models:

- Full-time equivalent (FTE) models
- Unit-based models
- Time & materials models
- Hybrid models

Talk with your account representative or visit **ppd.com/fsp-quality-assurance** to learn more about how PPD FSP Quality Assurance Solutions help you ensure the safety and integrity of your study.

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