OVERVIEW

Quality and Compliance: Maximizing Quality, Minimizing Risk

PPD has been executing quality and compliance programs for more than 30 years. We offer the full GxP range of effective quality solutions and expert guidance to rapidly identify and minimize risk to our customers.

Upholding quality in clinical research

When it comes to the integrity of your data in the trial conduct, minimizing risk is a priority. Seemingly small missteps in compliance can threaten your compound under investigation or can impact any evidence-based data used for real world evidence support or patient access work, all of which may impact market access or regulatory review and approval.

PPD is your partner, rigorously assessing systems and programs to identify and mitigate risks that could jeopardize your program's success.

WHO WE ARE AND HOW WE HELP

600+ GxP quality experts around the world

- Auditing
- Government Consulting
- Supply Chain Quality Management
- eTMF Analysis
- Study-Specific Quality Support
- Inspection Readiness
- QA Consulting

Our expert involvement

- We protect trial participants' rights and welfare
- We verify the integrity of scientific data
- We evaluate adherence to protocols and international regulatory guidelines

Targeted Advice, Coaching and Auditing in Every Region Worldwide

- Auditing all aspects of regulated operations including clinical investigator site, process, vendor, study file, database, pharmacovigilance, Qualified Person (QP) audits of the supply chain to support Clinical Trial submissions, computer systems and validation, electronic records and signatures, data integrity and suspected misconduct
- QA services specific to requirements of government funded studies
- Supply chain quality oversight of product manufacturing, clinical packaging and labeling, and distribution to clinical investigator sites, which may encompass Quality Agreement development, mock recalls and product release by QPs (all investigational product types, including cell and gene therapy)
- Compliance analysis of active electronic trial master files (eTMF) through independent review, contributing to TMF quality
- Study-specific, dedicated support to act as customer and study team QA point of contact, assisting with many quality aspects of the trial
- Inspection readiness including preparation, hosting, response management and follow-up
- QA consulting and oversight to assess quality management systems, including gap analysis, risk assessment and procedural development, as well as consultancy and training for validation and data integrity

More than **2,500** contracted audits since 2012 across **66** countries

Nearly **400** Clinical Supplies QA awards for almost **200** customers since 2012

WHY PPD?

CUSTOMIZED SOLUTIONS TO FIT EVERY TRIAL, EVERY COUNTRY AND EVERY CUSTOMER

Global Reach – Deep knowledge of country-specific regulatory requirements and broad experience interpreting the nuances of the global regulatory framework

Holistic View – Keen understanding of operations, clinical supplies, real world evidence and market access, pharmacovigilance, regulatory affairs and site procedures establishes a multidimensional view of study execution and performance, so that no detail is overloooked

Standardization – Consistent training and SOPs for every QA professional in every country ensure adherence to the highest standards

Accuracy and Specificity – Detailed reports written in understandable language enable informed and swift decision making

High Capacity – Rapid mobilization of auditors worldwide to perform high volumes of audits quickly

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