

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 trials

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, impacting regulatory review and approval.

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

WHO WE ARE AND HOW WE HELP.



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, clinical trial submissions by Qualified Person (QP), 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 Qualified Persons (all investigational product types, including cell and gene therapy)
- Compliance analysis of active electronic trial master files (eTMF) through independent review, contributing increasing 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



Nearly **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, pharmacovigilance, regulatory affairs and site procedures establishes a multidimensional view of study execution and performance, so that no detail is overlooked



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