Practical Solutions

THE PRACTICAL SOLUTIONS GROUP, LLC

Capability Statement

The Practical Solutions Group, LLC is a consultancy to pharma, biotech, medical device and supporting companies (e.g., CROs, CMOs, distribution centers, packaging/labeling facilities, software companies). We focus on GXP/ISO compliance and CMC from the operational perspective, allowing us to provide deliverables that help company management to make sound business decisions regarding the status of company operations. Our view is that every regulatory compliance issue is symptomatic of a much larger operational problem, and we help companies to avoid and/or remedy both. Our core areas of expertise are as follows:

Quality Infrastructure and Business Processes

- Quality system development (e.g., GMP, GLP, GCP, 21 CFR part 820, ISO 13485)
- FDA 483/warning letter remediation support
- Client representation at external audits
- Risk and operations assessment
- Audit program design and implementation
- Investigations/complaints
- Quality/operational problem resolution
- SOP review and development
- Change control process development
- Compliance and operations training
- Compliance/quality problem resolution
- QA/QC oversight: e-submissions, data migration, system integration/validation
- CMC support

Computer Systems Validation/21 CFR Part 11

- Develop and implement computer system qualification and validation strategies
- Assess and document regulatory compliance and operational system risks
- Develop documentation (e.g., master / test / remediation plan, IQ/OQ/PQ protocols, reports, traceability, requirements, SOPs, UAT)
- Provide 21 CFR part 11 regulatory training
- Develop 21 CFR part 11 interpretation
- IT infrastructure planning and assessment
- Evaluate operational, development, testing and/or documentation issues for 21 CFR part 11 compliance, HIPAA and Safe Harbor

Audits and Assessments

- Operational and regulatory due diligence
- Outsource partners/suppliers (e.g., CROs, raw material suppliers, imaging companies)
- Mock FDA inspections/PAI readiness
- Manufacturing operations
- Analytical/bioanalytical lab operations
- Labeling/packaging operations
- Distribution operations
- Internal QA operations
- Technology transfer/method validation/batch record review
- Annual product and stability program review
- Quality and fraud investigations
- Clinical operations

Client Base

- Analytical/clinical/pre-clinical laboratories
- Biotech companies
- Contract manufacturers/packagers
- Contract research organizations
- Data hosting facilities
- Distribution centers
- Environmental companies
- Financial institutions
- Healthcare companies
- Imaging core labs
- Medical device companies
- Pharmaceutical companies
- Software suppliers, including SaaS vendors
- Specialty sub-investigators

Selecting and Managing Outsource Partners

- Select/manage outsource partners/projects
- Streamline operations, identify required resources, establish realistic timelines
- Appraise maintenance/support capabilities

Our Value Proposition

Through assessing the efficiency of operations, we help you to achieve and maintain regulatory compliance without permanently increasing costs, expanding timelines and/or adding resources.

Regulatory Compliance Simplified

152 Witherspoon St. | Princeton, NJ 08542 | 609.683.0756 | Fax: 609.683.0758 | www.practicalsolutionsnj.com