Services Menu

Our industry, compliance, and business knowledge provide a unique, timely trifecta. Clients rely on PDC to efficiently align risk-based corporate and drug development strategies that ensure patient safety, data integrity, and overall compliance while meeting corporate goals.

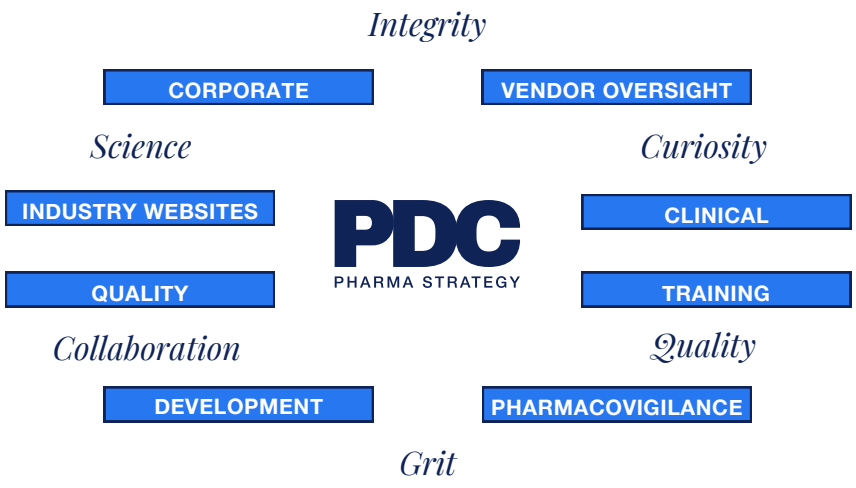
Our Service Menu contains *examples* of our service area solutions. PDC develops and implements fit-for-purpose solutions because we understand that every company is unique. Reach out to discuss your scenario and how we can help you.

We support clients across the development & product lifecycle

GLP | GCP | GDP | GMP | GVP | CSV

Our Unique Value

1. PDC was founded by a GxP QA and compliance leader with over 30 years of comprehensive industry experience.
2. Our quality standards are based on regulatory requirements and expectations, getting it right the first time, and doing the right thing every time; we exceed industry standards.
3. We champion client and sponsor oversight because we know why it's critical to patient safety, data integrity, public trust, and business success.



Quick Links

PDC PHARMA STRATEGY

Contact Us

+1 (267) 980 - 4566
hello@pdcstrategy.com
pdcstrategy.com
PDC Pharma Strategy

Corporate

Operations | Compliance | Communication

What We Do

Enable life science leaders to drive efficient, compliant product development and corporate success.

Why

The number of industry leaders has skyrocketed over the last fifteen years, bringing enhanced innovation and corporate change. Knowledge gaps negatively impact decision-making and slow progress. We are uniquely poised to offer services that fill those gaps and ensure your company is well positioned for success in our highly regulated industry.

Keys to Corporate Success

- Science
- Strategy
- Compliance
- Knowledge
- Leadership

> *While data integrity is of utmost importance in clinical research, moral integrity is of greater importance.*

- Ravi Madan, MD, Senior Clinician, NCI

Corporate Operations

- Organizational Structure Assessment & Development
- Senior & Functional Leadership Candidate Strategy & Assessment
- Job Description Development & Leveling
- Governance / Oversight Strategy & Development
- Business Process Development, Documentation & Training
- Project Management

Corporate Quality & Compliance

- Compliance Assessment & Strategy
- Fractional Chief Compliance Officer Services
- Compliance Manual & Policy Development
- Risk Management
- Legal Review & Consulting
- Quality Management
- Organizational Culture Assessment & Strategy
- Alignment of Corporate & GxP Requirements, Where Applicable
  - Documentation Templates / Development / Retention Strategies
  - Procurement / Service Vendor Selection /Electronic Systems
  - Data Privacy & Protection Consulting
  - Fractional Data Protection Officer Services
- Commercialization Organizational & Compliance

Corporate Growth & Communications

- Industry-Specific Website Development & Design
- Pitch Deck Development
- Due Diligence Preparation
- IPO Planning & Readiness
- Commercialization Operational Consulting
- Internal & External Presentations & Communications
- Corporate Board Presentation Development
- Intranet Development

Executive-Level Training

- Refer to our Training Services

Quality

Quality Management | Quality Assurance

What We Do

We develop and execute risk-based QA strategies that support comprehensive corporate and regulatory compliance throughout the drug development process and product lifecycle.

Why

Applying creative, innovative approaches to quality systems and assurance makes a positive, lasting impact on the industry's ability to ensure patient safety for decades to come.

Quality Management Systems

- Strategic QMS Development & Execution
- Functional & QA Process & Documentation Development & Assessment
- Quality Risk Management Development
- eQMS Solutions
- QMS Harmonization
- Quality Unit Resourcing
- Internal Audit & Remediation Services

Clinical Quality Assurance

- CQA Program Development & Infrastructure Planning
- Protocol-Specific CQA Plans
- Management & Execution of CQA Plans
- Clinical Investigator Site Audits
- TMF Audits
- Database Audits
- Document Audits
  - IB
  - Protocol
  - ICF
  - CSR
  - Safety Narrative
- Regulatory Submission Document Audits
  - Clinical Summaries
  - Safety Update Reports
  - ISEs / ISSs
- Data Quality Audits (TLF & Databases)
- Ad Hoc CQA Consulting

GxP Vendor Qualification & Oversight

- Vendor Oversight Process Development
- Vendor Qualification Assessment & Auditing
- Risk-Based Vendor Management Process Development & Execution
- Quality Agreement Development & Review
- Management of Audit Programs & Individual Audits
  - CROs
  - Phase I Units
  - Imaging
  - Packagers
  - Distributors
  - Clinical Laboratories
  - Non-Clinical Laboratories
  - eSystem Providers
  - Registries
  - IRBs / EC
- Vendor Quality & Timeliness KPI Development

> *Cost is more important than quality but quality is the best way to reduce cost.*
>
> - Genichi Taguchi, Engineer and Statistician

Quality

Quality Management | Quality Assurance

Quality Related Training

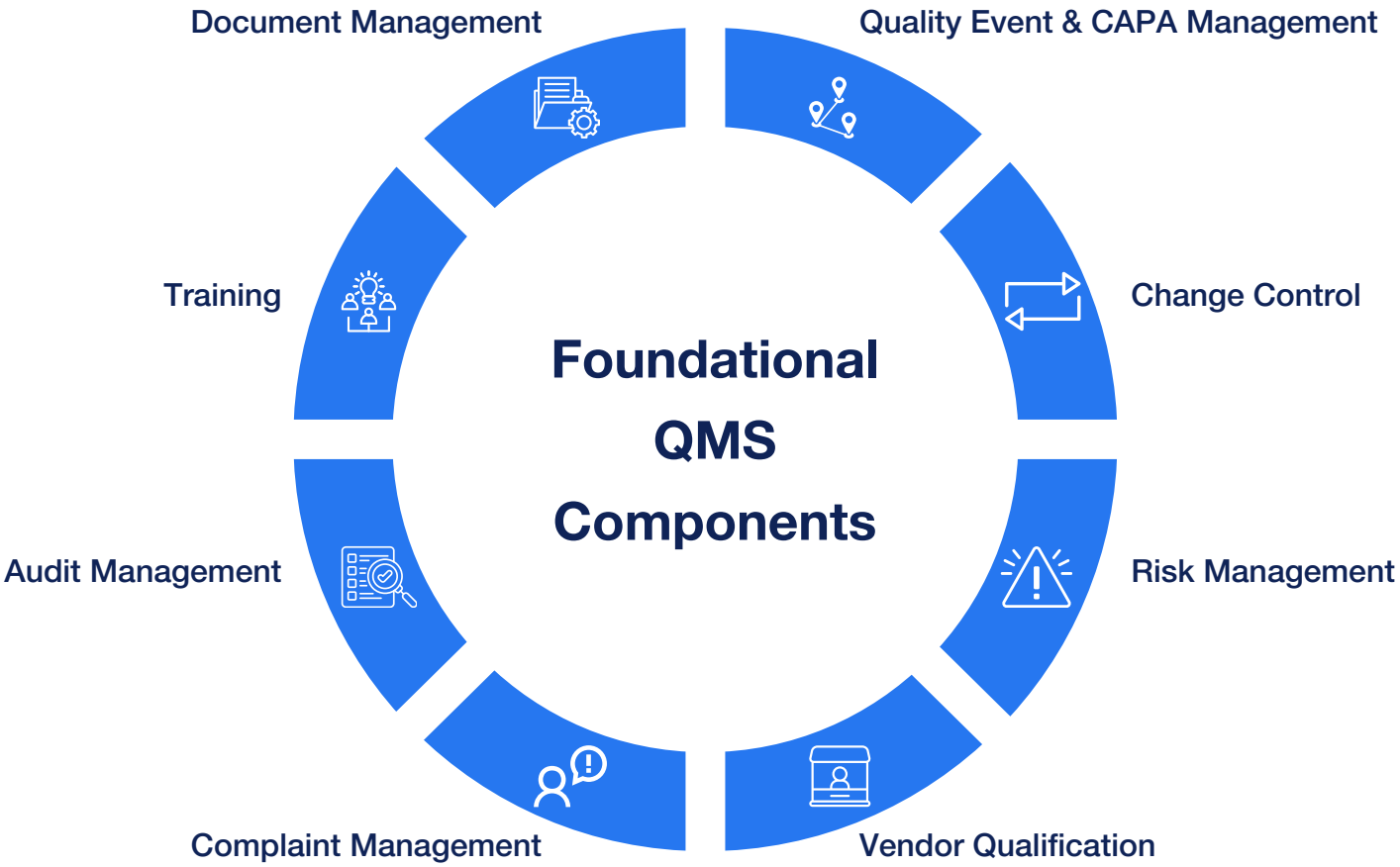
- Refer to our Training Services

Full-Service Solutions

- PDC offers an innovative full-service, plug-in QA function model.
- Contact us to find out if your company is a candidate for this unique industry solution.

GxP Inspection Readiness & Support

- Inspection Process Development
- Inspection Readiness Assessment & Preparation
- Storyboard Development
- Inspection Presentation Review & Development
- Functional & Individual Inspection Interview Coaching
- Mock Regulatory Inspections
- Tailored Mock Inspection Activities
- Inspection Facilitation Support
- Inspection Back Room Expert Support
- Regulatory Observation Response Consulting & Support
- Post-Inspection Remediation



Clinical

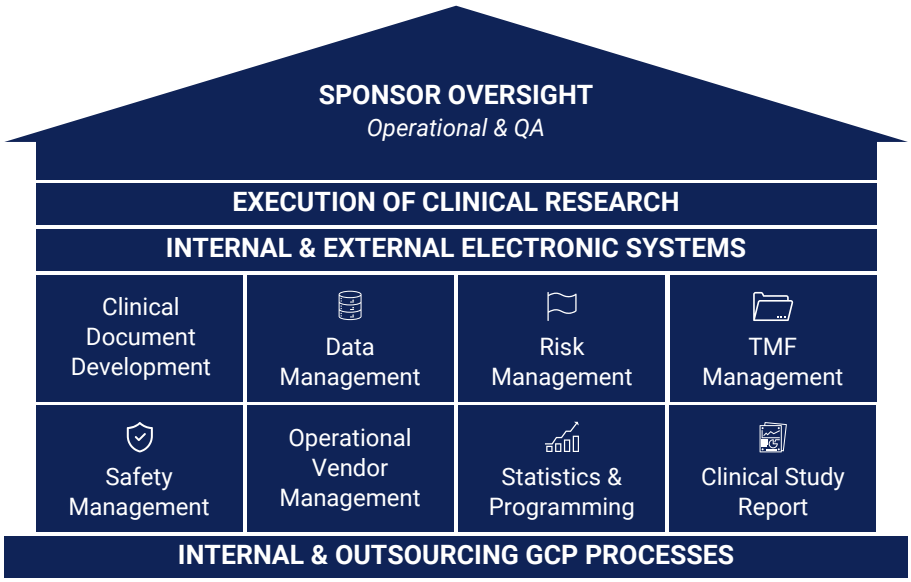
Clinical Development | Operations

What We Do

We offer innovative, efficient, risk-based clinical research services while proactively fueling client and sponsor oversight. We build bonds that drive success and keep sponsors appropriately engaged, aware, and in control of drug development.

Why

We understand the roles and responsibilities of clinical research - why they exist, and how they serve to ensure data integrity and patient safety. The current model can be improved.



Clinical Development

- Market Research & Product Development Planning
- Protocol Development / Coordination
- Clinical Process & SOP Development
- Risk Management Process Development & Execution
- Operational Vendor Oversight Strategy Development & Execution
- Operational Quality Control Strategy & Execution
- Clinical Electronic Systems Alignment & Strategy Consulting
- Operational Clinical Support for Audit & Inspection Responses

Clinical Document Quality Control

- IBs / Package Inserts
- Protocols & ICFs
- CSRs & Subject Safety Narratives
- Regulatory Submission Packages & PSURs
- CTD Clinical Summaries, ISE & ISS
- TMF QC & Support

Project Management

- PM Plan Development & Management
- PM: Start-Up, Maintenance, Follow-Up, Close-Out
- Internal & External Kick-Off Meetings
- Core Team Meetings
- Data Review Meeting(s)

Biostatistics & Statistical Programming

- Statistical Analysis Plan
- Statistics PM
- Data Review Plan Development
- TLF Development & Delivery
- ADaM Development & Delivery
- Trial Design Domains
- SDTM Development & Delivery
- Data Listing Programming for SAE Reconciliation
- Final Dataset Transfer

Clinical

Clinical Development | Operations

Medical Writing

- Protocol Development / Coordination
- ICF Preparation / Review
- CSR Patient Narrative Development & Review
- CSR Development & Review
- CSR ePublishing

Data Management & Clinical Programming

- DM Project Management
- DMP: Development & Management
- Data Validation Plan
- Annotated eCRF / eCRF Completion Guidelines
- eCRF Development
- Database Set-up
- Database User Access Administration
- Edit Check Programming
- UAT
- UAT of Integrated Modules
- Run & Deliver Listings
- Run & Deliver SAE Listings
- Medical Data Review Listings
- Custom Listings
- Secure Server Set-Up & Maintenance
- Coding Set-Up
- Coding
- Lab / Vendor Data Reconciliation
- Data Entry
- Query Management
- Data Validation / Manual Checks
- SAE Reconciliation
- Database Lock
- Database Archival

Site Monitoring & Management

- Clinical Monitoring Plan Development & Management
- Start-up Plan Development & Management
- CDAs
- Potential Site List Development
- Site Survey Template Development
- Site Survey Distribution & Reporting
- Final Site List Production
- CSA Templates & Management
- Site Contract Negotiations & Management
- Budget Management
- ICF Preparation & Review
- IRB / EC Submissions & Maintenance
- Essential Document Processing, Review, Submission & Approval
- Site Qualification Visits
- Site Monitoring: SIVs, IMVs, RIMVs, Site Handover Visits & COVs
- TMF Development & Management
- ISF Preparation & Distribution
- IB Distribution

Safety & Medical Monitoring (Including DSMB / DMC)

- Refer to our PV Services

Clinical Related Training

- Refer to our Training Services

Everything is theoretically impossible, until it is done.

- Robert A Heinlein, Author of *Stranger in a Strange Land*

Pharmacovigilance

Development | Oversight | Quality Assurance

What We Do

We offer risk-based PV solutions that support client and sponsor oversight. We enable clients and sponsors to execute safety governance of their investigational and marketed products with the joint goal of improving public health and growing consumer trust in our industry and the science that fuels it.

Why

Our highest goal is to impact and preserve patient safety now, and in the decades ahead. We understand the complexity of the PV universe, the numerous factors that fuel its expansion for a company and product, and why. We are compelled to use that knowledge for good.

Operational Oversight & Execution Services

- Internal Sponsor Process Development & Assessment
- PV Vendor Selection & QA Qualification
- Operational Oversight of PV Vendors
- PV Process & SOP Development
- Vendor & Safety Process Development
  - Clinical PV
  - Post-Marketing PV
  - Case Management
  - Signal Detection
  - Safety Governance
  - IB & Package Insert Management
  - PV eSystems
  - Reconciliation
  - Regulatory Reporting
- Operational & Safety Oversight Documentation
- Case Processing Flow Assessment & Streamlining
- PV Operational Post-Audit & Inspection Remediation
- Commercialization and Post-Marketing PV Strategy
- PSMF Development, Maintenance & Assessment
- REMS Program Assessment

> *Wherever the art of medicine is loved there is also a love of humanity.*
>
> - Hippocrates

PV Process Development & Improvement

- Operational PV Process Development
- PV Process Assessment & Streamlining
- PV Process, Job Description, & Org Chart Alignment

GVP Quality Systems & Assurance

- Refer to our Quality Services

PV Inspection Readiness & Support

- Refer to our Quality Services

PV Related Training

- Refer to our Training Services

Training

Corporate | Regulatory | Operational

What We Do

PDC offers a variety of training topics and options ranging from pre-developed training presentations, development of targeted training, development of training programs, provision of virtual or onsite training courses and programs, coaching, and on-the-job training.

Don't see what you're looking for? Contact us to discuss our needs and how we can help.

Corporate

We provide 1:1 and team executive-level training. Our goal is to provide targeted industry-specific knowledge. To understand the advantages for this, read the following articles by PDC Founder and CEO, Penelope Przekop:

- 3 Strategies To Lead Clinical Research With Moral Integrity (Clinical Leader)
- How Quality Management Science Can Build A 5-Star Company (Life Science Leader)
- How Biopharma Leaders Can Ward Off A Perfect Storm: Part 1 (Life Science Leader)
- How Biopharma Leaders Can Ward Off A Perfect Storm: Part 2 (Life Science Leader)

Industry Topics

- History of the Pharmaceutical Industry
- The Drug Development Process
- The Science of Quality Management
- Business & Technical Writing
- Business Model Development in Pharma

> *Knowing what you don't know is more useful than being brilliant.*
>
> - Charlie Munger, American Businessman, Investor, & Philanthropist

Quality

Regulatory Health Authority

- Global GxP Regulations & Guidelines
  - EU GDPR
  - ICH GCP
  - EMA PV Modules
  - FDA Part 11 Compliance
- Advanced GDPR in Clinical Research
- Advanced Regulatory Training
- HIPAA

Other

- Advantages of Quality Management in Clinical Research
- Quality Management Systems
- Quality Risk Management
- CAPA Management
- Quality Event Management
- Technical Writing
- Document Control

Training

Corporate | Regulatory | Operational

Quality Cont.

Other Cont.

- SOP Development
- SOP Writing
- Template & Form Development
- General Auditing
- GxP Auditing
- GVP Auditing for GCP Auditors
- Differences & Similarities of QA Roles Across GxPs
- Aligning Org Charts, Job Descriptions & CVs
- Quality Assurance Soft Skills
- Guiding Inspection Readiness
- GxP Inspection Readiness
- Inspection Facilitation
- Developing a Clinical QA Plan
- Quality Agreements
- Creating a Compliant Training Program

Pharmacovigilance

- GVP & PV Quality Systems
- PV Documentation & Retention
- Safety Governance
- PV Operations
- Case Processing
- Data Management Review Boards
- Clinical & Safety Database Reconcilition
- Post-Marketing GVP & The PV Universe
- Company-Wide AE & PC Reporting
- The Role of the QPPV
- The PSMF
- Unsolicited Versus Solicited AEs
- Signal Detection
- GVP for Biologics, Psychedelics & Radiopharma

Clinical

Sponsor & Vendor

- Clinical Research Overview
- PV for Clinical Staff
- Risk Management
- Clinical Vendor Selection & Oversight
- Sponsor Oversight Empowerment
- Quality by Design
- CRA Training
- Protocol Deviation Management
- Data Management
- eCRF Training
- Investigator Site Training
- Technical Writing
- Reviewing Monitoring Reports like an Inspector

Principal Investigator & Clinical Staff

- Intro to Clinical Research
- Patient Data Flow: From Visit to Submission
- Advanced Clinical Research Process
- The Role of the Study Coordinator
- Investigator Site Files Setup & Management
- How to Work with Clinical Monitors
- Informed Consent
- IP Management
- Safety & AE Reporting
- Regulatory Inspection Overview
- Inspection Preparedness

> *Risk comes from not knowing what you're doing.*
>
> - Warren Buffet, CEO Berkshire Hathaway

Acronyms

Acronym	Meaning
ADaM	Analysis Data Model
AE	Adverse Event
CAPA	Corrective and Preventive Action
CDA	Confidential Disclosure Agreement
COV	Close-Out Visit
CQA	Clinical Quality Assurance
CRA	Clinical Research Associate
CRO	Contract Research Organization
CSA	Clinical Services Agreement
CSR	Clinical Study Report
CSV	Computer System Validation
CTD	Common Technical Document
CV	Curriculum Vitae
DM	Data Management
DMC	Data Monitoring Committee
DMP	Data Management Plan
DSMB	Data and Safety Monitoring Board
EC	Ethics Commitee
eCRF	Electronic Case Report Form
EMA	European Medicines Agency
eQMS	Electronic Quality Management System
EU	European Union
FDA	U.S. Food and Drug Administration
GcLP	Good Clinical Laboratory Practices
GCP	Good Clinical Practices
GDP	Good Documentation Practices
GDPR	General Data Protection Regulation
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GVP	Good Pharmacovigilance Practices
GxP	Good “x” Practices
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator Brochure

Acronym	Meaning
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IMV	Interim Monitoring Visits
IP	Investigational Product
IPO	Initial Public Offering
IRB	Institutional Review Boards
ISE	Integrated Summary of Effectiveness
ISF	Investigator Site File
ISS	Integrated Summary of Safety
IT	Information Technology
KPI	Key Performance Indicator
NCI	National Cancer Institute
PC	Product Complaint
PHI	Protected Health Information
PI	Principal Investigator
PM	Project Management
PSMF	Pharmacovigilance System Master File
PSUR	PeriodicmSafety Update Report
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
QPPV	Qualified Person for Pharmacovigilance
REMS	Risk Evaluation and Mitigation Strategy
RIMV	Remote Interim Monitoring Visit
SAE	Serious Adverse Event
SDTM	Study Data Tabulation Model
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
TFL	Tables, Figures, and Listings
TMF	Trial Master File
UAT	User Acceptance Testing