

Contents

l
L
2
2
3
1
1
1
1
5
1

Nav Bar

Home	About	Services	Blog	Contact
		Corporate		
		Web Development		
		Quality		
		Clinical		
		Pharmacovigilance		

CTA

How can we help you?

Reach out to schedule a consultation.



Footer

Home	About	Services	Blog	Contact
		Corporate		
		Web Development		
		Quality		
		Clinical		
		Pharmacovigilance		

Home

Paving the way for a healthier future.

We innovate risk-based, data driven solutions that support corporate goals, fuel scientific passion, and meet global regulatory requirements.

Join our mission to build consumer trust for generations to come.

Our Solutions

Corporate

Build an industry-specific corporate infrastructure that supports patient safety, company growth, and business success.

Quality

Establish an innovative, fit-for-purpose quality management system that enables seamless risk management and produces required regulatory documentation.

Clinical

Develop clinical programs guided by practical processes that simplify risk-based compliance, maintain data integrity, and keep patients safe.

Pharmacovigilance

Develop and execute pharmacovigilance processes and oversight to ensure patient safety and data integrity.

We Know Pharma



100+ industry clients value our services and solutions.

Client Testimonials

XXXX

About

Our Mission

We develop risk-based, data driven solutions that spur positive industry change.

Our Vision

To pave the way for a healthier future

Our Guiding Values

Integrity: Drive progress with ethical actions.

Quality: Elevate the standard.

Curiosity: Unlock the door to endless possibilities.

Science: Disrupt with objectivity.

Collaboration: Build strong bonds; yield bright results.

Grit: Conquer insurmountable challenges.

Our Evolving Story

In 2008, Penelope Przekop founded PRZ Consulting after nearly 20 years of industry experience leading global quality and compliance teams across functional areas at Novartis, Covance, Wyeth, and Johnson & Johnson.

In 2017, PRZ Consulting was rebranded as PDC Pharma Strategy with a mission of developing innovative, fit-for-purpose quality and compliance solutions.



In January 2024, PDC Pharma Strategy expanded its team, focus, and service offerings, all with a goal to pave the way for a healthier future.

Our Core Team

Our passionate and dedicated team is a melting pot of diverse talents, combining creativity and innovation to tackle challenges head-on. Together, we unite under a common vision, leveraging our unique backgrounds to drive transformative solutions that leave a lasting impact.

Penelope Przekop, MSQA, RQAP-GCP

Janet Flisak, MBA, BSN

Valerie Przekop, MS

Robert Durkin, XXX

Malou Refuerzo, MBA

Mimi Kim, RPh

Jane Frost

Beth Nelson

Join Our Team

Discover how your skills and talents can not only thrive but also flourish in our supportive culture that encourages personal and professional growth.

As Seen In

Our contributions have been widely recognized by leaders across the industry.

Corporate

Corporate Solutions



Establish a foundation that supports regulatory requirements while driving financial success.

Our Services

We apply a broad and deep understanding of the industry, its history, the current landscape, and our vision for a healthier future to proactively address your challenges in the following areas and more:

- Corporate Compliance Assessment & Strategy Development
- Fractional Chief Compliance Officer Services
- Fractional Data Protection Officer Services
- Data Privacy & Protection Consulting
- Corporate Organizational Structure Consulting
- Job Description Development & Leveling
- Industry-Specific Website Development

Optimized AI Query Crafting: Enhance the quality of your AI interactions with our expert assistance. We'll guide you in framing ChatGPT and other AI questions to yield insightful, accurate, and high-quality results.

View our **Services Menu** for a detailed list of our solutions.

Training Solutions

We offer a variety of training options for corporate leaders and teams.

View our **Services Menu** for a detailed list of topics and options.

What Clients are Saying

XXX

Our Leadership

Penelope Przekop, MSQA, RQAP-GCP



CEO

<u>Bio</u>

<u>LinkedIn</u>

Robert Durkin

XXX

Bio

LinkedIn

Related Content

Read more from PDC's team of experts.

Web Development

Industry Website Solutions

Relay professionalism. Communicate expertise. Instill trust.

What Clients are Saying

XXX

Quality

Quality Solutions

Ensure quality and compliance with innovative, risk-based, fit-for-purpose solutions.



Our Services

Our expertise and experience spans GxPs and therapeutic areas.

We apply a broad and deep understanding of the industry, its history, the current landscape, and our vision for a healthier future to proactively address your challenges in the following areas and more:

- Quality Management Systems (QMS)
- Quality Risk Management
- Vendor Qualification & Oversight
- Clinical Quality Assurance
- Management of Audit Programs & Audit Execution
- Quality Event & CAPA Management
- Inspection Readiness, Facilitation & Support

Optimized AI Query Crafting: Enhance the quality of your AI interactions with our expert assistance. We'll guide you in framing ChatGPT and other AI questions to yield insightful, accurate, and high-quality results.

In addition to the areas listed above, we offer an innovative full-service, plug-in QA functional model. **Contact us** to find out if your company is a candidate for this unique industry solution.

View our **Services Menu** for a detailed list of our solutions.

Go here to explore our pharmacovigilance quality and operational services.

Our Vision for You

Align compliance and corporate strategies.

- Develop a flexible framework that supports and documents compliance.
- Proactively include quality assurance expertise to ensure GxP data integrity.



Build a fit-for-purpose Quality Management System (QMS).

- Establish a practical QMS that pivots and evolves with the clinical development program.
- Institute processes that optimize resources and demonstrate oversight.

Establish a risk-based approach that establishes proof of compliance.

- Team with an expert to ensure adequate risk-based oversight.
- Build a documented compliance profile throughout the drug development process.

Establish a reliable inspection readiness approach.

- Leverage our existing inspection readiness materials.
- Deploy our innovative mock inspection approaches and activities.

Training Solutions

We offer a variety of training options in the quality and compliance space.

View our **Services Menu** for a detailed list of topics and options.

What Clients are Saying

XXX

Our Leadership

Penelope Przekop, MSQA, RQAP-GCP

CEO

<u>Bio</u>

LinkedIn

Related Content



Read more from PDC's team of experts.

Clinical

Clinical Solutions

Maintain direct oversight and control over clinical development and operations with innovative, practical solutions and collaboration.

Our Services

Our services and solutions ensure appropriate, actionable sponsor oversight of GCP activities across therapeutic areas. We're dedicated to the open communication and collaboration required to build a cohesive team.

Founded and led by a quality assurance and compliance expert

Everything we do is rooted in dedication to customer focus, quality management, and the regulatory requirements designed to ensure high integrity data and patient safety.

We apply a broad and deep understanding of the industry, its history, the current landscape, and our vision for a healthier future to proactively address your challenges in the following areas and more:

- Market Research & Product Development Planning
- Clinical Process & SOP Development
- Project Management
- Vendor Selection & Operational Vendor Oversight
- Clinical Data Management
- Medical Writing
- Contract & Budget Management

Optimized AI Query Crafting: Enhance the quality of your AI interactions with our expert assistance. We'll guide you in framing ChatGPT and other AI questions to yield insightful, accurate, and high-quality results.



Visit our **pharmacovigilance page** to explore our clinical drug safety solutions.

View our **Services Menu** for a detailed list of our solutions.

Our Vision for You

Build clinical development and operations infrastructure that supports compliance.

- Establish internal expertise aligned with regulatory expectations for operational oversight.
- Create and document internal processes that clarify internal roles and responsibilities and the outsourcing model.

Build a fit-for-purpose clinical quality system.

- Establish practical processes and documentation that evolve with the clinical development program.
- Institute internal processes that optimize resources and demonstrate oversight.

Build clinical expertise that enables appropriate oversight of clinical vendors.

- Continuously improve pharma industry knowledge and subject matter expertise.
- Develop useful and efficient documentation of oversight that can be provided during regulatory inspection.

Build a roster of clinical vendors that will live up to their promises and produce high quality deliverables.

- Leverage our expertise to optimize vendor selection.
- Establish clear contractual and quality agreements.

Training Solutions

We offer a variety of clinical research-related training options.

View our **Services Menu** for a detailed list of topics and options.

What Clients are Saying

XXX



Our Leadership

Janet Flisak, MBA, BSN

Head of Clinical

<u>Bio</u>

LinkedIn

Related Content

Read more from PDC's team of experts.

Pharmacovigilance

Pharmacovigilance Solutions

Apply compliant, risk-based operational and quality assurance (QA) pharmacovigilance (PV) approaches to ensure patient safety throughout product development and commercialization.

Our Services

Our PV operational and QA services and solutions ensure appropriate, actionable safety oversight of PV activities. We're dedicated to open communication and collaboration required to build a cohesive team.

Founded and led by a quality assurance and compliance expert

Everything we do is rooted in dedication to customer focus, quality management, and the regulatory requirements designed to ensure data integrity and patient safety.

We apply a broad and deep understanding of the industry, its history, the current landscape, and our vision for a healthier future to proactively address your challenges in the following areas and more:

- PV Vendor Selection & QA Qualification
- Operational Oversight of PV Vendors



- PV Process & SOP Development
- Full-Service PV QA
- PV Master File Development Consulting
- PV Operational Post-Audit & Inspection Remediation
- Commercialization PV Strategy

Optimized AI Query Crafting: Enhance the quality of your AI interactions with our expert assistance. We'll guide you in framing ChatGPT and other AI questions to yield insightful, accurate, and high-quality results.

View our **Services Menu** for a detailed list of our solutions.

Our Vision for You

Establish infrastructure that supports GVP compliance.

- Establish internal expertise that aligns with regulatory expectations for operational oversight.
- Create and document internal processes that clarify internal roles and responsibilities, and the outsourcing model.

Build a fit-for-purpose PV quality system.

- Establish practical processes and documentation that evolve with your clinical development and commercialization strategy.
- Institute internal processes that optimize resources and demonstrate oversight.

Build PV operational knowledge that enables appropriate oversight of PV vendors.

- Continuously improve industry knowledge and subject matter expertise.
- Develop useful and efficient documentation of oversight.

Build a seamless case processing flow that includes all stakeholders in your PV universe.

- Leverage our expertise to optimize PV vendor selection.
- Clarify documentation and enhance clarity of your unique PV story.



Training Solutions

We offer a variety of PV training options, including company-wide PV and product complaint training, PV QA coaching and training, and more.

View our **Services Menu** for a detailed list of topics and options.

What Clients are Saying

XXX

Our Leadership

Penelope Przekop, MSQA, RQAP-GCP

CEO

<u>Bio</u>

<u>LinkedIn</u>

Related Content

Read more from PDC's team of experts