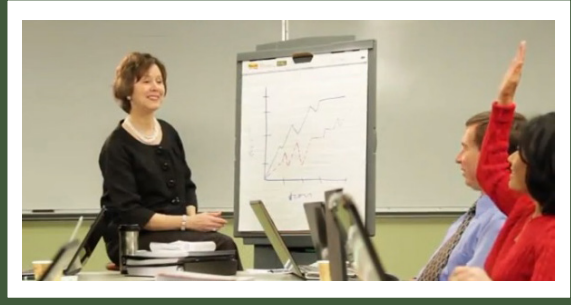


Corporate Consulting

A Passion for Results; The Expertise to Succeed



Services

Clients who choose P. Kasper and Associates are running clinical trials and need to be GCP compliant and inspection-ready at all times. In our fast-paced world of clinical research, this can sometimes be overwhelming. Our services provide the assistance you need.



Is Your Staff Properly Trained? GCP Training

Your team learns and retains more with P. Kasper & Associates' GCP Training. Standard and custom modules for fundamental and advanced topics are designed to reinforce and supplement your team's clinical research knowledge. Our experts ensure that your staff is knowledgeable by:

- Providing management training in skills such as identifying key performance indicators to hold CROs accountable and achieve timely results
- Summarizing and clarifying the new guidance documents and regulations to ensure GCP compliance
- Providing one-to-one mentoring and group training for Monitors, CRAs, and Clinical Trial Assistants to ensure group contribution and individual success
- Employing our hallmark hands-on interactive training programs to increase understanding and retention
- Providing BRN contact hours for each participant

Is Your Trial Properly Supported? Consulting for Clinical Operations

P. Kasper & Associates brings you the expertise of senior consultants to solve problems in clinical operations. Whether you need help with start-up operations or you have encountered problems mid-trial, we can put our professionals on your team when and where you need them. We can help you increase the efficiency and compliance of your organization by:

- Providing comprehensive support for Monitors, including a performance plan and co-monitoring visits to ensure accurate and complete clinical data
- Providing infrastructure by reconciling and verifying data queries from various sources to create a clean data set
- Compiling documents and creating data-tracking systems so that clinical departments and investigative sites are audit-ready

Are Your Documents GCP Compliant? Clinical Research Writing

P. Kasper & Associates offers a full complement of writing services to meet the needs of your organization. Our experienced writers work directly with your team to create or revise the GCP compliant documents you need. This includes:

- Performing a gap analysis to ensure your Standard Operating Procedures are complete
- Writing or revising Standard Operating Procedures to be clear and concise
- Creating protocols in a timely and effective manner
- Preparing accurate Clinical Study Reports that meet tight deadlines

“Patty is such a knowledgeable and experienced clinical research professional and consultant. She is always on top of things, and provides insightful and amendable opinions and suggestions. I can always expect the guidance I need from her.”

-Shirley F.
Research Associate III

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Patty Kasper, MS

Owner, P. Kasper & Associates

Patty Kasper is a recognized expert in clinical research training and operations with more than 20 years of industry experience. Since founding P. Kasper & Associates in 1995, Patty has provided well-designed training programs to the biopharmaceutical and medical device industries. More than 1,300 professionals have benefited from her hallmark hands-on interactive learning modules that bring an exciting real-world element to her classes.

Patty has direct experience with Phase I through 4 clinical research trials in numerous indications and has directed studies in the US, Canada, and Europe. Over the years, she has successfully guided numerous biopharmaceutical companies through the rigors of drug development.

Patty earned her Masters of Science degree in Bacteriology and Public Health from Washington State University. She has been on the faculty of UC Santa Cruz Extension as part of its prestigious Clinical Trials Design and Management Certificate Program.



Learn to Grow

"Because I have a passion for learning and training, my personal philosophy is Learn to Grow. That's also the philosophy that I have brought to P.Kasper & Associates because that quest for knowledge is what moves us forward in our life, as well as our career, and creates recognition of the necessity to continually expand our horizons."

-Patty Kasper

The Passion for Results; The Expertise to Succeed

At P. Kasper & Associates, we provide the best in GCP Training, Clinical Operations Consulting, and Clinical Research Writing. Our senior consultants provide the assistance you need by:

- Offering hands-on GCP Training
- Providing BRN contact hours
- Supporting Monitors in the field
- Coaching Site Coordinators
- Auditing Training Records
- Writing SOPs
- Researching and developing Protocols
- Writing Clinical Study Reports

Since 1995, P. Kasper & Associates has provided clinical operations training and support to more than 30 biopharmaceutical and medical device companies, as well as trained more than 1,300 individuals in the corporate and academic environments.

"P. Kasper & Associates came to our company with a very proactive approach. They asked questions, found the gaps, and then helped us through a difficult transition. We are now much more efficient in our processes in clinical operations."

*-Leslie G.
Sr. Director, Clinical Operations*