

Cayuga Consulting

Medical Writing ~ **Clinical Research** ~ Electronic Documents ~ Regulatory Affairs

Company Description

Cayuga Consulting is a full-service Medical Writing and Clinical Research Consulting firm. Headquartered in Providence, RI, Cayuga Consulting provides contract medical writing, clinical development support, and electronic document services to the Pharmaceutical, Biotech and Device industries. President and Cayuga Consulting founder, Donna D. Walczak, Ph.D., leads the scientific and medical writing teams, provides clinical development expertise, and manages the Electronic Document Center.

Clinical Research Services

The clinical research professionals that make up the Cayuga Consulting group possess extensive and effective experience in all phases of clinical development. In addition, our expertise covers a wide range of therapeutic areas for development of small molecules, biologics and medical devices. Cayuga provides a wide range of Clinical Research and Development services, including

- Study Design, Protocol and Informed Consent Forms
- Investigational Drug Brochures
- Product Dossiers and White Papers
- Evaluation of Data Management Plans and Statistical Analysis Plans
- Data Analysis and Interpretation (Phases I through IV)
- Clinical Study Reports and Manuscripts
- Meta-analyses, Systematic Overviews, Data Mining
- Clinical Program Development, Clinical Candidate Evaluation
- FDA Briefing Documents
- Regulatory Submissions (IND, Investigator IND, NDA, BLA, ANDA, 510k, eCTD, Annual Reports)
- Study/Program Newsletters, Compendia, Meeting Handouts
- Posters and Slide Presentations
- Bibliography Management, Annotated References Binders

In addition, Cayuga can provide access to a wide range of specialized product development activity through our network of Alliance Partners. Through our quality-tested alliance partners, you can access high-quality, efficient, and cost-effective services to round out your product development suite on an as-needed basis.

Services available through Cayuga's Alliance Partners include:

- Clinical Operations Services (study initiation, monitoring, closeouts, clinical drug supplies, data retrieval sweeps for regulatory submissions, GCP site auditing): visit Clinical Research Management, Inc. at www.clinicalresearchmgt.com or email scincotta@clinicalresearchmgt.com
- Data Entry/Data Management Services: visit Quartesian, Inc. at www.quartesian.com or e-mail Vladimir Mats, PhD, at vamats@quartesian.com
- Statistical and Programming Services: visit Quartesian, Inc. at www.quartesian.com or e-mail Vladimir Mats, PhD, at vamats@quartesian.com
- Advisory Panel Preparation, Risk Management Planning, and Medical Education: visit ProEd Communications, Inc. at www.proedcom.com
- Branding and Postmarket Planning, Publication Planning, Product Launch Preparation: visit ProEd Communications, Inc. at www.proedcom.com

Want to know more?

Contact:

Donna D. Walczak, Ph.D, President
Cayuga Consulting, 20 Dewey St, Providence, RI 02909
(401) 942-3458 office dwalczak@cayugaconsult.com