

Beckloff Associates

Strategic Medical Writing Services



Let us help you tell your Drug Development Story . . .

Beckloff Associates can add value to your development programs by:

- Rapidly understanding and interpreting strategic and scientific aspects of your development program
- Aligning our data into approaches and formats that meet regulatory agency and potential licensor expectations
- Rapidly integrating dissimilar data into documents that will help you to accelerate your development program and reduce time to proof-of-concept or market approval
- Bringing together the experienced technical writing staff needed to prepare documents that include Clinical, CMC and Nonclinical expertise
- Preparing e-submission-ready documents as part of the overall document preparation process, and acting as the U.S. sponsor representative for FDA submissions, as needed

We can do this by:

- Bringing together the combined strategic, technical and writing expertise of the Beckloff Associates' staff, collectively representing 100+ years of pharmaceutical and scientific experience
- Starting with detailed templates for standard documents such as protocol synopsis, study protocols and Clinical Study Reports, that meet all ICH and FDA requirements
- Using "smart" project management approaches that emphasize effective communication, parallel processing, and efficient hand-offs
- Functioning as an extension of your team to help you leverage your company's expertise and knowledge of your compounds in a way that is consistent with your corporate objectives

Contact Us:

To obtain more information, or to request a proposal for Strategic Medical Writing Services, please contact Beckloff Associates at **913.451.3955**, or send an e-mail to **info@beckloff.com**, or visit our web page at <http://www.cardinalhealth.com/beckloff/services>

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How our Strategic Medical Writing is different from what others offer:

- We are not a CRO, but a technical and strategy-based group of scientists and technical writers
- We are an experienced, industry-trained, hands-on group of writers who have been involved with all aspects of clinical drug development and numerous interfaces with regulatory agencies
- We can leverage our regulatory experience to ensure that clear, concise and meaningful documents are submitted to meet regulatory agency standards and expectations

What are our high quality, on-time deliverables?

- Study protocol synopsis and protocols for all phases of development
- Investigator's Brochures
- Initial IND and IND Amendments in paper or eCTD format
- Clinical Study Reports for all phases of development
- Integrated Summary of Safety and Efficacy (ISS/ISE)
- NDAs/BLAs in eCTD format

Why Beckloff Associates?

- A track record of success spanning four decades;
- Experience with all classes of pharmaceutical products;
- A strategic global approach to regulatory planning and product development;
- Successful relationships with regulatory agencies worldwide;
- Continuity of service from the laboratory bench to the pharmacy shelf and beyond;
- A commitment to quality, efficiency, and our clients' needs;
- The leveraged resources of a Fortune 20 company.

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