

Beckloff Associates eCTD Consulting



Achieve Greater Return on Your eCTD Investment

- > *Readiness assessment & planning*
- > *Operational throughput evaluation*
- > *Submission process design*
- > *System validation and optimization*
- > *Training for authors and publishers*

Who is it for?

Pharmaceutical, biotech, medical device companies and their partners with electronic publishing platforms in the planning, implementation or production stages can take advantage of our consulting offers today. Put our experience and expertise to use to get more value from your investment.

Benefits?

Through our flexible outsourcing and consulting business models, you can improve your submission capabilities and workflows, resulting in:

- Optimized systems delivering full functionality
- Efficient and effective processes for end-to-end submission projects
- Improved submission throughput, greater return on your investment

Contact Us:

To obtain more information, or to request a proposal for eCTD Consulting, please contact Beckloff Associates at: **913.451.3955**, or send an e-mail to **info@beckloff.com**, or visit our web pages at www.cardinalhealth.com/beckloff/eCTD/

Beckloff Associates eCTD Consulting



Your eCTD:

Professionally Done

We are not a software company

... we are pharmaceutical professionals

... with a great record of success

Expertise:

- Evaluation of publishing, electronic document management (EDM) and electronic labeling (SPL/PLR) components, and 21 CFR Part 11 validation;
- Design of professional, project-managed publishing processes;
- Experience: 100's of electronic submissions, including NDA, ANDA, 505(b)(2), IND, DMF, MAA;
- Templates (over 1000) and tools to ensure content and output quality, consistency and ease of navigation

Why Beckloff Associates?

- A track record of success: 33 years of scientific and regulatory consulting and publishing;
- 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 to the market and beyond;
- A commitment to quality, efficiency and our clients' needs;
- The leveraged resources of a Fortune 20 company

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