

# Beckloff Associates eCTD Services



*Your eCTD:*

*Prepared and Submitted*

*The benefits of electronic submission*

*... without the headache*

*... without the investment*

Electronic Common Technical Document (eCTD) preparation and submission are part of Beckloff's broad range of regulatory publishing and content management services. While designed for eCTD, our system also efficiently supports printed output formats.

#### **Who is it for?**

Pharmaceutical, biotech, medical device companies and their partners with needs to submit to global regulatory agencies can take advantage of our services today. Use these services instead of or in advance of designing, building, testing and optimizing your own system.

#### **What is provided?**

Through our flexible outsourcing / service delivery model, you can take advantage of a full suite of service elements:

- Conversion of source documents to pdf format;
- Organization of content according to eCTD specifications;
- Creation of efficient navigation (structures, bookmarks, hyperlinks);
- Pre-submission quality and compliance assessment, technical and quality reviews.

#### **Contact Us:**

To request more information, or to request a proposal for eCTD Services, please contact Beckloff Associates at: **913.451.3955**, or send an e-mail to **info@beckloff.com**, or visit our eCTD web page at [www.cardinal.com/beckloff/ectd](http://www.cardinal.com/beckloff/ectd).

# Beckloff Associates eCTD Services



*Your eCTD:*

*Professionally Done*

*We are not a software company*

*... we are pharmaceutical professionals*

*... with a great record of success*

## **Features and Advantages:**

- 21 CFR Part 11 validated hardware/software system, including robust publishing, electronic content management (ECM) and electronic labeling (SPL/PLR) components;
- Professional, project-managed publishing process;
- Diverse experience with 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 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 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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