

Beckloff Associates Strategic Labeling, Pre- and Postmarketing Services



Labeling Elements

Strategic, Competitive Premarketing Initiatives

Postmarketing Consulting and Outsourcing

> *More efficient FDA interaction*

> *Increased market success for your product*

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 to strengthen your development programs and increase the business success of your marketed products.

What is provided?

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

- Preparation of Target Product Profile (TPP) to streamline FDA interactions;
- Reconstruction of Prescribing Information (PI) in compliance with Physician Labeling Rule (PLR);
- Preparation of highlight summaries and highlight element coding;
- Conversion of labeling content to SPL or SPL-PLR formats;
- Electronic submission of labeling, Drug Establishment Registration and Drug Listing Information through the FDA Electronic Submissions Gateway (ESG);
- Fully-outsourced regulatory maintenance for approved products

Contact Us:

To obtain more information, or to request a proposal for Labeling, Pre- and Postmarketing Services, please contact Beckloff Associates at: **913.451.3955**, or send an e-mail to **info@beckloff.com**, or visit our web pages at www.beckloff.com

Strategic Labeling, Pre- and Postmarketing Services



Increased Success

Competitive Advantage For Your Product

Take early pre-approval steps

... begin with the end in mind

... maximize your return on investment

Expertise:

- Clinical, Non-Clinical, Regulatory Affairs
- Development, submission and maintenance of Prescribing Information;
- Review and approval of promotional and professional labeling;
- Extensive interactions with DDMAC and APLS

Why Beckloff Associates?

- A track record of success: 33 years of scientific and regulatory consulting and publishing;
- Experience with all classes of pharmaceutical products, over 100 product approvals;
- 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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