

Beckloff Associates Electronic Drug Registration and Drug Listing Submissions



Preparation and Submission of Files via the FDA Electronic Submission Gateway (ESG)

- ... *electronic Labeler Code Request (eLCR)*
- ... *electronic Drug Establishment Registration (eDR)*
- ... *electronic Drug Listing/Content of Labeling (eDL/CoL)*

Who is it for?

Pharmaceutical and biotech manufacturers, contract manufacturers, label repackers, relabelers, contract testing labs, contract sterilizers, fulfillment packagers, drug substance manufacturers, foreign drug manufacturers, and manufacturing pharmacies. As of June 1, 2009, the FDA requires that drug establishment registrations and drug listings be prepared in SPL-R4 format and transmitted electronically to FDA.

What is provided?

- Preparation of eLCR, eDR, eDL/CoL files
- Assistance with Letters of Non-Repudiation for digital signatures;
- Secure electronic submission of files via the FDA ESG;
- Regulatory guidance and submissions for other vital post-marketing projects;
- Fully outsourced regulatory maintenance for approved products.

Contact Us:

To obtain more information, or to request a proposal for Electronic Drug Registration or Drug Listing Services, please contact Beckloff Associates at **913.451.3955**, or send an e-mail to **info@beckloff.com**, or visit our web page at **www.cardinalhealth.com/beckloff/services**

Beckloff Associates Electronic Drug Registration and Drug Listing Submissions

Your Electronic Submissions and eCTDs: 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-R4) components;
- Professional, project-managed publishing process;
- Diverse submission experience, including DR, DL, Labeling, NDA, ANDA, 505(b)(2), IND, DMF, MAA;
- Extensive in-house regulatory and scientific expertise.

Why Beckloff Associates?

- A track record of successful interaction with regulatory authorities worldwide: over 4 decades of scientific and regulatory consulting and publishing experience;
- Experience in all of the major therapeutic areas and all classes of pharmaceutical products, over 100 product approvals, including pharmaceuticals, biologics, generics, over-the-counter, combination medicinal products and veterinary products;
- A strategic global approach to regulatory planning and product development;
- Continuity of service from the laboratory bench to 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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