

Beckloff Associates Biotechnology Consulting Services



Expert Support Throughout the Biologics Development Process

*... Competitive advantage for your biotechnology product
... Product development consulting*

Who is it for?

Biotechnology, pharmaceutical, medical device companies and their partners that require additional resources in development, preparation of regulatory documentation, training, auditing, or postapproval support. Use our experience and expertise to facilitate multi-national approvals and achieve greater return on your development investment.

What is provided?

- Product Development and Registration Strategies
- Data Review and Gap Analysis Activities
- Program Management
- Facility Inspections (GMP, GTP, GLP, GCP)
- Validation Consulting
- Global Regulatory Strategies

Pre-IND and IND Support:

- CMC Development Consultation
- Pharmacology/Toxicology Guidance
- Nonclinical Product Development Consultation
- Clinical Development Consultation
- Preparation for Pre-IND Meetings
- IND Preparation, Review and Publishing (eCTD)
- Preparation of IND Amendments and Annual Reports
- Preparation of Responses to CBER

BLA Support:

- Review of Nonclinical, Clinical and CMC Data
- Preparation for Pre-BLA Meetings
- Electronic Content Management
- BLA Preparation, Review and Publishing (eCTD)
- Preparation of Responses to CBER
- Electronic Labeling (SPL/PLR)

Contact Us:

To obtain more information, or to request a proposal for Biotechnology 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>

Beckloff Associates Biotechnology Consulting Services

Faster to Market for your Biotechnology Derived Products

... Regulatory application preparation

... Interaction with Regulatory Authorities

... Compliance and auditing services

... Postapproval support



Biotechnology Expertise:

- Antibodies
- Antisense Oligonucleotides
- Oligonucleotides (DNA and RNA)
- Aptamers
- Blood Derivatives
- Cells (Manipulated)
- Cells (Transplanted)
- Genetically Modified Microorganism
- Genetically Modified Virus
- Gene Therapy
- Proteins
- Recombinant Peptides
- Synthetic Peptides
- Vaccines

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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