

Beckloff Associates Nonclinical Services



Design and Implement Product Development Programs

*... Nonclinical strategic partnering for all
development phases*

*... Nonclinical study designs, monitoring,
and reporting*

Who is it for?

Pharmaceutical, biotechnology, medical device organizations and their partners that require any phase of nonclinical submissions to domestic and global regulatory agencies.

What is provided?

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

- Nonclinical program gap analysis and development plans
- Positioning of scientific data and leveraging published data for preparation of regulatory documents to support agency meetings, INDs, CTAs, IMPDs, NDAs, MAAs, and Investigator's Brochures
- Attendance and support at regulatory agency meetings
- Determination of impurity limits for genotoxicity
- Selection, qualification, management, and monitoring of nonclinical study sites
- Good Laboratory Practice (GLP) and 21 CFR Part 11 audits and training programs
- Development and review of study and bridging protocols
- Study Director and/or Study Monitor capabilities
- Preparation and/or review of nonclinical study reports, nonclinical summaries, and tabulations

Contact Us:

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

Beckloff Associates Nonclinical Services



Experienced Partner in Drug Development

... Minimize development time with a comprehensive nonclinical strategy

... Ensure successful worldwide development by conducting essential and critical studies

Expertise:

- Nonclinical, Clinical, Regulatory Affairs
- Development of strategic nonclinical study designs, management, and reporting
- Nonclinical facility and process audits
- Positioning of scientific data for regulatory submission documents
- Determination of impurity limits for genotoxicity assessments

Why Beckloff Associates?

- A track record of success in developing compounds spanning four decades
- Diverse experience in multiple scientific disciplines with all classes of pharmaceutical products, with over 100 products approved
- A strategic global approach to regulatory planning and product development
- Successful interactions with regulatory agencies worldwide
- Continuity of service from the laboratory bench to the 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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