

# Beckloff Associates Compliance Services

## Ensure the Quality of your Products

... By being proactive

... By thinking globally



Regulatory compliance services are an integral part of Beckloff Associates' broad range of services. In a global economy, our compliance services are designed to help domestic and foreign companies (including those located in India, China, and other countries in Asia, Europe, North, Central and South America, as well as Australia) meet the regulatory requirements of the United States, Canada and the European Union, thus ensuring that your products will be acceptable in these markets.

### Who is it for?

Pharmaceutical, biotechnology and medical device companies and their partners with goals of developing and marketing products in domestic and international markets. These services are geared toward early recognition of compliance needs as applied to the specific products and stage of development.

### What is provided?

Through our flexible compliance model, your company can take advantage of a full set of service elements:

- Ability to serve as a remote Quality Unit
- Good Manufacturing Practices (GMP) audits in accordance with US FDA and EU requirements
- Compliance remediation support
- Pre-Approval Inspection (PAI) Readiness programs
- Good Laboratory Practice (GLP) audits
- Good Clinical Practice (GCP) audits
- Quality System Regulatory (QSR) audits
- 21 CFR Part 11 audits and consultation services
- Preparation of Standard Operating Procedures (SOPs)
- Training programs

### Contact Us:

To obtain more information, or to request a proposal for Compliance Services, please contact Beckloff Associates at **913.451.3955**, or send an e-mail to **info@beckloff.com**, or visit our regulatory compliance web page at <http://www.cardinalhealth.com/beckloff/services/compliance>

# Beckloff Associates Compliance Services

## Are your Facilities Ready for an Inspection by a Regulatory Agency?

*... Do your contracted facilities  
meet compliance regulations?*

### Expertise:

- Chemistry, Manufacturing and Controls (CMC)
- Clinical and nonclinical studies
- Bioanalytical methodology
- Medical devices
- Performance of audits worldwide and understanding of current standards of regulatory compliance

### 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 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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