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# Partnering Model for Pharmaceutical Companies

## Post-Approval Regulatory and Compliance Support

# Beckloff Associates Introduction

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- ◆ A specialized pharmaceutical research and development **consulting** group
- ◆ Scientific and strategic regulatory focus
- ◆ Established: 1976
- ◆ Acquired: 2004 by Cardinal Health
- ◆ Staff: **84 Staff** - >75% technical staff with advanced scientific, technical, professional degree/certifications

# Our Resources

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- ◆ Consulting team comprised of scientist with deep technical and regulatory backgrounds (majority with 15-30 years experience in the pharmaceutical industry)
- ◆ Team has been involved in over 100 product approvals and is currently providing marketed product regulatory and compliance services for 10 marketed products

# Where are we?

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# The “Challenge”

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- ◆ Pharmaceutical Company has resources dedicated to the regulatory and compliance aspects for pipeline (pre-IND through Phase III) and approved products (mature marketed products)
- ◆ Challenge – resource restrictions limit the ability to dedicate staff to pipeline programs
  - Inability to hire additional staff (economic downturn)
  - More ongoing programs (non-approved and approved) than current staff can support

# Ideal vs. Reality

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- ◆ **Ideal:** Hire additional resources
- ◆ **Reality:** Get more done with the current (or less) staff
- ◆ **Option:** Find a partner (outsource)
- ◆ **Beckloff Associates' Solution:** Our partnering model is designed to allow the customer to direct and dedicate their regulatory resources to new product development while Beckloff Associates maintains the mature marketed products from a regulatory and compliance perspective

# Beckloff Associates' Solution

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- ◆ Set up a partnership where:
  - Dedicated team is put in place for your products
  - Resources can be added or removed from team based on workload (flexibility)
  - Our team becomes fully integrated with your requirements (training, IT systems, etc.)
  - Cost model can be set up based on your needs
    - ◆ FTE approach (most flexible option)
    - ◆ Fixed cost based on deliverables

# Beckloff Associates' Solutions

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## ◆ Services available

- On-site Training or Support (as needed)
- Regular Secure Communication (on-site meeting or teleconferencing, FTP, Share-Point)
- Regulatory Strategy Recommendations
- Project Management
- Agency Interactions
- Customized Regulatory Strategy
- Regulatory Affairs Activity Management
- Application Life-cycle Management

# Beckloff Associates' Solutions

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## ◆ Services available (*continued*)

- Product Development
- Vendor Management
- Manufacturing Change Assessments (Change Control, Deviations, Global Regulatory Impact)
- Compliance Audits
- Market Expansion
- Regulatory Filing Category Recommendations
- Preparation and Submission of Agency Responses (during review process) and Post-Approval
- Regulatory Publishing Services (paper and electronic)

# Beckloff Associates' Solutions

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## ◆ Services Available (*continued*)

- Application Preparation and Submission (Agency Responses, Amendments, Supplements, Periodic Safety Reports and Annual Reports)
  - ◆ CTD Format (conversions)
  - ◆ Changes to API supplier
  - ◆ Changes to formulated product
  - ◆ Packaging/Labeling changes
  - ◆ Drug Listing
  - ◆ Marketing Materials (DDMAC)
  - ◆ Scale-up prior to launch
  - ◆ Product Transfer (to new Company)
  - ◆ DMF/ASMF

# Partnering Model “Goal”

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- ◆ Allow our customers to maintain regulatory and compliance aspects of marketed products without dedicating internal staff
  - ◆ Allow our customers to have more pipeline programs moving forward using their internal staff
  - ◆ Allow customer to have *control*; BAI resources provide the support under the customer’s direction
  - ◆ Establish a long-term partnership with a firm that can be a valued resource for products in any phase of development
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# Partnering Model “It Works”

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- ◆ Model currently in place with several U.S. Pharmaceutical Companies (large, mid-sized, and small)
- ◆ Customers have management oversight of activities and BAI dedicated team provides support for marketed products maintenance
  - Small molecules
  - Large molecules (biologics)
  - Products supported range from \$1B to \$500-700MM dollars in yearly sales

# Why Choose Beckloff Associates?

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- ◆ We are experienced scientists, toxicologists, clinicians, chemists, pharmaceuticals specialists who understand the regulatory and compliance aspects for development and approved products
- ◆ We are a fully integrated consulting firm—CMC, nonclinical, clinical, regulatory, and publishing within one organization
- ◆ We are the right team for a successful partnership