Your Partner in Quality Systems Design

DBT offers complete regulatory and quality services for the development, implementation or updating of quality systems tailored to your product and company needs.

DBT helps in the development of strategic planning and quality systems improvement programs directed at both the pharmaceutical and medical device environment with an eye towards FDA 21st Century Initiatives and all that entails.

Our approach is to help evaluate, develop specific training and participate in the development of the plan needed for the task at hand.

We have the technical resources to address your needs. Call us today and we can discuss your needs and how DBT can help.

Careful examination of complex problems—a DBT specialty

Service Brochure

Diversified Biomedical Technologies, Inc.

For more information, see us at www.dbtco.com.

Science and Compliance

Diversified Biomedical Technologies, Inc.

1110 Thackeray Drive
Suite 170
Palatine IL 60067-2752 USA

Phone: (847)-934-8080
Fax: (847) 496-5172
Email: info@dbtco.com

Visit us at WWW.DBTCO.COM

Consulting Services Offered

DBT becomes an active partner in developing and implementing solutions tailored to your specific needs. DBT interfaces with Quality and Regulatory Groups, as well as the Research and Engineering Groups. **DBT** augments your existing staff when issues arise that outstrip your resource or in those instances where new strategic thinking is needed.

DBT and its affiliates stand ready to help define and implement solutions to your product approvals, compliance and quality system development --- professionally and cost-effectively.

Finding new solutions to quality problems

Directory of Services

Validation
Test methods, design and process validation strategies including the role of characterization as part of the pre-validation activities.

Quality Strategies
Development of an integrated quality plan assuring bidirectional communication between top management and function management.

Gap Assessments
Determine where your quality system stands as a function of regulatory requirements or current industry practice.

Project Management
Providing oversight for the implementation of quality system improvement plans. Strategies for regulatory filings.

Post-inspection Corrective Actions
Help in responding to FDA actions along with the development of appropriate.

Pre-inspection Activities
Develop strategies for regulatory inspections and gap assessments made to measure compliance to promised actions

Site Specific Training
We provide an array of training ranging from risk assessment and hazard analysis, DOE, SPC, characterization and validation, MDR and more.

21st Century Initiatives
Provide insight into the concepts of risk management, process analytical technology (PAT) and understanding the manufacturing operation

Supplier Assessments
We help assess the status of the quality system used by your supplier's to assure that the system is appropriate and in compliance.

Trending and CAPA
Review and assessment of the trending programs used to assure that all relevant input are addressed in terms of MDR and more.

Regulatory Submissions
Help define approach to 510k, PMA from perspective of content, approach and definition of clinical studies as required.

International in scope
Our services have been applied to off-shore manufacturing as well as foreign manufacturers distributing in the US.

Special Projects
We can affectively integrate quality systems into due diligence reviews of potential acquisitions.

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