

# EXECUTIVE BRIEF



**Cleanroom Cleaning & Disinfection Experts**

**Your Cleanroom... Your Profits... Our Priority**

# Vision and Values

To be recognized as *the* premier provider of cleanroom cleaning and disinfection services in New England. We provide advanced contamination control expertise combined with regulatory know how.

## We do this by:

- a. Safely removing organic and inorganic surface contamination.
- b. Protecting our client partners product from contamination
- c. Strict adherence to cGMP's, cGDP's and SOP's.
- d. Serve as invested partners in manufacturing quality

# Expertise and Experience

## Cleanroom Cleaning & Disinfection - Regulatory & Compliance Intelligence

- Alkermes
- Analog Devices
- Autoimmune
- Bausch & Lomb
- Biogen
- Boston Scientific
- Corning
- Covance
- Dow Chemical
- Dupont
- Eisai, Inc.
- Genzyme Corp
- Global Foundries
- Harvard (LISE Nanotech Center)
- Hospira
- Insulet
- Integra Life Sciences
- Lahey Clinic
- Lonza
- Mass General Hospital
- Merck
- Novartis
- Organogenesis
- Organon, Inc
- Pfizer
- Raytheon
- Roche Labs
- Siemens Medical
- Smith & Nephew
- Stryker
- Texas Instruments
- United Technologies

# Professional Affiliations



- Institute of Environmental Sciences and Technology (IEST)
- American Biological Safety Association (ABSA)
- International Society of Pharmaceutical Engineers (ISPE)
- Massachusetts Biotech Council (MBC)
- Parenteral Drug Association (PDA)



# Science – Standards - Regulations

- USP 797 Pharmaceutical Compounding- Sterile Preparations
- ISO 14644-5 Cleanroom Operations
- IEST CC018- Cleanroom Housekeeping—Operating and Monitoring Procedures
- IEST CC023- Microorganisms in Cleanrooms
- IEST CC026- Cleanroom Operations
- IEST CC027- Personnel Practices and Procedures in Cleanrooms and Controlled Environments
- IEST CC040- Cleaning of Equipment Surfaces in the Cleanroom and Controlled Environments

**100% FDA Audit Compliance to Date!**

# Cleanroom Services

- Engineered Cleaning Programs
- Technical Cleaning, Disinfection & Decontamination
- Gown Room Management
- Interstitial Cleans
- Clean-Builds
- Post-Construction Cleans
- Protocol Training
- Surface Particle Testing
- Ionizer Wipe Downs
- Federal and International Standards GAP Analysis Audits
- Protocol Training
- Document (SOP) Writing
- Bio Safety Level 2&3
- Lab Support Services- Autoclaving and Glass Wash

# Cleanroom Approach



- CleanTech pursues and maintains close working partnerships in pursuit of customer product and process protection.
- We leverage subject matter expertise, extensive and current industry knowledge, and best practices.
- We constantly look for ways to improve our organization by working closely with our customers in identifying areas where we can further deliver effective quality technical cleaning services.

# Employee Training



All CleanTech employees are thoroughly trained in a three-tiered approach:

- Reads & Understands (RU) – multi-media classroom training with required exam
- Works with Supervisor (WS) – on-the-job training and knowledge assessment
- Works Independently (WI) – has demonstrated and proven expertise of both CTS and customer-specific SOP training.





# Training Specifics



- Customer-Specific SOP's
- Introduction to Cleanrooms
- Basic Contamination Control
- Basic Microbiology
- Human Contamination
- Gowning
- Customer Manufacturing Process
- IDs & Sources of Customer-Specific Contamination Threats
- Equipment, Tools, Materials
- Disinfectant/Sporicidal Use
- Cleaning/Disinfection Process
- Federal and International Regulations



# Understanding and Commitment



- We understand the cleanroom is our customer's most valuable real estate.
- This is also where our customer's make all of their revenue.
- We understand federal and international regulations and deliver on SOP specifics.
- Our job is to protect our client partners product and process from environmental contamination.



*Management Excellence,  
Superior, Guaranteed*



## Contact Information

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