



## **IAN WALLIS - DIRECTOR OF QUALITY OPERATIONS**

### **EXPERIENCE**

30 years as a cleanroom contamination control consultant, Expert Witness, cleaning and disinfection service provider to cleanroom manufacturing industries, including: bio-pharmaceutical, medical device, semiconductor, aerospace and nanotechnology companies nationwide. Founder and President of Microcomplete Inc., a cleanroom cleaning company with \$8.5 million in annual revenue and over 400 employees.

### **PROFESSIONAL MEMBERSHIPS/AFFILIATIONS (PAST AND PRESENT)**

- *Institute of Environmental Sciences and Technology (IEST): New England Chapter President & National Board Member*
- *International Society of Pharmaceutical Engineers (ISPE)*
- *Parenteral Drug Association (PDA)*
- *Mass Biotech Council (MBC)*
- *American Biological Safety Association (ABSA)*

### **TEACHING**

Have provided technical instruction and presentations at requests of clients and trade organizations on contamination control subject matter such as:  
*Cleanroom Fundamentals*

- *Managing the Risk of Contamination*
- *Cleaning and Disinfection Validation*
- *ISO 14644 Cleanroom Series*
- *IEST CC-Recommended Practices Documents*

- *SOP Writing*
- *Cleanroom Management*
- *Clean-Build Protocol*
- *Gowning, Material Entry, Behaviors*
- *Preparing for FDA Inspections*
- *Risk Assessment, Control, and Management*

## ***AUDITING, TRAINING, TECHNICAL CLEANING/DISINFECTION, CORPORATE BENCHMARKING, TROUBLE-SHOOTING***

Have provided Compliance Audits, contamination control consulting, and cleaning and disinfection services to more than 100 clients nationwide. A partial list of cleanroom clients served is as follows:

Alkermes  
Analog Devices  
Anika Therapeutics  
Antigenics  
Applied Materials  
Autoimmune  
Bausch & Lomb  
Biogen  
BAE Aerospace  
Bausch and Lomb  
Becton Dickinson  
Boston Scientific  
Brooks Automation  
Corning  
Covance  
Dow Chemical  
Dupont  
Dyosynth  
Eisai, Inc.  
Fresenius Kabi  
Genzyme Corp  
Global Foundries  
Harvard (LISE Nanotech Center)  
Hospira  
Integra Life Sciences  
Johnson & Johnson (OCD)  
Lockheed Martin  
Lonza

Mass General Hospital  
Memorial Sloane Kettering

Merck

Micron

Novartis

Organogenesis

Organon, Inc

Pfizer

Raytheon

Roche

Siemens Medical

Smith & Nephew

Stryker

Texas Instruments

ThermoFisher

US Air Force

United Technologies

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## ***NOTABLE PROFESSIONAL INVOLVEMENT:***

- 1) Expert Witness in New England Compounding Lab litigation.
- 2) ISO 14644-5 Cleanroom Operations Contributor/ Editor- The scope of Working Group 5 was to provide those basic requirements for operating and maintaining cleanrooms and associated controlled environments to meet the standards of the particular cleanroom as designed, built, and used. Required topics include:
  - Operational systems that must be in place
  - Selection and use of appropriate cleanroom garments
  - Training and monitoring of personnel and activities
  - Installation and use of equipment
  - Requirements for materials used in the cleanroom
  - Maintaining the cleanroom environment in a clean, usable condition conforming to design standards
- 2) Contributor to the Parenteral Drug Association (PDA) Technical Report on Cleaning and Disinfection
- 3) Published in a variety of national trade publications; lectured at industry trade shows and technical meetings.
- 4) Trained by the Centers for Disease Control's, Director of the Office of Health and Safety in Bio-Security and Bio-Safety Work Practices.
- 5) Voting Committee Member/ Standards Writer for the following Institute of Environmental Sciences and Technology (IEST) Working Groups:
  - I. Working Group on 797 Compounding Labs
  - II. CC003- Garment System Considerations for Cleanrooms and Other Controlled Environments
  - III. CC004- Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments
  - IV. CC006- Testing Cleanrooms
  - V. CC018- Cleanroom Housekeeping—Operating and Monitoring Procedures
  - VI. CC023- Microorganisms in Cleanrooms
  - VII. CC026- Cleanroom Operations
  - VIII. CC027- Personnel Practices and Procedures in Cleanrooms and Controlled Environments
  - IX. CC040- Cleaning of Equipment Surfaces in the Cleanroom and Controlled Environments
  - X. CC041- Recovery from Disruption to Cleanrooms and Other Controlled Environments
  - XI. CC043- Surface Molecular Contamination
  - XII. CC044- Vacuum Cleaners and Systems for Cleanrooms and Other Controlled Environments
  - XIII. CC046- Contamination Control in Controlled Environments
  - XIV. CC902- MIL-HDBK-406 Contamination Control Technology: Cleaning Materials for Precision Pre-Cleaning and Use in Cleanrooms and Clean Work Stations; MIL-HDBK-407: Contamination Control Technology: Precision Cleaning Methods and Procedures.