



## IAN M WALLIS - WALLIS & ASSOCIATES

### EXPERIENCE

24 years as a contamination control scientist/consultant and service provider to cleanroom manufacturing industries, including: bio-pharmaceutical, medical device, semiconductor, aerospace and nanotechnology companies nationwide.

### 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:

- *Contamination Control*
- *SOP Writing*
- *Cleaning Validation*
- *ISO 14644-5 Cleanroom Operations*
- *IEST CC-RP 18 Cleanroom Housekeeping*
- *Protocol issues*
- *Clean-Build*
- *Pre-Approval Inspections*
- *Preparing for FDA Inspections*
- *Risk Assessment, Control, and Management*

### CORPORATE BENCHMARKING, AUDITING, TRAINING, TECHNICAL CLEANING/ DISINFECTION/ DECONTAMINATION

Have provided Compliance Audits and technical cleaning consulting to more than 100 clients nationwide. A partial list of pharmaceutical clients served is as follows:

- Alkermes
- Analog Devices
- Antigenics
- Autoimmune
- Bausch & Lomb
- Biogen
- BAE Aerospace
- Bausch and Lomb
- Brooks Automation
- Corning
- Covance
- Digital Equipment
- Dow Chemical
- Dupont
- Dyosynth
- Eisai, Inc.
- Fresenius Kabi
- Genzyme Corp
- Harvard (LISE Nanotech Center)
- Hospira
- Hughes Aircraft
- Integra Life Sciences
- Johnson & Johnson (OCD)
- Lonza
- Lucent Technologies
- Merck
- Novartis
- Organogenesis
- Organon, Inc
- Pfizer
- Precision Robotics
- Raytheon
- Roche
- Sanofi
- Siemens Medical
- Smith & Nephew
- Stryker
- Texas Instruments
- United Technologies
- Wyeth

## NOTABLE PROFESSIONAL INVOLVEMENT:

- 1) 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.

\*The IEST is the Secretariat for ISO