



IAN WALLIS - DIRECTOR OF QUALITY OPERATIONS

EXPERIENCE

- 1) 30 years of experience as a cleanroom contamination control consultant.
- 2) Expert Witness in New England Compounding Lab litigation.
- 3) 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.
- 4) 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 CDCs, Director of Office Health and Safety in Bio-Security and Bio-Safety Work Practices.
- 5) Formerly, Founder and President of Microcomplete Inc., a cleanroom cleaning company with \$8.5 million 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)*
- *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:

<ul style="list-style-type: none"> • <i>Cleanroom Fundamentals</i> • <i>Managing the Risk of Contamination</i> • <i>Cleaning and Disinfection Validation</i> • <i>ISO 14644 Cleanroom Series</i> • <i>IEST CC-Recommended Practices Documents</i> • <i>SOP Writing</i> 	<ul style="list-style-type: none"> • <i>Cleanroom Management</i> • <i>Clean-Build Protocol</i> • <i>Gowning, Material Entry, Behaviors</i> • <i>Preparing for FDA Inspections</i> • <i>Risk Assessment, Control, and Management</i>
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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	Dupont	Micron
Analog Devices	Dyosynth	Novartis
Anika Therapeutics	Eisai, Inc.	Organogenesis
Antigenics	Fresenius Kabi	Organon, Inc
Applied Materials	Genzyme Corp	Pfizer
Autoimmune	Global Foundries	Raytheon
Bausch & Lomb	Harvard (LISE Nanotech Center)	Roche
Biogen	Hospira	Siemens Medical
BAE Aerospace	Integra Life Sciences	Smith & Nephew
Bausch and Lomb	Johnson & Johnson (OCD)	Stryker
Becton Dickinson	Lockheed Martin	Texas Instruments
Boston Scientific	Lonza	ThermoFisher
Brooks Automation	Mass General Hospital	US Air Force
Corning	Memorial Sloane Kettering	United Technologies
Covance	Merck	
Dow Chemical		

Served as a 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.