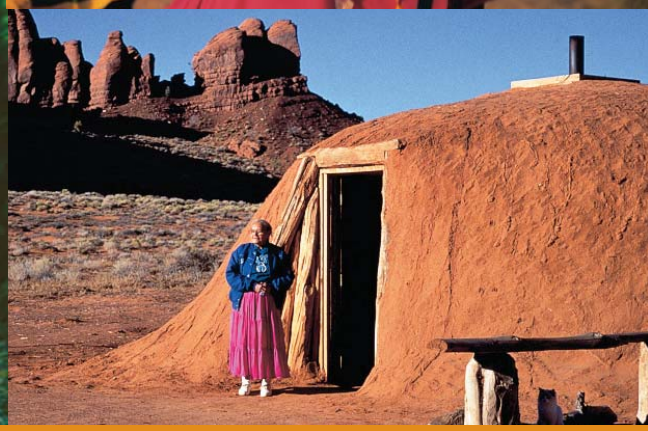
Controlled Environment
Testing Association

Eighteenth Annual Meeting



April 9-13, 2010 • Chaparral Suites Resort • Scottsdale, Arizona

Schedule of Events

Friday, April 9, 2010

12:00 - 2:00 pm — **Esco Manufacturer Update**
Kiva I, II, III

1:30 pm — **Wally Whitt Golf Tournament**
The Legend at Arrowhead

3:00 - 5:00 pm — **Baker Company Manufacturer Update**
Kiva I, II, III

Saturday, April 10, 2010

11:00 am — **Registration**
North Foyer

8:00 - 10:00 am — **NuAire Manufacturer Update**
Kiva I, II, III

10:00 am - 12:00 pm — **Esco Manufacturer Update**
Kiva I, II, III

1:00 - 5:00 pm — **CETA Series: Viable Sample Processing**
Joseph Manfrida, PhD - EMLab P&K, Charlene Schoenberger - Schoenenberger Associates Certification Inc., Kym Faylor - Microbiological Environments
Kiva I – III

7:00 - 9:00 pm — **CETA Annual Meeting Opening Reception**
North Patio (Mohave I – Kiva III in case of rain)

Sunday, April 11, 2010

6:00 am — **Exhibit Setup**
West Foyer

7:15 am - 1:30 pm — **Registration**
North Foyer

8:00 am - 1:00 pm — **CETA Annual Meeting General Session**
Mohave I, Kiva I, II, III (unless otherwise noted)

8:00 - 8:10 am — **Conference Welcome**
Marc DuBois

8:10 - 8:30 am — **President's Address**
Jeff Smith, CETA President

8:30 - 8:40 am — **NSF Revision Standard 49 & New CETA Application Guide (CAG-007-2010)**
Bill Peters, NuAire

8:45 - 9:00 am — **CETA Spec Guide Update**
Greg Bashe, Cert-Pro

9:00 - 9:15 am — **Introducing fume hood CAG on non-traditional fume hoods**
Chandler Papas, C-Scan

9:15 - 9:30 am — **New CETA High Efficiency Application Guide (CAG-006-2010)**
Gene Klingbeil, Filtration Group
The purpose of this new CETA Applications Guide; CAG-006-2010 is to offer guidelines to assist you with a general understanding of what is necessary for understanding all aspects of high efficiency filters used in biosafety cabinets, laminar flow cabinets, isolators and other applications. These guidelines are intended to supplement the filter specification portion of the CETA Specification Guide for HEPA and ULPA filters procured for field replacement applications. The information enclosed is also intended to provide you with some pertinent information regarding filters selection based on application, and other useful information to assist you with working around high efficiency filters.

Learning Objectives: Reviewing this guide, will assist you in better understanding filter…

- Application and Qualification
- Construction Requirements
- Testing and Labeling
- Field Replacement
- Patching and Repairing
- Shipping and Storage
- Receiving and Handling filters
- Filter Inspection and Installation
- Recommended Shelf Life
- Extending Filter Life

9:30 - 10:00 am — **ISO 14644-1 and EU GMP Annex 1**
Timothy S. Russell, TSI Inc
The particle cleanliness classification requirements of EU GMP Annex 1 will be presented. Key differences between EU GMP Annex 1 and the FDA Aseptic Processing guidance in terms of the classification of particle cleanliness will be highlighted. How ISO 14644-1 is related to EU GMP Annex 1 and the FDA Aseptic Processing guidance is described. The impact any proposed changes to ISO 14644-1 will have on particle cleanliness classification activities will be discussed.

10:00 - 10:30 am — **CETA Cleanroom Program**
Chris Rowe, CETA National Board of Testing

10:30 - 11:00 am — **Break/Exhibits**
West Foyer

11:00 - 11:30 am — **Energy Savings by Addition of Zone Presence Sensors (ZPS)**
Ken Mangis, Eli Lilly and Company (LLY)
The presentation describes the process executed to add Zone Presence Sensors to existing Variable Air Volume Chemistry Fume Hoods in order to save Energy in the form of outside air consumption. The presentation will provide an overview of the financial justification, technical justification, and project execution.

Learning Objectives:

- A modified ASHRAE 110 test can be used to evaluate Fume hood containment at reduced flow rate during unoccupied time.
- Lab air turbulence through excessive air change rates can negatively affect fume hood containment.
- Engineering Based controls (ZPS) can be applied to existing Fume Hoods to reduce outside air consumption and utility cost.
- A reduction in utility cost is not always A reduction in safety (e.g. containment). In a fume hood dense area, ZPS can be a win-win project for utility cost and safety.

Schedule of Events

11:30 am - 12:00 pm **New Testing Method Developed for the New FlexAIR Canopy Connection for Biological Safety Cabinets**
Bob Lloyd, The Baker Company
Exhausting type A2 biological safety cabinets to a building exhaust system is safely accomplished by using what is commonly called a canopy connection on the top of the cabinet. This paper presents a new canopy design which improves safety and requires fifteen percent less airflow than present designs.

Since there is no quantitative test in NSF 49 for exhaust canopy performance, a new qualitative test procedure was developed. This new method for testing a canopy is presented.

The test results for the new design canopy are reviewed and documentation is presented to show that safety has been improved while air flow has been decreased.

Learning Objectives

- Understand how to set up a cabinet to leak check a canopy using an Ashrae ejector and a helium leak detector.
- Understand how to test for the maximum exhaust system flow for a canopy connected BSC

12:00 - 1:00 pm **Lunch**
Hacienda I – Paloma III

1:00 - 4:00 pm **Equipment Manufacture's Forum** (see schedule)
Mohave I, II, III, & Kiva I – III

4:00 - 5:00 pm **NSF Steering Committee**
Kiva I – III

Monday, April 12, 2010

7:15 am - 1:30 pm **Registration**
North Foyer

7:00 am - 4:00 pm **Exhibiting**
West Foyer

8:00 am - 1:00 pm **CETA Annual Meeting General Session**
Mohave I – Kiva III (unless otherwise noted)

8:00 - 8:10 am **Conference Updates**
Marc DuBois, CETA President-elect

8:15 - 9:00 am **History of CETA**
David Brande, Cleanroom Project Management, Inc.
A short review of the industry dynamics that precipitated the formation of our association and the subsequent direction set by the earlier officers of the association that have brought the professional society to our present day leadership role in our industry.

Learning Objectives:

- For our newer members to better understand the background and the beginning efforts of our association
- Better understand the long range objectives of our association and the effect that CETA has had on our industry

Equipment Manufacturer's Forum

1:00 pm

Particle Measuring Sytems	Mohave I
ESCO	Mohave II
TSI	Mohave II
AAF International	Kiva I-III

1:30 pm

Particle Measuring Systems	Mohave I
ESCO	Mohave II
Teknipure	Mohave III
AAF International	Kiva I-III

2:00 pm

Thermo Fisher	Mohave I
Holland Safety Equipment (TEL)	Mohave II
Lighthouse Worldwide Solutions	Mohave III
Clordisys Solutions, Inc.	Kiva I-III

2:30 pm

Thermo Fisher	Mohave I
Holland Safety Equipment (TEL)	Mohave II
BioScience International, Inc.	Mohave III
Clordisys Solutions, Inc.	Kiva I-III

3:00 pm

DRS Laboratories, Inc.	Mohave I
Cert-Pro/CETA Spec Guide	Mohave II
TEC Services	Mohave III
Baker	Kiva I- III

3:30 pm

DRS Laboratories, Inc	Mohave I
NuAire	Mohave II
Raven Labs	Mohave III
Baker	Kiva I- III

Schedule of Events

Monday, April 12, 2010 (continued)

9:00 - 9:30 am

USP 797: How to Add Value to your Business
Christi Larson, Pharm. D.
The purpose of this presentation is to educate the audience on how one can add value to their business by educating clients on the importance of compliance with USP 797. The audience will be introduced to the two main reasons why compliance with USP 797 is important and be given tips that may be offered to clients to aid them in their journey to USP 797 compliance.

Learning Objectives: Upon completion of this presentation, the participant should be able to:

- Identify the 2 main reasons why compliance with USP 797 is important.
- Recognize that non-compliance with USP 797 can impact patient safety.
- Recognize that non-compliance with USP 797 may affect a facility's ability to become accredited and therefore affect the facility's bottom line.
- Identify steps clients can take to become compliant with USP 797.
- Recognize that being able to educate clients on the importance of compliance with USP 797 can add value to one's business.

9:30 - 10:15 am

Break/Exhibits
West Foyer

10:15 - 10:45 am

Current Considerations for USP <797>
Jim Wagner
The presenter is a member of the USP committee responsible for the revisions to Chapter <797>. As such he regularly receives questions and comments relating to the chapter. The current version is now almost two years old. This presentation will discuss the most frequently asked questions and provide an update of the current facilities issues pertaining to sterile compounding.

Learning Objectives:
At the end of this session, you will be able to:

1. Evaluate the latest information from USP regarding chapter <797>
2. Analyze solutions to a multitude of challenges that the chapter has presented for compounders of sterile preparations.
3. Describe the USP reference to CETA for guidance on testing cleanrooms.
4. Summarize the unique facilities challenges presented by Nuclear Pharmacy and Gene Therapy.

10:45 - 11:15 am

Update on the American National Standards Institute (ANSI)/American Industrial Hygiene Association (AIHA) Z9.5 Standard on Laboratory Ventilation
Steven Mark Crooks, MS, CIH, CSP, People, Property, and Environmental Protection, Inc. (and also representing the American Industrial Hygiene Association in the context of the presentation.)
After more than a year in active deliberation, the ANSI/AIHA Z9.5 standard on Laboratory Ventilation is being released in May. This will highlight the first major revision since 2003. The final incorporates the last several changes resulting from both public and full Z9 Committee review. While the revision isn't expected to have any major impact on laboratory owners, designers and occupants, there are certainly important changes to be aware of. This presentation will focus on the final outcomes of the sections within the standard having the most change.

Learning Objectives: At the conclusion of the presentation, attendees will be able to note the following areas of revision and where practical, the thinking behind the committee's final position.

- Increasing emphasis on a Laboratory Ventilation Management Plan
- Design information relative to emergency modes of operation (e.g., ensuring that emergency mode operations do not prevent emergency egress due to extreme pressure differentials)
- Replacing the current lower limit on air flow through a fume hood (25 cfm/sq. ft.) with a range of values and guidance on how to select the minimum flow
- Reverting back to use of the term "fume hood," which the committee tried to banish with the 2003 standard because the technical AIHA definition of "fume" as a solid particle
- The addition of energy considerations within the scope of standard
- Expanded coverage and education on the installation and use of perchloric acid hoods
- Further information on capabilities and Limitation of ductless fume hoods
- New information concerning the "hazardous exhaust" designation and related ICC interpretations.
- Updates to the Preventive Maintenance section

11:15 am - 12:00 pm

Trust but Verify: Validation of ventilation in health care facilities for infection control
Andrew J. Streifel MPH REHS, Department of Environmental Health & Safety University of Minnesota
Airborne infectious diseases in health care facilities are detrimental to patients and employees. Infectious airborne bacteria and virus can be transmitted to patients and employees. Airborne Infection Isolation rooms (AIIR) require certain physical and ventilation criteria to contain aerosols from an infectious patient. These rooms often do not meet basic controls. Likewise, certain patients are subjected under to immune suppressing therapies that make them susceptible to common airborne fungi. The management of the environment protective for these types of patient qualities requires objective assurance for safety. This presentation will explore the airborne infectious disease hazard in hospitals, the conditions causing disease transmission and the performance testing methods for mitigating risk.

Schedule of Events

Learning Objectives: At the conclusion participants will understand and be able to list:

- The primary airborne spread diseases for occupational and patient hazard analysis
- The specific ventilation parameters associated with protecting patients and employees
- The source management methods of airborne spread diseases from patients and the environment
- The tools available to test the environment
- The interpretation of the data for such testing
- The infection control mitigation strategies for design and maintenance of sustainable hospitals

12:00 - 1:00 pm **Lunch**
Hacienda I – Paloma III

1:00 - 5:00 pm **CETA Series - Alarms in Critical Environments**
Mohave I – Kiva III

6:00 pm **CETA Annual Awards Banquet**
West Patio (Hacienda I – Paloma II in case of rain

Tuesday, April 13, 2010

7:15 am - 1:30 pm **Registration**
North Foyer

8:00 am - 1:00 pm **CETA Annual Meeting General Session**
Mohave I – Kiva III (unless otherwise noted)

8:00 - 8:10 am **Conference Updates**
Marc DuBois, CETA President-elect

8:15 - 9:00 am **Compliance Issues with Cleanroom Results**
Darrin Pearson, Greer Labs
In this session we will discuss the implication of finding OOL's during the certification process of a facility. We will follow the path from the time an OOL is found unto the time it is closed out.

Learning Objectives:

- What is required by the FDA.
- What is an OOL. Who is involved in an OOL investigation.
- What is involved in an OOL Investigation.
- What is the impact of an OOL.

9:00 - 9:30 am **Using USP 797 as a guide to better designed modular and small Clean rooms**
Andrew C. Milliner
With the need to create more and more Cleanroom space for both large and small scale Pharmacies USP797 has given us a great goal for final completion? But what about the temporary rooms designed to "make do" until the permanent large scale rooms are ready. And also the small "family run" Cleanrooms that are popping up all around us. This talk will cover these "temporary and smaller Modular Cleans rooms with all of their problems with space, temperature control and of course costs.

Learning Objectives:

- A good clean installation with as little down time as possible to your client.
- To be able to spot bad design issues when testing's somebody else's disasters

9:30 - 10:00 am **ISO 21501-4 Particle counter calibration standard**
Timothy S. Russell, TSI Inc
The objective of ISO 21501-4 will be discussed. A brief explanation of how particle counters work will be given, followed by a review of the scope of ISO 21501-4. Why this calibration standard is important, and how it relates to the FDA Aseptic Processing guidance and EU GMP Annex 1 will be examined.

10:00 - 10:15 am **Conference Evaluation Form Review**

10:15 - 10:45 am **Break/Exhibits**
West Foyer

10:45 - 11:00 am **General Election/Member Business Meeting**

11:00 am **Adjourn**

11:00 am - 1:00 pm **Thermo Fisher Scientific Manufacturer Update**

1:00 - 5:00 pm **CETA Certification Examination**
Hacienda I – Paloma III

Mark Your Calendars!

CETA's 19th Annual Conference | April 15-19, 2011
SanDestin Golf and Beach Resort | Destin, FL

Officers

President: **Jeff Smith,** *Agape Instruments Service Inc..*
President-Elect: **Marc DuBois,** *C-Scan Technologies*
Secretary/Treasurer: **Troy Tillman,** *TSI Incorporated*
Immediate Past President: **William Peters,** *NuAire, Inc*

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Dave Crosby, *Air Techniques International*
Nicholas T. Flynn, *B&V Testing Inc.*
Gene Klingbeil, *Filtration Group, Inc.*
Kenneth W. Mangis, *Eli Lilly Inc.*
Arthur (Tony) McGrath, *The Baker Company*
Chris Rowe, *NNE US Inc.*
Rob Peat, *H.E.P.A Filter Services, Inc.*
Jim Wagner, *Controlled Environment Consulting*

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Executive Director: **Felicia Kenan Boyles**
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A Special Thanks to Our Sponsors & Exhibitors

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Airflotek, Inc.

Exhibitors

1. Aerobiology Lab
2. Airflotek, Inc.
3. EMLab P&K
4. Holland Safety Equipment (TEL)
5. Clordisys Solutions Inc.
6. DRS Laboratories, Inc
7. EMSL Analytical Inc.
8. Flow Sciences, Inc.
9. Teknipure
10. Particle Measuring Systems
11. Cert-Pro
12. Raven Labs
13. AAF International
14. Quip Laboratories, Inc.
15. PathCon Laboratories
16. Lighthouse Worldwide Solutions
17. Bioscience International
18. Shortridge Instruments, Inc.

Exhibit Times

SUNDAY:
7:00 - 8:00 am
10:30 - 11:00 am
12:00 - 5:00 pm

MONDAY:
7:00 - 8:00 am
9:30 - 10:15 am
12:00 - 5:00 pm

TUESDAY
7:00 - 8:00 am
10:15 - 10:45 am

Exhibitor Descriptions

Booth 1: The Baker Company
Multiple energy-saving features equal significant ongoing cost savings Continuously safe work environment with self-adjusting motor technology Quietest operation available Most comfortable with lowest noise and reduced heat generation Easier, faster maintenance Industry's most durable and reliable cabinet means lower life cycle costs and years of trouble – free operation. www.bakerco.com

Booth 2: Teknipure
Teknipure utilizes innovative technology to maximize purity; technically superior cleaning products, and cost reduction thru improved efficiency. We manufacture critical use wipers that meet your most stringent micro-contamination control needs. These include TekniClean polyester knit and microfiber wipers, TekniSat pre-saturated wipers, & TekniZorb nonwoven wipers. Teknipure; The Intelligent Choice. www.teknipure.com

Booth 3: Aerobiology Lab
Aerobiology Laboratory Associates, Inc. is an environmental laboratory focused on client support with laboratories in Atlanta, GA, Denver CO, and the Washington D.C. area. With numerous accreditations, we offer a wide range of services to help with any environmental concerns. Our expertise in building-related health issues and microbial applications allows Aerobiology to consult with professionals in all areas. Our expanded capabilities help to encompass the developing needs of our clients, while maintaining our outstanding level of quality and customer service.

Booth 4: Holland Safety Equipment
Holland Safety Equipment is the North American distributor for all products manufactured by TEL-Temperature Electronics Ltd. TEL offers fume hood monitors and VAV fume hood controls products including dampers and actuators. TEL also provides fresh air bleed controllers and dampers as well as room pressure monitors, controllers and transducers.

Booth 5: Particle Measuring Systems
With 35 years experience, Particle Measuring Systems is the established global leader in designing, manufacturing, and servicing particle counters and molecular/gas analyzers.

Booth 6: CertPro.
Cert-Pro Company develops software and tools for the certification industry. Software products include ASHRAE 110 test system, Hood Certification program and Cleanroom Classifier Certification software. All software systems provide full data collection and automated reporting. Cert-Pro also offers the LPC-100 low pressure calibrator for calibrating pressure gages and transmitters. www.cert-pro.com

Booth 7: Filtration Group
We are the largest privately held filter manufacturer in North America. We manufacture products under the Aerostar, Filtrair, Flowstar and PowerSystem brands for HVAC, cleanroom, biosafety, gas phase, turbine, paint and filter media market applications. Our commit¬ments to quality, communication and continuous improvement has made us a filtration products leader. www.filtrationgroup.com

Exhibitor Descriptions

Booth 8: Airflotek
We are a premier marketer of Fan/Filter Modules, HEPA/ULPA filters, Terminal Ducted Modules, Cleanroom Ceiling Systems, Cleanroom Lighting Fixtures, Softwall Cleanrooms, Air Showers, Pass-Through, HEPA Filtered Vacuums, Shoe Cleaners, Cleanroom Furniture, Laminar Flow Equipment and Cleanroom Construction. www.airflotek.com

Booth 9: Air Techniques International
ATI is the industry leader in the design and manufacture of a comprehensive line of test equipment for filter media testing, panel filter testing, respirator cartridge testing, respirator testing and in-place HEPA/ULPA filter certification. For more information, or a price quotation, contact the ATI sales department. www.atitest.com

Booth 10: Camfil Farr
Camfil Farr is the world leader in air filtration and clean air solutions, with 22 production plants and R&D centers in the Americas, Europe and the Asia-Pacific region. In North America our facilities are in Riverdale NJ, Washington NC, Conover NC, Crystal Lake IL, Corcoran CA, Toronto and Laval Canada. www.camfilfarr.com

Booth 11: DRS Laboratories
DRS Laboratories Inc. is a supplier of Chlorine Dioxide Decontamination Equipment and Services. Having explored alternative technologies to improve quality and timelines of performing routine BSC decontaminations, DRS Labs has produced the first affordable, and portable device; including tools, procedures, and training. We also offer Decontamination Services in all types of facilities; Bio-containment, Vivariums, including Equipment, and HVAC. www.drslaboratories.com

Booth 12: NuAire
NuAire has been universally recognized as a leader for more than 30 years in providing laboratory professionals with reliable products such as biological safety cabinets, CO_2 incubators, Laminar Airflow equipment, animal facility products, and ultra-low temperature freezers for the most demanding environments. www.nuaire.com

Booth 13: Eagleson Institute
Celebrating twenty years, the Eagleson Institute is a non-profit foundation with a mission to promote the principles and practices of laboratory safety. We value the role that certifiers play in the advancement of a safe work environment and look forward to supporting the industry's future training needs.

Booth 14: PathCon Laboratories
PathCon Laboratories offers microbiological laboratory and consulting services in indoor air quality issues. We provide custom sampling protocols, sampling media, air sampler rental, bacterial and fungal counts and identifications, and data interpretation to assist pharmaceutical compounding facilities in evaluating microbial bioburden as described in USP 797.

Booth 15: Lighthouse Worldwide Solutions
Lighthouse Worldwide Solutions is a world leading supplier of real time contamination monitoring systems and offers a complete line of handheld, portable and remote particle counters for cleanroom certification, filter testing and high pressure gas particle counting. Visit www.golighthouse.com for further information. Tel: 877-949-1530

Booth 16: Raven Labs
Raven Labs is announcing the release of its newest product, RCT kit for ClO_2, a biological indicator culture test kit for use with Chlorine Dioxide sterilization at the 2010 CETA expo, booth #16. Raven Labs, a division of Mesa Laboratories, Inc, manufactures biological indicators for validating sterilization processes since 1949.

Booth 17: TEC Services, Inc.
TEC Services was founded in 1994 and has since built a strong reputation in the controlled environment products, calibration, and service industry. TEC specializes in the production of aerosol photometers, aerosol generators, calibrations, as well as repair and service all within the field of HEPA filter testing and certification.

Booth 18: Thermo Fisher Scientific
Thermo Scientific technologies are backed by our global commitment to provide the safest and most reliable biological safety cabinets available. We deliver unmatched quality and world-renowned service and support. Our newest product designs minimize costs of operation and maintenance and maximize comfort for extended use applications. www.thermoscientific.com/bsc

Booth 19: Quip Laboratories, Inc
Quip Laboratories is your source for innovative and effective bio-safety products and services. Our eco-gentle products, including Vimoba®, MB-10® and Quiptrol 3000® increase sanitation while reducing energy consumption. Visit your bio-safety expert at Quip to learn how our unsurpassed variety of products, equipment, training, monitoring and advisory services cure bio-anxiety.

Booth 20: EMLab P&K
EMLab P&K is recognized as one of the leading commercial indoor air quality (IAQ) testing laboratories in North America with over 60 service and drop-off. We specialize in analyzing air and surface samples for fungi, asbestos, bacteria, allergens, radon and USP 797. We carry a full line of (IAQ) products.

Booth 21: AAF International
AAF International introduces the MEGAcel® family of filters incorporating our proprietary ePTFE media, combining ultra-high HEPA/ULPA efficiency, extremely low pressure drop, and 8X tensile strength that is damage resistant to rough handling in transportation and installation. AAF also offers a complete line of HVAC, cleanroom, and laminar flow filtration products. www.aafintl.com

Booth 22: Flow Sciences, Inc.
Flow Sciences' mission is to provide containment systems for laboratory, pilot plant and manufacturing areas. The products are designed to protect operators from exposure to hazardous particulates and vapors while performing delicate operations.

Flow Sciences, Inc. is focused on achieving the following goals for all of its enclosures:

- maximized containment
- ergonomic ease of use
- high performance standards
- minimal energy consumption
- design flexibility

The Flow Sciences' team, with over thirty years experience in laboratory containment, is committed to finding containment solutions that meet your needs.

Exhibitor Descriptions

Booth 23: Clordisys Solutions, Inc.
ClorDiSys supplies a broad line of products for Certifier companies for BSC, incubator, and room decontamination. We have automated and manual generators that generate chlorine dioxide gas as well as powders for a more portable method. We also lease additional equip¬ment and can provide on-site support for larger decontamina-tions. www.clordisys.com

Booth 24: EMSL Analytical, Inc.
As the nation's leading environmental testing firm, EMSL's network of nationwide laboratories has been providing quality analytical services since 1981. We offer a wide array of analytical testing services to support environmental investigations focused on asbestos, microbiology, lead paint, environmental chemistry, indoor air quality, industrial hygiene and food testing. Additionally, we also provide materials testing, characterization, and forensic laboratory services for a wide range of commercial, industrial, regulatory, and law enforcement clients. www.emsl.com

Booth 25: TSI, Inc.
TSI Incorporated is a leading supplier of Instrumentation for Certifiers. Products include AeroTrak™ Particle Counters, VelociCalc™ Thermal Anemometers, DP-Calc™ Micromanometers, and EBT721 Capture Hoods that can be used as Direct Inflow Measurement (DIM) devices for Biological Safety Cabinets. TSI also supplies fume hood monitors and laboratory controls. www.tsi.com

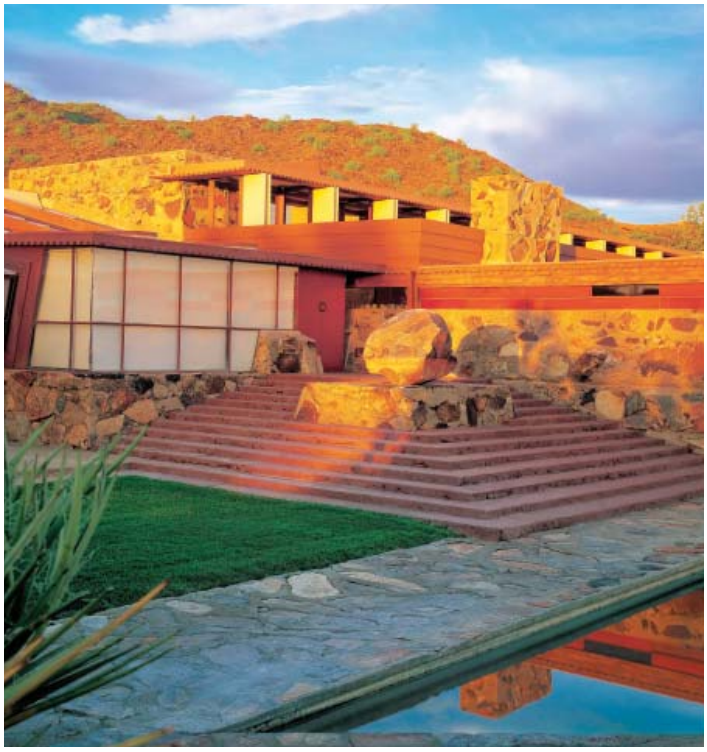
Booth 26: ESCO Technologies, Inc.
ESCO Technologies Inc. - Since 1978 ESCO has emerged as a leader in the development of controlled environment, laboratory and cleanroom equipment solutions. Products sold include biological safety cabinets, fume hoods, ductless fume hoods, laminar flow benches, PCR cabinets, animal workstations, isolators, downflow booths, airshowers, transfer boxes, and more. www.us.escoglobal.com

Booth 27: Bioscience International, Inc.
The newest generation of SAS microbial air monitors, for ensuring full compliance with USP 797 guidelines, cGMP and international monitoring requirements will be displayed.

Trade Show Contact Is Peter Pratt at ppratt@biosci-intl.com 301-231-7400

Booth 28: Shortridge Instruments, Inc.
The ADA series AirData Multimeters are used as hand-held portable meters for air velocity, pressure, and temperature measurement.

These meters may also be used to obtain direct air flow readings with an 8400 Flowhood Kit.



Speaker Bios

David Brande, Lead Consultant, Cleanroom Project Management, Inc.

David Brande brings 26 years of experience in the cleanroom industry. David was the founder and President of Contamination Control Technologies, Inc., for 19 years. The company specialized in providing cleanroom and biological containment certifications, as well as international consulting services, to the pharmaceutical, medical device and biomedical research industries until purchased by nnepharmaplan in August of 2005. David left nnepharmaplan in 2007 and is now consulting under the corporate name of Cleanroom Project Management, Inc.

David is currently the Chairman of the ISO/Technical Committee 209 that oversees the eleven documents that govern cleanroom industries worldwide, known as ISO 14644 and ISO 14698.

David is a 1977 graduate from North Carolina State University with a Bachelor of Science Degree.

Steven Mark Crooks, MS, CIH, CSP: People, Property, and Environmental Protection, Inc.

(and also representing the American Industrial Hygiene Association in the context of the presentation.)

Mr. Steve Crooks is currently President at People, Property, and Environmental Protection, Inc., a start-up consulting firm in North Carolina. Steve led the Office of Occupational Health and Environment at RTI International from 2007 – 2009 and was their senior industrial hygienist the previous three years. Prior to joining RTI, Steve enjoyed nearly fifteen years at GlaxoSmithKline, coming up through the ranks working in radiation protection, safety, hazardous waste and industrial hygiene. Steve is a board certified industrial hygienist and safety professional and enjoys coaching and playing hockey in his spare time. He earned his B.S. in Safety Sciences from Indiana University of Pennsylvania and his M.S. in Occupational Safety from East Carolina University. He currently Chair's the ANSI/AIHA Z9.5 subcommittee on Laboratory Ventilation and is here to update us on recent changes to that standard from the last edition published in 200

Kym Faylor CMQ/OE, CQA, Microbiological Environments - Laboratory Director

Kym Faylor has fourteen years experience in managing a microbiology laboratory and assuring compliance with governing agencies, client specifications, and developing the quality assurance aspect to conform to current advances in pharmaceutical, medical device, biotechnology and cosmetic industries. She has an extensive background in microbiology, specializing in validation of microbiological methods and compendia testing. Her experience includes general microbiology testing, Environmental Monitoring data analysis and trending and microbiology quality assurance programs. Recent certifications include a graduate studies certificate from UCSD in regulatory affairs, Certified Manager of Quality/Organizational Excellence & Certified Quality Auditor from ASQ. Kym also serves on the PDA Task Force for Technical Report #13, American Society for Microbiology as a Science Educators Network Mentor & Reviewer, Society for General Microbiology as a reviewer. She is also a member of Regulatory Affairs Professional Society (RAPS), American Society for Quality (ASQ) -Senior Member, Parenteral Drug Association (PDA), Institute for Validation Technology (IVT) and Bio-pharmaceutical Education and Training Association (BETA). She has several publications and has served as a lecturer & trainer for USP <797> compliance.

Gary Holland, Owner, Holland Safety Equipment Member of ASHE, ASHRAE, CETA

Over 20 years experience in the lab controls, fume hood monitor and fume hood controls business. Working for Landis & Gyr (prior to becoming Seimens), Alnor, TSI, and distributor for TEL products. Familiar with all fume hood manufacturers in North America.

Gene Klingbeil, Filtration Group, Inc.

Gene is the Biosafety Market Manager for the Filtrair HPP Division of Filtration Group, Inc. in York, SC. He manages Biosafety O.E. and Aftermarket accounts with related activities including product development, training, technical direction, and product support for customer service.

Prior to joining Filtration Group in 2001, he spent 21 years with Donaldson Company's High Purity Products Group, where he managed high-efficiency filter cleanroom and bio-safety accounts.

He provides training of HEPA/ULPA filtration principles and applications to his O.E. customers, training seminars for field certifiers, technicians, plant engineers, etc. He also has spoken at industry conferences, and written a number of technical articles for industry publications.

He is a past President of the Controlled Environment Testing Association (CETA) also serving as its' Specification Guide Committee Chair person; and a member of ASHRAE, ABSA and IEST.

His customer focused correspondence with sales, service and technical field personnel draws on his product knowledge and understanding of industry standards as well as his experience in troubleshooting field issues with high-efficiency filters and related systems. He supports this strong customer focus with a pragmatic emphasis on proper and efficient use of high-efficiency filtration.

Christi Larson, Pharm. D., Owner, Chief Consultant of I.V. Insights

Christi Larson, Pharm. D. practices as a home infusion pharmacist and is the owner and Chief Consultant of I.V. Insights. After completing her Doctorate in Pharmacy, she completed a one year Pharmacy Practice Residency. She then went on to practice in a variety of clinical pharmacy settings before specializing in home infusion and assuming the role of Pharmacy Director for one of the largest health systems in the Western United States.

Dr. Larson's expertise in the field of home infusion has allowed her to help clients develop policies and procedures aimed at implementing best practices with regard to I.V. admixtures and infection control in the hospital, clinic and infusion pharmacy settings.

Robert Lloyd, Engineering Manager, The Baker Company

Masters of Science degree in Mechanical Engineering from The University of New Hampshire

Nuclear Engineer, Portsmouth Naval Shipyard

President, New Hampshire Community Technical College, Portsmouth, New Hampshire

Joseph Peter Manfrida, PhD, EMLab P&K

Dr. Joseph Manfrida has worked as a bacteriologist and mycologist for EMLab P&K since 2007 and has been instrumental in establishing EMLab P&K's USP <797> services. He holds a BS in Biology from the University of Texas and a PhD in Microbiology from Arizona State University.

Speaker Bios

Ken Mangis, Eli Lilly and Company (LLY)

Bachelor of Science in Mechanical Engineering - Rose-Hulman Institute of Technology
Master of Business Administration - Xavier University
Engineering Intern - State of Indiana

Ken Mangis is an Associate Consultant Engineer at Eli Lilly and Company. As an engineer in Discovery Research Facilities Management, Ken is responsible for a $6.1 million capital budget and $20 million operating budget annually. Prior to joining Eli Lilly, Ken worked as a consultant in corrosion control and pharmaceutical validation. Additionally, Ken has worked as a manufacturing process engineer at Ford and Toyota. Since joining Lilly in 2001, he has held a variety of engineering assignments and is currently leading the Laboratory HVAC Technology Team within Eli Lilly. He obtained a BS degree in mechanical engineering from Rose-Hulman Institute of Technology in Terre Haute, Indiana. He is registered as an engineering intern in Indiana and obtained his MBA from Xavier University in Cincinnati, Ohio. He is a member of the International Society for Pharmaceutical Engineering (ISPE) and is a member of the Controlled Environment Testing Association (CETA). Ken has been serving as a member of the Board of Directors for CETA since 2008.

Andrew C. Milliner

Vice-President of Operations and Senior Partner at Design Filtration Inc, Ottawa, Canada. Design Filtration Inc designs, builds, and installs custom Cleanroom and Containment enclosures. Design Filtration also manufactures a wide variety of HEPA filtered products, including custom containment enclosures, fan filter modules, laminar flow hoods and polypropylene casework.

Spent 10 years as a Health Physics Monitor in the radiation division of a Nuclear power station in the UK. Moved to Canada in 1981. I began working for Microzone Corporation in Ottawa where I started the Quality Control dept which over saw all product manufacturing and design stages of their products. This included the final Certification, documentation and hand over of Cleanroom and Containment Labs located throughout North America and Europe. During this period I became the Biohood Division Manager overseeing new Biological Containment Hood designs and manufacturing. In 1986 my responsibilities expanded to include supervision of the Service department, training and creating reports for day to day operations. In 1997 I joined HEPA Filter Services as an Area Manager, areas of work included repairs, certification and installations. In 2000, along with my partners we formed Design Filtration where I am V.P. of Operations, responsible for all new designs and manufacturing of all custom products and oversee day to day operations.

Darrin Pearson, Facilities Manager, Greer Laboratories Inc. Lenoir NC

Darrin Pearson join Greer Laboratories in April 1994. He currently serves as the facilities manager for a world class Pharmaceutical facility that specializes in allergy immunotherapy. Mr. Pearson joined Greer to start a validation department which included the testing and certification of all HEPA's. These filters ranged in areas from class 100 clean rooms to filters inside a BL-3 containment facility. Mr. Pearson received a degree in Bio-medical engineering from Caldwell in 1990.

Timothy S Russell, TSI Inc

Tim Russell is a Field Market Developer for TSI Inc , he was one of the founding Directors of Facility Monitoring Systems Ltd., now integrated into the TSI Contamination Control group, specializing in the supply of compliant environmental and particulate monitoring systems.

He has 23 years experience in particle counting instrumentation and associated systems. During that period he has helped design, install and maintain 100s of compliant monitoring systems into the Pharmaceutical industry.

Charlene Freeman Schoenenberger, Burgh and Schoenenberger Associates Inc., Schoenenberger Associates Certification Inc.: Vice-President and co-owner.

A.A. in Nursing, Freed-Hardeman University; B.S. in Chemistry, Abilene Christian University: M.B.A. , Rochester Institute of Technology. Prior work positions include Research Chemist at Clairol Inc. and Director of Quality Control, Contact Lens Division of Coopervision.

Andrew J. Streifel MPH REHS, Department of Environmental Health & Safety

University of Minnesota , Hospital Environment Specialist, Minneapolis, MN 55455

Andrew J. Streifel is a Hospital Environment Specialist with the Department of Environmental Health & Safety. His primary responsibility is to assist with the environmental management of infectious diseases at the University of Minnesota Medical Center. He is a registered Environmental Health Specialist in Minnesota.

He is currently serving on the Maintenance Committee for the SSPC 170: ASHRAE Standard for Ventilation of Health Care Facilities. Mr. Streifel is also serving on the revision committee for the 2010 edition of the FGI Guidelines for Design and Construction of Health Care Facilities. He has served on this committee since 1994 and has participated in the development of the 1996, 2001, and 2006 & 2010 editions. During work as a health care consultant, he has been involved in the investigation of over 60 clusters of infection related to hospital air quality. He has served as a consultant in over 400 hospitals world wide on a variety of indoor air quality issues, water microbial contamination and has investigated clusters of bacterial infections due to unsanitary clinical practice. His current research interests nvolve sanitation validation and ventilation optimization with out compromising safety in healthcare facilities.

Jim Wagner

Mr. Wagner has been involved with certification and design of controlled environments since 1979. He serves on the NSF joint committee responsible for NSF standard 49 (Class II Biological Safety Cabinets), the Institute of Environmental Sciences and Technology working groups responsible for HEPA filters, laminar flow equipment, and cleanrooms, and the CETA working groups for the applications guides for certification of engineering controls used in sterile compounding.

Mr. Wagner serves on the 2005-2010 USP expert committee for sterile compounding. He has twice served as president of the Controlled Environment Testing association.

A frequent speaker at industry meetings and workshops on contamination control issues, Mr. Wagner is the primary instructor for the Eagleson Institute's "Advanced Certification" class for certification of Biological Safety Cabinets. He is a co-developer and frequent presenter at the USP/Baxa training class "Aseptic Processing and Compliance Tools for USP <797>.

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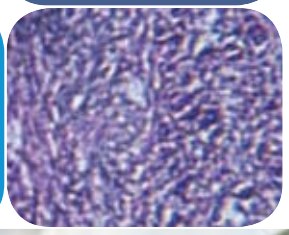

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