

PROGRAM & EXHIBITOR INFORMATION



Controlled Environment Testing Association 24th Annual Conference

April 15-19, 2016 • Red Rock Casino Resort & Spa • Las Vegas, NV

Schedule of Events

CETA 24th Annual Meeting

April 15-19, 2016 • Red Rock Casino • Las Vegas, NV

Thursday, April 14

3:00pm-7:00pm **CETA BOD Meeting**
Hills

Friday, April 15

7:00am-6:00pm **Registration**
Summerlin Foyer

9:00am-12:00pm **RCCP-SCF Written Multiple Choice Exam**
Veranda DE

1:00pm-5:00pm **CETA Series Presentation: USP 800 Cleanroom Training, CVE Certification, & Chemo EM Swabbing.**
Summerlin DE
Moderator: Nick Karlowsky, Filtech, Inc.

Saturday, April 16

7:00am-7:00pm **Registration**
Summerlin Foyer

8:00am-10:00am **NuAire Platinum Sponsor Update**
Summerlin DE

9:00am-12:00pm **RCCP-SCF Practical Exam**
Stripview A

10:00am-12:00pm **Labconco Platinum Sponsor Update**
Summerlin DE

1:00pm-5:00pm **CETA Series Presentation: Certification of Special Containment Devices**
Summerlin DE
Moderator: Jeff Serle, Germfree

12:00pm-7:00pm **Exhibitor Setup**
Summerlin ABC

7:00pm-9:00pm **Opening Reception**
Summerlin ABC

Sunday, April 17

7:00am-4:00pm **Registration**
Summerlin Foyer

7:00am-8:00am **Breakfast/Exhibits**
Summerlin ABC

8:00am-2:00pm **CETA Annual Meeting General Session**
Unless otherwise noted Summerlin DE

8:00am-8:05am **Conference Welcome**
Speaker: Todd Urton - 2015 CETA Program Chair

8:05am-8:15am **President's Address**
Speaker: Tony Caughron - 2015 CETA President

8:15am-10:15am **Presentation: Update on USP Chapter <797> and <800>**
Speaker(s): Jim Wagner, Controlled Environment Consulting and Abby Roth, CMQ/OE, Azzur, Inc.

The intent of this session is to provide an update on the proposed changes to USP Chapter <797> and to discuss important points of the new USP Chapter <800>, as relevant to certification and the services provided by the certifier.

Learning Objectives:

1. To be familiar with the new layout of USP Chapter <797>
2. To understand the proposed changes to USP Chapter <797>, as they relate to certification and certifier services.
3. To recognize the requirements of USP Chapter <800>, as they relate to certification and certifier services.

10:15am-10:45am **Break**
Summerlin ABC

10:45am-11:15am **Presentation: ISO TC209 Overview**
Speaker: Gordon J Farquharson, B.Sc., C.Eng. Critical Systems Ltd.

11:15am-12:00pm **Presentation: Revisions to ISO 14644-1 and 14644-2**
Speaker: Gordon J Farquharson, B.Sc., C.Eng. Critical Systems Ltd.

Learning Objectives:

1. Get a heads-up on the development of new and revised ISO cleanroom standards in the ISO 14644 series.
2. Understand the essential changes found in revised ISO 14644-1&2:2015. These revised standards were published on 15th December 2015.
3. Discover how the revised ISO 14644-1:2015 impacts on Pharma GMPs.
4. What's new in cleanroom monitoring to ISO 14644-2:2015.

12:00pm-1:00pm **Lunch**
T-Bones Steak House
Sponsored by Shortridge Instruments, Inc.

1:00pm-2:00pm **Presentation: Understanding and Implementing ISO 14644-1 and 14644-2**
Speaker: Gordon J Farquharson, B.Sc., C.Eng. Critical Systems Ltd.

2:00pm-4:00pm **Equipment Manufacturer Forum (See Schedule, page 3)**

4:00pm-5:00pm **NSF Steering Committee**
Stripview A
Moderator: Maren Roush, NSF

Monday, April 18

7:00am-11:30am **Registration**
Summerlin Foyer

7:00am-8:00am **Breakfast/Exhibits**
Summerlin ABC

8:00am-11:30am **CETA Annual Meeting General Session**
Unless otherwise noted Summerlin DE

8:00am-8:05am **Conference Updates**
Speaker: Todd Urton, 2015 Program Chair

Schedule of Events (continued)

8:05am-9:00am

Presentation: Dressing For Success In Your Cleanroom

Speaker: Mike Rataj, ARamARK Cleanroom Service

This presentation will provide basic information to allow for identification and implementation of an effective cleanroom gowning program. Including:

- Garment selection and performance
- Vendor selection and requirements
- Financial considerations.

9:00am-9:30am

Presentation: HVAC Design in Controlled Environments

Speaker: Ken Mangis, El MBA, Eli Lilly & Company

The presentation will review mechanical design topics applicable to Controlled Environments. Within the presentation, mechanical design approach will be explained for the following:

- Positive cleanroom (pharma or OR)
- Negative isolation room (hospital)
- Negative Lab (many hoods)

In each example, the presentation will focus on ACH, thermal load, offset pos/neg, and hood demand/ snorkel demand. The presentation will not include focus on detailed duct design or filtration.

Learning Objectives:

1. Provide certifiers with the tools needed to understand the different controlled environment room designs and related design principles. Gaining a better understanding of the room design process will offer a certifier better insight to identifying, troubleshooting, and resolving field performance issues

9:30am-10:00am

Break

Summerlin ABC

10:00am-10:45am

Presentation: Filter Testing for Space Habitats

Speaker: R. Vijaykumar, PhD of AERFIL

Terrestrial IAQ problems pales in comparison with the IAQ challenge in space habitats. The air cleaning and filtration systems required not only need to remove a broad size range of particles such as food, skin flakes, hair and clothing fibers, but it must also remove any extra- terrestrial planetary dust tracked into the habitat by the crew returning from exploration, as well as debris from operating machinery and equipment inside the habitat. The partial gravity conditions in the spacecraft and on the planetary surfaces add to the problem and in maintaining them. This brief presentation will highlight some of these challenges in building and testing filters for space applications.

Learning Objectives:

1. Constraints of testing in space
2. Test rigs to fit unique size and shape of filters and meet standard practices

10:45am-11:00am

Industry Updates: NSF

Speaker: Bill Peter, NuAire, Inc.

11:00am-11:30am

Presentation: Design & Energy considerations for cleanrooms

Speaker: Gordon J Farquharson, B.Sc., C.Eng. Critical Systems Ltd.

continued on next page



Equipment Manufacturer's Forum

2:00 pm

Baker.....Siena
LABCONCO.....Hills
STERIS Life Sciences Summerlin DE
Degree Controls..... Summerlin F

2:30 pm

Baker.....Siena
LABCONCO.....Hills
STERIS Life Sciences Summerlin DE
Degree Controls..... Summerlin F

3:00 pm

Air Techniques International.....Siena
Clordisys Solutions, Inc.....Hills
Contamination Prevention Technologies, Inc..... Summerlin DE
NuAire Inc. Summerlin F

3:30 pm

Evergreen TelemetrySiena
Holland Safety EquipmentHills
ThermoFisher Scientific..... Summerlin DE

4:00 pm

ThermoFisher Scientific..... Summerlin DE

Officers

PRESIDENT: Tony Caughron ,TEC Services, Inc.

PRESIDENT-ELECT: Todd Urton, Quality Cleanroom Consulting

SECRETARY/TREASURER: Kym Faylor, Azzur, LLC

IMMEDIATE PAST PRESIDENT: Jeff Serle, Germfree Laboratories, Inc.

Directors

David Brande, Cleanroom PM

Wayne A. Copeland, CEPA Operations, Inc.

Kimberly Coughlin, B&V Testing, A Stericycle Company

Nick Karlowsky, Filtech, Inc.

Terry Lewis, Lewis Testing Services, Inc.

Kenneth W. Mangis, Eli Lilly and Company

Tony McGrath, The Baker Company

Chandler Papas, C-Scan Technologies, Inc.

Staff

Executive Director: Felicia Kenan, CMP

Membership Services: Holly Currie

Schedule of Events *(continued)*

| | |
|------------------------|-----------------------------------------------------------------------------|
| 11:30am-12:30pm | Lunch <i>T-Bones Steak House</i> |
| 12:15pm-6:15pm | Wally Whitt Memorial Golf Tournament <i>Red Rock Country Club</i> |
| 12:15pm-4:15pm | "I Don't Golf" - Bowling Tournament <i>Red Rock Lanes</i> |
| 7:00pm-10:00pm | Annual Banquet <i>Summerlin DEF</i> |

Tuesday, April 19

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|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7:00am-10:00am | Registration <i>Summerlin Foyer</i> |
| 7:00am-8:00am | Breakfast/Exhibits <i>Summerlin ABC</i> |
| 8:00am-12:30pm | CETA Annual Meeting General Session <i>Unless otherwise noted Summerlin DE</i> |
| 8:00am-8:05am | Conference Updates <i>Speaker: Todd Urton, 2015 Program Chair</i> |
| 8:05am-8:35am | <p>Presentation: Thinking Outside The Box - How prefilters in the application work alongside certifiers <i>Speaker: Shawn Windley, Flanders, Inc.</i></p> <p>Trade organizations such CETA spend a great deal of time educating the industry on the benefits of HEPA and ULPA filtration. We study in depth testing, procurement, and handling practices to ensure the best possible products are being used within our laboratories and safety hoods. Hidden behind the scenes often located upstream of the certifiers playground are pre-filtration methods and concepts aiding in the life expectancy and performance of the filters used within the workspace.</p> <p>This presentation plans on covering in detail these often inexpensive products that ultimately save certifiers and end users money.</p> <p>Learning Objectives:</p> <ol style="list-style-type: none"> 1. Filter Theory 2. How Pre-filters work 3. What distinguishes one choice from another 4. d. Total Operational Costs Analysis |
| 8:35am-9:20am | <p>Presentation: Cleaning and Disinfection for Compounding Pharmacies <i>Speaker: Jim Polorine, Steris Corporation.</i></p> <p>Recently regulators have been placing a larger emphasis on compounding pharmacies using both a disinfectant to address daily routine cleaning and a sporicide to address mold and bacterial spores. Currently the majority of cleanrooms use phenolics, quats, or quat mixes for routine disinfection. Therefore, rotation of a disinfectant and a sporicide is common in the industry today. Certain regulations such as USP 38 <1072> Disinfectants and Antiseptics and the Aseptic Processing Guide (2004) support the use a disinfectant and sporicide as a rotational program. Typically tacky rollers and HEPA vacuums are used to remove larger debris on the floors before the implementation of the cleaning and disinfection program. The application equipment used is also critical to successful cleaning and disinfection and most end users will us a two or three bucket system for routine cleaning and disinfection and they will conduct a fogging or triple clean</p> |

for extraordinary events. Extraordinary events would be at a facility shut down, power failure, construction event, after a hurricane or after any lengthy downtime period. Fogging would typically be conducted with a sporicidal agent such as Hydrogen Peroxide/Peracetic Acid blends, Hydrogen peroxide, or Chlorine Dioxide. The triple clean generally means conducting the cleaning and disinfection program including the sporicidal application three times. Cleanroom wipes are also a routine part of the cleaning and disinfection program for cleaning equipment, windows, and walls. Following several applications of disinfectant and sporicide end users typically will rinse the walls and floors with Water for Injection and rinse equipment and windows with 70% Isopropyl Alcohol to remove the residual build up. Rinsing is typically based on visual observation and is carried out once a week, once a month, or once a quarter depending on the levels of residues. To summarize a sound cleaning and disinfection program consists of choosing the most effective products against your microbial isolates as well as the most effective technologies to apply the disinfectants and sporicides. Additionally, a rinsing step has really become standard best practice in the industry following several applications of products.

Learning Objectives:

1. Current industry trends in disinfectant rotation
2. The need to control bioburden involves a sound cleaning and disinfection program
3. The most current industry methods for applying disinfectants
4. Effective methods for controlling and removing residues
5. Developing a robust and effective cleaning and disinfection program to satisfy FDA industry regulators

| | |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9:20am-9:30am | Industry Updates: CNBT Update <i>Speaker: Kim Coughlin, CNBT Co-Chair</i> |
| 9:30am-10:00am | Break <i>Summerlin ABC</i> |
| 10:00am | Exhibitor Breakdown <i>Summerlin ABC</i> |
| 10:00am-10:15am | Industry Updates: CETA Spec Guide <i>Speaker: Terry Lewis, Spec Guide Committee Chair</i> |
| 10:15am-10:30am | General Election & CETA Business Meeting <i>Moderator: Tony Caughron, 2015 President</i> |
| 10:30am-11:30am | <p>CAG Working Groups: CAG 002 <i>Summerlin D</i> <i>Moderator: Bill Peters</i></p> <p>CAG Working Groups: CAG 003 <i>Summerlin E</i> <i>Moderator: Jim Wagner</i></p> |
| 11:30am-12:30pm | <p>CAG Working Groups: CAG 008 <i>Summerlin D</i> <i>Moderator: Nick Karlowsky</i></p> <p>CAG Working Groups: CAG 009 <i>Summerlin E</i> <i>Moderator: Kym Faylor</i></p> |
| 12:30pm | Meeting Adjourned |
| 12:30pm-2:00pm | CETA Follow-Up Board Meeting <i>Summerlin F</i> |

A Special Thanks to Our Sponsors and Exhibitors

Platinum Sponsors

NuAire Inc.
LABCONCO

Gold Sponsors

Flanders Corporation
Baker

Bronze Sponsors

Filtration Group Inc.
Germfree Laboratories, Inc.
CAMFIL USA, Inc
ThermoFisher Scientific
AAF International
Kewaunee Scientific Corporation
STERIS Life Sciences
TEC Services, Inc.

Exhibitors

Booth 101: U.S. Micro-Solutions, Inc.
Booth 103: Flanders Corporation
Booth 105: Analytics Corporation
Booth 106: The Cleanroom Parts Guys
Booth 107: Aerobiology Laboratory Associates, Inc.
Booth 108: EMSL Analytical Inc.
Booth 109: Bioscience International, Inc.
Booth 113: Clordisys Solutions, Inc.
Booth 115: LABCONCO
Booth 117: Filtration Group Inc.
Booth 119: Germfree Laboratories, Inc.
Booth 121: Contamination Prevention Technologies, Inc.
Booth 123: Degree Controls Inc.
Booth 200: CAMFIL USA, Inc
Booth 201: Eagleson Institute
Booth 202: American Biological Safety Association
Booth 203: Baker
Booth 204: Air Techniques International
Booth 205: TSI Incorporated
Booth 206: ThermoFisher Scientific
Booth 207: EMLab P&K
Booth 208: DRS Laboratories, Inc.
Booth 209: AAF International
Booth 212: Kewaunee Scientific Corporation
Booth 213: Shortridge Instruments, Inc.
Booth 214: MilliporeSigma
Booth 215: Holland Safety Equipment
Booth 216: STERIS Life Sciences
Booth 217: Modular Cleanrooms Inc.
Booth 218: Chattanooga Environmental Laboratory, LLC
Booth 219: Evergreen Telemetry
Booth 220: NuAire Inc.
Booth 221: TEC Services, Inc.
Booth 222: Kanomax USA

Exhibiting Times

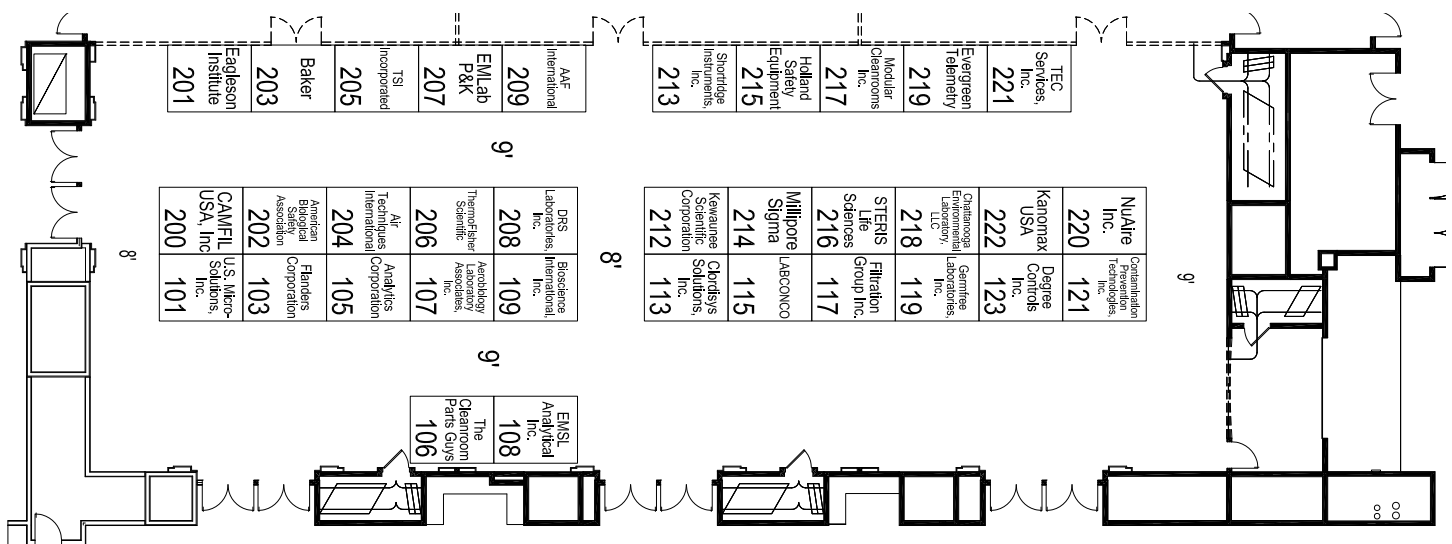
Saturday, April 16
7:00 - 9:00 PM

Sunday, April 17
7:00 - 8:00 am
10:15 - 10:45 am

Monday, April 18
7:00 - 8:00 am
9:30 - 10:30 am

Tuesday, April 19
7:00 - 8:00 am
9:30 - 10:00 am

Exhibit Hall Floor Plan – Summerlin Ballroom



Exhibitor Descriptions

Booth 101: U.S. Micro-Solutions, Inc.

U.S. Micro-Solutions, Inc. specializes in the laboratory analysis of USP 797 culturable air, contact, and finger tip plates. We provide our customers with a specialized ISO classification report that enables them to accurately identify violations of USP 797 regulations. Call 724-853-4047 or visit www.usmicro-solutions.com for more information on USP 797 testing and analysis.

www.usmicro-solutions.com

Booth 103: Flanders Corp

Flanders provides the most complete line of filtration products available, specializing in high efficiency air filtration products. We design, manufacture and market the highest quality filter and containment filtration systems necessary to filter and contain dangerous airborne contaminants for the medical, biological and pharmaceutical industry. Flanders is Foremost in Air Filtration

www.flanderscorp.com

Booth 105: Analytics Corporation

Analytics Corp was founded in 1977 as an industrial hygiene laboratory and we received our AIHA-LAP, LLC accreditation in 1981. Based on the needs of our IH clients, Analytics began testing environmental samples in the late 90s and received our NELAC certification in 2000. In addition, we are now participating and proficient in the Pharmaceutical Round Robin PT program.

By combining scientific expertise, state-of-the-art instrumentation and leading edge information management systems, Analytics Corp is committed to delivering the highest quality analytical laboratory services to our clients.

www.analyticscorp.com

Booth 106: The Cleanroom Parts Guys

The Cleanroom Parts Guys are a small startup company located in Ft. Worth, Texas. Our goal is to fill the market need for the much needed parts and supplies that are absent from the cleanroom industry. We are manufacturing our own name brand products. Have an idea we can help you design contract manufacture for you as well.

www.TheCleanroomPartsGuys.com

Booth 107: Aerobiology Laboratory

Aerobiology Laboratory is an AIHA accredited environmental microbiology laboratory. Our AeroMetric 797 report provides our clients and end users a summary of their results. We now provide nationwide coverage with six locations in Atlanta, GA, Denver, CO, Phoenix, AZ, Los Angeles, CA, Cherry Hill, NJ and Washington D.C. Aerobiology's focus on microbiology, quality and customer support, provides the technical expertise to your market.

www.aerobiology.net

Booth 108: EMSL Analytical

EMSL Analytical is a nationally recognized and locally focused provider of environmental, indoor air quality (IAQ) and materials testing services and products to professionals and the general public. The company has an extensive list of accreditations from leading organizations as well as state and federal regulating bodies.

www.EMSL.com

Booth 109: 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.

Contact: Peter Pratt - ppratt@biosci-intl.com; 301-231-7400 ext 101

Booth 113: ClorDiSys Solutions

Clordisys provides chlorine dioxide gas decontamination equipment for use on BSC's, HEPA housings, Incubators, Isolators, Rooms, and other enclosures. Chlorine dioxide gas is a safer alternative to formaldehyde and our CHEM-CD process is a simple, easily portable, NSF approved replacement for the decontamination of BSCs.

www.clordisys.com

Booth 115: Labconco Corp.

Labconco is an ISO 9001 certified company which prides itself on the quality of our people and products. Labconco products adhere to high standards including ETL and NSF Standard 49. From biosafety cabinets to fume hood, Labconco protects your laboratory environment.

www.labconco.com

Booth 117: Filtration Group, Inc.

Filtration Group is the market leader in HEPA and ULPA filters designed for the Biosafety Cabinet manufacturers. Utilizing our Sentinel Pleat technology we custom engineer filter designs to meet the stringent performance requirements of the market. Filtration Group implores quality assurance throughout the process to ensure the finished product meets the design specifications.

www.filtrationgroup.com

Booth 119: Germfree Laboratories, Inc.

Germfree designs, engineers and manufactures laboratory equipment, hospital pharmacy equipment and turnkey mobile and modular labs. Germfree's Class III Biosafety Cabinets provide containment in the world's most advanced laboratories. Germfree systems have been purchased by more than 6,000 institutions and companies in the U.S. & 60 other countries worldwide.

www.germfree.com

Exhibitor Descriptions *(continued)*

Booth 121: Contamination Prevention Technologies

Contamination Prevention Technologies' products were developed to proactively prevent contamination such as our hand sink which will immediately sanitize and sterilize hands. Our regulatory consultants can review and validate any system and resolve most compliance issues organizations have regarding sterilization and mold prevention.

www.contaminationprevention.com/home.html

Booth 123: Degree Controls

Degree Controls, a leading airflow monitoring company, will be discussing the latest generation of Rooster Monitor100/200 cabinet airflow monitoring and control products, with emphasis on new features for NSF compliance, and value-add features. A demonstration of the °C Breeze portable fog machine will also be conducted for attendees

www.degreec.com

Booth 200: CAMFIL

World leader in air filtration technology, Camfil offers state-of-the-art filtration solutions for cleanrooms, Biological Safety Cabinets and high containment spaces. Camfil manufactures HEPA and ULPA filters with flows as high as 600 fpm; and adsorbers for removing gaseous contaminants. Camfil's highly-engineered filter housings have reset the industry standard for biocontainment systems.

www.camfil.com

Booth 201: Eagleson Institute

The Eagleson Institute is a non-profit foundation with a mission to globally promote the principles and practices of health and safety in the life sciences community. Our highly interactive classes, cover a wide range of biosafety topics including: BSC certification, BSL3 laboratory performance verification and certification of sterile compounding facilities.

www.eagleson.org

Booth 202: ABSA International

ABSA International (American Biological Safety Association) was founded in 1984 to promote biosafety as a scientific discipline and serve the growing needs of biosafety professionals internationally. ABSA's core purpose is to promote and expand biosafety expertise through training, laboratory accreditation, publications, networking, biosafety resources advocacy, an annual biosafety conference, and professional credentials.

www.absa.org

Booth 203: The Baker Company

As the world leader in the design and manufacture of biological safety cabinets, clean benches and fume hoods, Baker thrives on helping scientists and researchers achieve their mission in almost every kind of endeavor and a wide variety of industries, including biotech, pharmacy, governmental, clinical and medical education research.

www.bakerco.com

Booth 204: Air Techniques International

Air Techniques International (ATI) is the global leader in testing equipment for specialized air filters and masks. Since 1961, we've enabled our customers to improve product quality, ensure worker health and safety; complying with the most stringent testing standards and regulations. ATI is the trusted resource for government, military, nuclear, and commercial industries.

www.ATItest.com

Booth 205: TSI, Inc.

TSI Incorporated is a leading supplier of Instrumentation for Certifiers. Products include AeroTrak™ Particle Counters, VelociCalc™ Thermal Anemometers, DP-Calc™ Micromanometers, and EBT731 Capture Hoods that can be used as Direct Inflow Measurement (DIM) devices for biological safety cabinets. TSI also supplies hospital isolation room monitors and laboratory controls.

www.tsi.com

Booth 206: ThermoFisher Scientific

With Thermo Scientific biological safety cabinets, the certified performance and protection you receive on Day 1 stays with you every day. Not true with ordinary cabinets. With our proven reliability, ergonomics and energy efficiency, the ideal choice is the one you can trust completely. And not just on day one. Visit us at booth 23 or see our full portfolio of BSCs at:

www.thermoscientific.com/bsc

Booth 207: EMLab P&K

EMLab P&K, a TestAmerica company, is one of the leading commercial IAQ laboratories in North America. EMLab P&K has over 90 service and drop-off locations throughout the United States. EMLab P&K specializes in microbial analysis including mold, bacteria, and USP <797> testing. More information about USP <797> services at:

www.emlabpk.com/USP_797

Booth 208: DRS Laboratories, Inc.

DRS Laboratories, Inc. is the Manufacturer of the MCS (Mini Chlorine dioxide System). Having explored alternative technologies to improve quality, timeliness, and cost 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 conjunction w/current certification contractors or independently.

www.drslaboratories.com

Booth 209: AAF International

AAF International is a world leader in air filtration products and understands the critical requirements of the biosafety industry applications. AAF provides the industry with AstroCel II plenum filters, MEGAcel II ePTFE media filters, HTP High Temp filters, and other accessory items. AAF also supplies filters for other critical applications.

www.aafintl.com

continued on next page

Exhibitor Descriptions *(continued)*

Booth 212: Kewaunee Scientific Corp.

Kewaunee Scientific designs, manufactures and installs innovative products of high quality to the laboratory market. The Company's corporate headquarters and manufacturing facilities are located in Statesville, North Carolina. The Interceptor Class II, A2 Biological Safety Cabinet is Kewaunee's latest design developed with comprehensive features enhance both safety and ergonomics.

www.kewaunee.com

Booth 213: Shortridge Instruments

AirData Multimeter kits include industry-standard pitot tubes, static pressure probes, tubing and two proprietary probes, which make air-balancing faster and easier. The AirFoil probe is a single-point velocity probe with a straight shaft design for easy duct insertion. The VelGrid is a 16-point, velocity-averaging grid, which is useful for exhaust hoods, cleanroom filter outlets, laminar flow workstations and large filters and coils.

www.shortridge.com

Booth 214: MilliporeSigma

MilliporeSigma is the U.S. life science business of Merck KGaA, Darmstadt, Germany. With 19,000 employees and 72 manufacturing sites worldwide, MilliporeSigma's portfolio spans more than 300,000 products enabling scientific discovery. MilliporeSigma has customers in life science companies, university and government institutions, hospitals and industry. More than 1 million scientists and technologists use its products. The company is committed to solving the toughest problems in life science by collaborating with the global scientific community.

www.??????

Booth 215: Holland Safety Equipment

Holland Safety Equipment is the North American distributor for Temperature Electronics Ltd. TEL offers fume hood monitors and VAV fume hood control products, fresh air bleed controllers and dampers and room pressure monitors, controllers and transducers. HSE also offers smoke sources for airflow visualization and various other consumables for CETA certifiers.

www.hollandsafety.com

Booth 216: STERIS Life Sciences

For over 100 years STERIS Corporation has been known as a global leader and solutions provider in the field of sterilization. With our full portfolio of VHP® Biodecontamination Systems utilizing patented VHP Process Technology and proprietary Vaprox® Hydrogen Peroxide Sterilant, STERIS Life Sciences is Science and Solutions for Life.

www.sterislifesciences.com

Booth 217: Modular Cleanrooms

Modular Cleanrooms provides cleanroom solutions to support your new or existing needs. We offer several lines of pharmacy ready cleanrooms and will retrofit existing labs and upgrade existing cleanrooms. Our rooms meet or exceed USP 797 and 800, ISO class 8 to 5 and Federal Standard 209E, class 100,000 to 10.

www.modularcleanrooms.com

Booth 218: Chattanooga Environmental Laboratory, LLC

Our company offers environmental monitoring products and services so pharmacies no longer have to worry about expensive third-party services.

The MicroBio MB1, MB2, and MB2-HiFlow are all economically friendly air samplers that are very easy to use. Each unit is capable of fulfilling all your sampling need.

www.chattalab.com

Booth 219: Evergreen Telemetry

Evergreen Telemetry is dedicated to doubling the productivity of industrial technicians in HVAC, TAB, building commissioning, building automation, process control, weather monitoring, and other applications. These challenging work environments demand faster, smaller, and more convenient tools.

www.evergreentelemetry.com/Home.html

Booth 220: NuAire

NuAire provides laboratory professionals with reliable products for demanding environments: Biological Safety Cabinets, Laminar Airflow Equipment, CO2 Incubators, Animal Handling Stations, Isolators, Ultra-low Temperature Freezers, along with a variety of complementary products and systems serving the needs of laboratory communities, with the best in the industry Sales and Service support.

www2.nuair.com/13382

Booth 221: TEC Services

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.

www.tecservicesinc.com

Booth 222: Kanomax USA

Since our beginning eighty years ago, with the founding of Kano Laboratories, Kanomax has been the market leader in the development of fine measuring instruments including our fluid mechanics, environmental, aerosol, particles and customized system products.

www.kanomax-usa.com

Speaker Bios

Gordon J Farquharson, BSc, CEng.

Gordon Farquharson, B.Sc.(Hons), C.Eng. is a Chartered Consulting Engineer with more than 30 years experience of quality & safety critical processes and facilities used by industries such as Healthcare, Life Science, Micro-electronics, etc. He is Principal and Managing Director of Critical Systems Ltd, an international consultancy firm. He is also an executive consultant for CM-Plus Corporation Ltd. (Japan), PharmOut Pty Ltd. (Australia), and FactoryTalk Ltd. (Thailand) working in the Asia Pacific and ASEAN regions.

In recent years he has focused on technologies such as isolators, barrier technology, mini-environments, critical utility systems and bio-containment applications. He has been responsible for the development of technical solutions in product development, primary manufacturing and device and dosage form manufacturing.

Standards and regulatory compliance issues in the Pharma/Life Science sectors are a major interest and responsibility. In this context he has a high degree of expertise in the practical interpretation & application of EU/PIC-S/WHO GMPs and US FDA cGMP requirements. Experience with the variation in expectations gives an ability to dovetail the differing regulatory requirements together. In recent years, he has been heavily involved in the development of the new regulatory guidance and standards. In particular, he is active working on CEN/ISO Cleanroom & Contamination Control Standards, WHO GMP guidance and ISPE Baseline Guides. He is Chairman of BSI's LBI 30 Committee and of CEN Technical Committee 243, and is Convenor of WG1 and a UK expert working on the ISO TC209 and CEN TC243 family of contamination control standards that provide the platform for contamination control standardisation and practice in this millennium. He worked with the EMA in London to help update and improve the cleanroom classification and monitoring requirements in the 2008 version of Annex 1 of the EU and PIC/S GMPs and has contributed writing WHO's Pharmaceutical water GMP Guidance. He was a member of the WHO expert panel that revised the WHO GMP guidance on sterile products in alignment with the PIC/S GMP, and is active in WHO regulatory work. He is currently (2016) advising the joint EMA/PIC-S Annex 1 revision rapporteur on the application of EN ISO 14644-1&2:2015.

He is a founding member, management committee member, past Chairman, and Honorary Member of the UK Pharmaceutical & Healthcare Sciences Society (formerly Parenteral Society), and is Editor in Chief of the European Journal of Parenteral & Pharmaceutical Sciences. He is also active in ISPE, the R3 Nordic Association, and PDA. He is a past chair of the ISPE European Education Committee and was voted ISPE International Member of the year 2001, UK Affiliate Member of the year in 2008, and recipient of the Richard B Purdy Distinguished Achievement Award 2009. He is a former member of the PDA Science Advisory Board (SAB) and is an honorary senior lecturer at UCL (London) and the University of Manchester PEAT & PIAT programmes.

He lectures and teaches extensively, is an author of many papers, and contributor to books on contamination control, cleanroom and isolator technology.

Ken Mangis, EI MBA

Ken Mangis, EI MBA is a Project Manager at Eli Lilly and Company focused on delivery of Local Capital Projects in the Parenteral Site Projects group at Lilly Technology Center in Indianapolis. As a Project Manager in Parenteral Manufacturing, Ken is responsible for executing projects from Facilities related HVAC and infrastructure projects to Packaging equipment recapitalization and serialization deployment. Ken has spent time in Facilities Engineering roles in Dry Products Manufacturing and Lilly Research Labs. Prior to joining Eli Lilly, Ken worked as a channel partner for Phoenix Controls, Aircuity, Strobic, EnviroSep, and Flanders in the Indiana area. He obtained a BS degree in mechanical engineering from Rose-Hulman Institute of Technology in Terre Haute, Indiana. He is registered as an engineer intern in Indiana and obtained his MBA from Xavier University in Cincinnati, Ohio.

Jim Polarine, MA

Mr. Polarine is a technical service manager at STERIS Corporation. He has been with STERIS Corporation for fifteen years. His current technical focus is microbial control in cleanrooms and other critical environments. He has lectured in North America, Europe, Middle East, Asia, and Latin America on issues related to cleaning and disinfection in cleanrooms. Mr. Polarine is a frequent industry speaker and published several PDA book chapters and articles related to cleaning and disinfection and contamination control. He is active as co-chair on the PDA's microbial investigations task force. He was a co-author on PDA's Technical Report #70 on Cleaning and Disinfection. He is a member of the PDA's Environmental Monitoring Group, Contamination Control Group, and Biotech Interest Group. He is a board member with the PDA Missouri Valley Chapter. He is part of the faculty at the University of Tennessee Parenteral Medication course. He is also active with the IEST Special Topics Committee on Cleaning and Disinfection. He has presented at key industry venues for NASA, USP, PDA, ISPE, FDA, SIMB, GBPR, IPA, AALAS, IVT, IEST, University of Tennessee, SWE, Isomedix, and Barnett International on cleaning and disinfection, disinfectant validation, and contamination control. Mr. Polarine frequently presents global industry webinars on Cleaning and Disinfection for several industry seminar circuits including Compliance Online, STERIS, and Executive Conferences. Mr. Polarine graduated from the University of Illinois with a Master of Arts in Biology, and is a member of the PDA, SIMB, ISPE, IEST, ASM, ASTM, AAAS, AOAC, and ACS. He previously worked as a clinical research coordinator with the Department of Veterans Affairs in St. Louis, MO and as a biology and microbiology instructor at the University of Illinois. His main hobby is storm chasing and is very active in tornado research and tornado safety.

continued on next page

Speaker Bios (continued)

Mike Rataj

Mike Rataj is the Director of Quality Assurance for Aramark Cleanroom services, and has > 20 years of experience in the contamination control and pharmaceutical manufacturing industries. Chairman of the IEST working group "Garment Considerations for Cleanroom and Other Controlled Environments" and others. Holds an MS degree in Biology from the University of Illinois in Urbana.

Abby Roth, CMQ/OE

Abby Roth is the Quality Director at Azzur Labs in Schnecksville, Pennsylvania. She has been with Azzur Labs since 2012 and has over 12 years of experience in supporting the testing and consultation needs of the pharmaceutical, medical device and compounding industries. Her areas of expertise include environmental monitoring, including program development, sampling and analysis, product and water testing, aseptic technique, and consultation on contamination sources and control. She holds a bachelor of science degree in Biology from York College of Pennsylvania, is a Certified Manager of Quality/Organizational Excellence through the American Society of Quality and is an expert committee member of the 2015 to 2020 USP Sterile Compounding Committee

R. Vijayakumar, PhD

Vijayakumar is the founder and head of AERFIL, a consulting company devoted to providing technical and business solutions and services for the filtration and contamination control industry, as well as educational and training support for the industry. His current clients include major filtration companies in China, Brazil and India.

With over 30 years' experience in leading filtration and particle test instrument companies to go with his PhD in particle technology, Vijayakumar is a globally recognized expert and mentor in contamination control and filtration sought after by clients worldwide. He is an advisor to NASA for air filtration systems for space habitat.

In keeping with his philosophy that knowledge grows only by sharing, he teaches freely and often wherever someone wants to learn the subject. He has been on the faculty of the short course on air and gas filtration at the University of Minnesota since its inception and is a Distinguished Visiting Professor at the Chinese Academy of Building Research. He has taught courses in cleanroom designs for ASHRAE, and is a Distinguished Lecturer for them lecturing around the world on various aspects of filtration and cleanroom designs. He has recently published an eBook on Aerosol Mechanics for the general user. He has served as the President of the IEST, the premiere contamination control organization in the US. Currently, he chairs standards development committees at the ISO and in the US writing standards for high efficiency filtration and filter media used in cleanrooms, hospitals, and indoor environments.

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>".

Shawn Windley

Shawn Windley has been in the air filtration industry for over 20 years serving in various capacities such as Engineering, Manufacturing, Research and Development, and Sales. He is currently the Vice President of High Purity Products for Flanders Corporation. He graduated from East Carolina University in 2002 with a B.S. in Industrial Technology with a concentration in Industrial Engineering. He holds a certificate in ISO 14644, USP 797 Cleanroom Operations, and lastly USP 797 Cleanroom Design all through the IEST. He is actively involved in IEST, ASHE, ASHRAE, ABSA, CETA, and currently serves on the HVAC COP Steering Committee for ISPE and is the current President of the IEST.





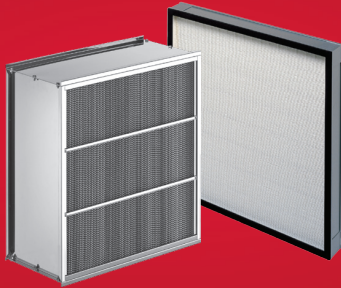
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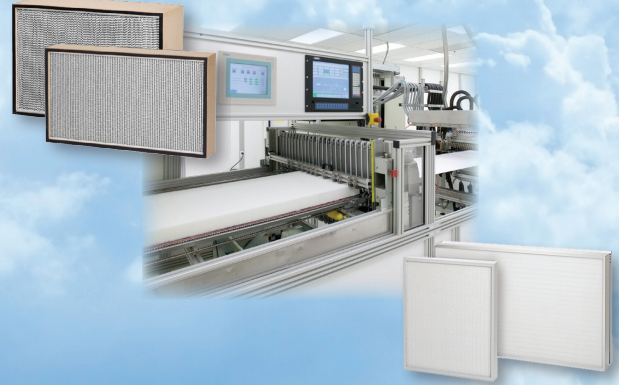
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