



Controlled Environment Testing Association

23rd Annual Meeting

April 17-21, 2015 • Sandestin Golf and Beach Resort • Destin, FL

PROGRAM & EXHIBITOR INFORMATION

Schedule of Events

CETA 23rd Annual Meeting

April 17-21, 2015 • Sandestin Golf and Beach Resort • Destin, FL

Thursday, April 16

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

Friday, April 17

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

9:00 am - 12:00 pm **RCCP-SCF Multiple Choice Exam**
Camellia II

2:00 pm - 6:00 pm **CETA Series Presentation: CAG 002**
Moderator: Todd Urton, Quality Cleanroom Consulting
Camellia I

Saturday, April 18

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

8:00 am - 10:00 am **Germfree Platinum Sponsor Update**
Camellia I

9:00 am - 12:00 pm **RCCP-SCF Written Practical Exam**
Camellia II

10:00 am - 12:00 pm **Labconco Platinum Sponsor Update**
Camellia I

12:00 pm - 1:00 pm **NSF Steering Committee**
Oak Boardroom

1:00 pm - 5:45 pm **CETA Series Presentation: Electrical Troubleshooting**
Moderator: Tony McGrath, Baker
Camellia I

5:00 pm - 7:00 pm **Exhibitor Setup**
Magnolia E&F

7:00 pm - 9:00 pm **Opening Reception w/ tribute to Fred Delle**
Baytowne Marina
Sponsored by B&V Testing, A Stericycle Business

Sunday, April 19

7:00 am - 5:00 pm **Registration**
Magnolia Registration D

7:00 am - 8:00 am **Breakfast/Exhibits**
Magnolia Ballroom E&F

8:00 am - 2:00 pm **CETA Annual Meeting General Session**
Magnolia Ballroom A&B unless otherwise noted

8:00 am - 8:10 am **Conference Welcome**
Tony Caughron, CETA Program Chair

8:10 am - 8:25 am **President's Address**
Jeff Serle, CETA President

8:25 am - 9:25 am **Presentation: Sterile Compounding and Safety in Handling Chemotherapy Administration**
Speaker: Tom Van Hassel, RPh, MPA

9:25 am - 10:00 am **Presentation: ISO-14644 Series Revisions**
Speaker: Daniel Dennison, NNE Pharmaplan

With the long awaited revisions to the ISO series standards it finally looks like we have some daylight at the end of the tunnel. ISO 14644 parts 1, 2 and 3 are on the move to be published. There are some major and minor changes pending in the documents that will change the way testing is done and reported as well as additional testing that will more modernize testing parameters and methods as well as provide test methods for situations that today are questionable at best.

Learning Objective:

1. Overview of pending changes coming in the ISO 14644 series standards

10:00 am - 10:30 am **Break/Exhibitors**
Magnolia Ballroom E&F

10:30 am - 11:15 am **Presentation: USP800 / USP797 / Niosh Alert**
Speaker: Jim Wagner, Controlled Environment Consulting

11:15 am - 11:45 am **Presentation: Certifying a Controlled Environment**
Speaker: David Brande, Cleanroompm

This presentation is designed to provide a foundational instruction and guidance for an entry level understanding of controlled environments. The presentation will discuss what four objectives constitute a controlled environment and the minimum that is required in certifying the area, or equipment, as satisfying those objectives. There will be discussion of the different test procedures available and the pros and cons of each.

Learning Objectives:

1. What is a controlled environment
2. How to satisfactorily prove a controlled environment

11:45 am - 12:00 pm **Industry Updates: NSF / Spec Guide**
Speaker(s): Bill Peters, NuAire, and Rob Peat, CETA Spec Guide Chairman, H.E.P.A. Filter Services Inc.

12:00 pm - 1:00 pm **Lunch**
Sponsored by Shortridge Instruments, Inc.
Camellia I&II

12:30 pm - 2:00 pm **CAG Working Groups:**
CAG 003 – Magnolia C
CAG 008 – Magnolia D

2:00 pm - 4:00 pm **Equipment Manufacturer Forum (See Schedule)**
Magnolia A-D

Schedule of Events *(continued)*

Monday, April 20

7:00 am - 1:00 pm

Registration

Magnolia D Registration

7:00 am - 8:00 am

Breakfast/Exhibits

Magnolia Ballroom E&F

8:00 am - 11:30 am

CETA Annual Meeting General Session

Magnolia Ballroom A&B unless otherwise noted

8:00 am - 8:10 am

Conference Updates

Tony Caughron, CETA 2015 Program Chair

8:10 am - 8:40 am

Presentation: cGMP - GDocP Guidelines

Speaker: Todd Urton, Quality Cleanroom Consulting

This presentation will discuss the core functions and responsibilities of the Food and Drug Administration as well as the regulations they enforce.

Learning Objectives:

1. Discussion of FDA's responsibilities and the regulations they enforce
2. Discussion of the Drug Quality Security Act and how it impacts compounding pharmacies
3. Discuss CDER guidance documents

8:40 am - 9:10 am

Presentation: ECM Fan Filter Units to achieve Energy Savings

Speaker: Les Goldsmith, Envirco

9:10 am - 9:45 am

Presentation: RCCP Certification Examination - Development and Validation

Speaker: Michael H. Jones, PhD, Senior Psychometrician, Professional Testing, Inc.

An overview of the process followed to develop and validate the: Registered Cleanroom Certification in Sterile Compounding Credentialing Examination. The process is guided by testing industry standards and includes: job analysis, item development, item review, pilot testing, item/test analysis, standard setting, pre-equating and examiner correlational analysis.

Learning Objectives:

1. To provide participants with a better understand of the process for validating the RCCP-SCF certification examination
2. To give participants a chance to ask questions about how the test was developed and ongoing validation efforts

9:45 am - 10:15 am

Break/Exhibitors

Magnolia Ballroom E&F



Equipment Manufacturer's Forum

2:00 pm

| | |
|--------------------------------|---------------------|
| Baker..... | Magnolia Ballroom A |
| Steris Life Sciences | Magnolia Ballroom B |
| Holland Safety Equipment | Magnolia Ballroom C |
| TEC Services | Magnolia Ballroom D |

2:30 pm

| | |
|--------------------------------|---------------------|
| Baker..... | Magnolia Ballroom A |
| Steris Life Sciences | Magnolia Ballroom B |
| Holland Safety Equipment | Magnolia Ballroom C |
| TEC Services | Magnolia Ballroom D |

3:00 pm

| | |
|-------------------------------|---------------------|
| Degree Controls..... | Magnolia Ballroom A |
| Lighthouse International..... | Magnolia Ballroom B |
| ThermoFisher Scientific..... | Magnolia Ballroom C |
| AAF International | Magnolia Ballroom D |

3:30 pm

| | |
|------------------------------|---------------------|
| Degree Controls..... | Magnolia Ballroom A |
| Lighthousernational | Magnolia B |
| ThermoFisher Scientific..... | Magnolia Ballroom C |

Officers

PRESIDENT: Jeff Serle, Germfree Laboratories, Inc.

PRESIDENT-ELECT: Tony Caughron, TEC SERVICES, INC.

SECRETARY/TREASURER: David Brande, Cleanroom PM

IMMEDIATE PAST PRESIDENT: Nicholas T. Flynn, B&V Testing. a Stericycle Company

Directors

Wayne A. Copeland, CEPA Operations, Inc.

Marc DuBois, Advanced Testing and Certification

Kym Faylor, Azzur

Nick Karlowsky, Filtech, Inc.

Kenneth W. Mangis, Eli Lilly and Company

Tony McGrath, Baker

Rob Peat, H.E.P.A Filter Services, Inc.

Todd Urton, Quality Cleanroom Consulting

Staff

Executive Director: Felicia Kenan Boyles

Membership Services: Brittni Adams

continued on next page

Schedule of Events *(continued)*

10:15 am - 11:00 am **Presentation: The RCCP Exam with Q&A**
Speakers: David Brande, Cleanroom pm, and Nick Karlowsky, Filtech, Inc.

This interactive presentation is designed to educate and share insight to the current and potential examinees of how the CNBT Sterile Compounding exams are compiled and administered to the association.

Learning Objectives:

1. How the CNBT program is administered
2. What to do and NOT do when preparing for and taking the exams

11:00 am - 11:30 am **Presentation: HEPA and ULPA Filter Leak Tests IEST-CC-034 History, Summary of Content and Current Status**
Speaker: R. Vijaykumar, PhD, AERFIL

IEST CC RP 034 is the most widely used standard for filter integrity testing, especially in the field. The standard has been periodically revised to keep up with current practices. In the latest revision, the content of the RP has been thoroughly reviewed and many of the statements made clearer. Wherever possible, equations have been simplified. Although filter integrity testing continues to be predominantly performed with photometers, particle counter testing is also addressed. The highlights of these revisions will be presented in this lecture.

Learning Objectives

1. New features of RP
2. The basis behind leak testing standards
3. The state of leak testing in other standards

11:30 am - 12:30 pm **Lunch**
Azalea I&II

12:15 pm - 6:15 pm **Wally Whitt Memorial Golf Tournament**
Links Golf Course

7:00 pm - 10:00 pm **CETA 23rd Annual Banquet**
Magnolia A&B

Tuesday, April 21

7:00 am - 1:00 pm **Registration**
Magnolia D Registration

7:00 am - 8:00 am **Breakfast/Exhibits**
Magnolia Ballroom E&F

8:00 am - 12:15 pm **CETA Annual Meeting General Session**
Magnolia Ballroom A&B unless otherwise noted

8:00 am - 8:10 am **Conference Updates**
Tony Caughron, CETA 2015 Program Chair

8:10 am - 8:40 am **Presentation: Testing & Balancing A Relationship is Required**
Speaker: Douglas Meacham, Kahoe Air Balance Company, AABC

Discuss the relationship requirements between Balancers and Certifiers. This will be incorporated into the types of systems, methods of testing and types of projects. I will stress the importance of knowing who does what and when. With the proper integration and communication between us the owners will be more satisfied. This will translate into a better product and repeat customers.

Learning Objectives:

- a. Understanding what the Balancer is responsible for
- b. Limitations in calibration
- c. Development of relationships

8:40 am - 9:25 am **Presentation: Microbiology and Laboratory Aspects of USP <797>**
Speaker: Suzanne S. Blevins, BS, SM(ASCP), Aerobiology Laboratory Associates, Inc.

The USP <797> addresses the setting in which sterile preparations are compounded, how to sample for microbials (viable) in addition to the guidelines and standards for compounding these sterile preparations. The enforceable set of guidelines dictates the locations, frequency and types of air, surface, gloved fingertip and media- fill samples be taken. Technique, viable impactors, types of media, shipment, incubation temperatures, action levels and significant microorganisms will be discussed in detail.

Learning Objectives:

1. Understanding samplers and detection limits as it pertains to action levels
2. Discussion of media types and incubation temperatures
3. Sampling protocols for bacteria and fungi
4. Discussion of action levels - concentration of bacteria/fungi and target organisms
5. Packing and the importance of transport of samples to laboratory

9:25 am - 9:45 am **General Election & CETA Business Meeting**
Jeff Serle, CETA 2015 President

9:45 am - 10:15 am **Break/Exhibits**
Magnolia E&F

10:15 am **Exhibitor Breakdown**
Magnolia E&F

10:15 am - 11:45 am **CAG Working Groups: CAG 002 & CAG 009**
CAG 002: *Azalea I*
CAG 009: *Azalea II*

10:15 am - 12:15 pm **NuAire Platinum Sponsor Update**

12:15 pm **Meeting Adjourned**

12:30 pm - 2:30 pm **CETA Follow-up Board Meeting**
Azalea I

A Special Thanks to Our Sponsors and Exhibitors

Platinum Sponsors

AAF International
Germfree Laboratories, Inc.
LABCONCO
NuAire Inc.

Gold Sponsors

Baker
C-Scan Technologies Inc.
CAMFIL USA, Inc
Flanders Corporation
STERIS Life Sciences
TEC Services, Inc.

Bronze Sponsors

Air Techniques International
Filtration Group Inc.
Kewaunee Scientific Corporation
ThermoFisher Scientific

Exhibitors

Booth 1: Aerobiology Laboratory
Booth 2: Baker
Booth 3: Camfil USA, Inc.
Booth 4: STERIS Life Sciences
Booth 5: Bioscience International
Booth 6: Labconco Corp.
Booth 7: Shortridge Instruments
Booth 8: TEC Services
Booth 9: American Biological Safety Association (ABSA)
Booth 10: Degree Controls, Inc.
Booth 11: NuAire
Booth 12: EMLab P&K
Booth 13: EMD Millipore BioMonitoring
Booth 14: Eagleson Institute
Booth 15: Flanders Corp
Booth 16: Air Techniques International
Booth 17: Airflotek
Booth 18: Holland Safety Equipment
Booth 19: ClorDiSys Solutions
Booth 20: Lighthouse Worldwide Solutions

Booth 21: AAF International
Booth 22: DRS Laboratories, Inc
Booth 23: ThermoFisher Scientific
Booth 24: EMSL Analytical, Inc.
Booth 25: Germfree Laboratories
Booth 26: Filtration Group Inc.
Booth 27: TSI, Inc.
Booth 28: Kewaunee Scientific Corp.
Booth 29: U.S. Micro-Solutions, Inc.

Exhibiting Times

Sunday, April 19

7:00 - 8:00 am
10:00 - 10:30 am

Monday, April 20

7:00 - 8:00 am
9:45 - 10:15 am

Tuesday, April 21

7:00 - 8:00 am
9:45 - 10:15 am



Exhibitor Descriptions

Booth 1: 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 2: Baker

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 3: Camfil USA, Inc.

World leader in air filtration technology, Camfil offers state-of-the-art filtration solutions for cleanrooms 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.camfilfarr.com

Booth 4: 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 5: Bioscience International

Our products are used in all areas of the public and private sectors: from the National Institutes of Health, to NASA, to the largest hospitals, medical device, and pharmaceutical companies in the world.

www.biosci-intl.com

Booth 6: 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 7: 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 8: 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 9: American Biological Safety Association (ABSA)

The American Biological Safety Association (ABSA) was founded in 1984 to promote and expand biological safety expertise. To accomplish this core purpose, ABSA offers training opportunities, laboratory accreditation, publications, networking, biosafety resources, and an annual biological safety conference.

www.absa.org

Booth 10: Degree Controls, Inc.

Degree Controls, Inc. provides laboratory-grade airflow sensing, visualization and control solutions for critical containment facilities. Our technology portfolio includes robust environmental sensors, data acquisition software, hand-held test instruments and alarm monitors specifically designed to fulfill airflow safety regulations in laboratories and medical ventilation systems.

www.degreec.com

Booth 11: NuAire

NuAire has been universally recognized as a leader for more than 40 years in providing laboratory professionals with reliable products such as biological safety cabinets, CO2 incubators, Laminar Airflow equipment, animal facility products, ultra-low temperature freezers and centrifuges for the most demanding environments.

www.nuaire.com

Exhibitor Descriptions *(continued)*

Booth 12: 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 13: EMD Millipore BioMonitoring

EMD Millipore BioMonitoring is a top player in the field of industrial microbiology and process monitoring. This business field provides state-of-the-art testing methods, regulatory expertise and outstanding service to provide that one invaluable result: maintaining the safety of your products. Focus markets include Pharmaceutical, BioPharma, Food and Beverage, Environmental and Cosmetics.

www.merckmillipore.com

Booth 14: 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 15: 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 16: 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 17: Airflotek

Airflotek, Inc. is one of the largest HEPA filter distributors in the United States, and our vast inventory and knowledge of Biosafety and Laminar Flow Equipment make us a key supplier in the certification industry. We also supply Fan Filter Modules, and other items required for Clean Room Construction.

www.airflotek.com

Booth 18: 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 19: 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 20: Lighthouse Worldwide Solutions

Lighthouse Worldwide Solutions is the leader in contamination monitoring solutions for air, liquid and gas particle counting. Lighthouse can provide a complete real time environmental monitoring system or portable instruments for your contamination monitoring needs.

Come see the new Lighthouse portable and remote particle counter in our booth.

www.golighthouse.com

Booth 21: 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

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Exhibitor Descriptions *(continued)*

Booth 22: 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 23: 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 24: EMSL Analytical, Inc.

EMSL Analytical, Inc. is an AIHA accredited, FDA registered, DEA licensed, and cGMP compliant laboratory for compounding pharmacies and parenteral drug manufacturers impacted by USP 797. We offer microbiological, chemical, and physical testing for active pharmaceutical ingredients, environmental monitoring samples, and product release testing required under USP guidelines.

www.emsl.com

Booth 25: Germfree Laboratories

Established in 1962, Germfree Laboratories, Inc. is an industry leader in the design and fabrication of hospital pharmacy equipment including Compounding Aseptic Isolators (CAI) and Chemo Hoods. Germfree manufactures high containment equipment including Class II and Class III Biological Safety Cabinets as well as custom, turnkey Mobile and Modular Laboratories.

www.GERMFREE.com

Booth 26: Filtration Group Inc.

Filtration Group LLC is committed to product excellence, innovative solutions and customer service. We provide a full line of high quality filtration products for the HVAC, Turbine, Gas Phase, Cleanroom, Biosafety, along with their aftermarkets. Our extensive product line allows us to provide custom filtration solutions for a wide variety of challenging markets. Our service model has always been 'Right Filter... Right Place... Right Time'.

www.filtrationgroup.com

Booth 27: 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 28: 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 29: 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



Speaker Bios

Suzanne Blevins

Suzanne Blevins, founder of Aerobiology Laboratory is a graduate of Virginia Tech. She has thirty nine years' experience in areas of clinical and healthcare microbiology, environmental and building science microbiology and industrial microbiology applications.

Aerobiology Laboratory now in its 18th year, has a national presence with six microbiology and asbestos testing laboratories in the Washington DC area, Atlanta, Denver, Phoenix, Huntington Beach, CA and recently acquired Pure Earth Environmental Laboratory in Cherry Hill, New Jersey. Suzanne holds a board position from the Commonwealth on the Virginia Board for Asbestos, Lead, Mold and Home Inspectors and is also an owner of Apheresis Associates of Northern Virginia which is a collection clinic for donors of stem cells through the National Marrow Donor Program.

David Brande

David Brande brings 29 years of experience in the controlled environment industry, specializing in providing cleanroom and biological containment certifications, as well as international consulting services, to the pharmaceutical, medical device and biomedical research industries and is currently Lead Consultant for Cleanroom Project Management, Inc.

David served for six years (2006-2012) as Chairman of the ISO/Technical Committee 209 an international committee that oversees the two ISO standards governing cleanroom industries worldwide, known as ISO-14644 and ISO-14698 and the eleven documents they comprise.

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

With CETA, David served as President in 1996/1997 and is currently Treasurer of the Board of Directors and also a committee member of the CETA National Board of Testing (CNBT) charged with writing, both written and practical, test questions for certification tests administered to technicians worldwide.

Dan Dennison

Daniel J. Dennison is currently the Regional Manager of Cleanroom Performance Testing (North America) for NNE Pharmaplan and has been involved in testing for the life sciences industry for 26 years. He is currently certified as a NEBB Cleanroom Performance Testing Professional and was accredited by NSF International as BioSafety Cabinet Field Certifier from 1996 to 2001.

Daniel is currently the US delegate to TC209WG 3 revising ISO 14644-3, a member of the International Society of Pharmaceutical Engineers, National Environmental Balancing Bureau, Controlled Environment Testing Association, an active member and tutorial instructor of the Institute of Environmental Sciences & Technology with voting chairs on RP002, 006, 013, 19 and 034.

Les Goldsmith

Les Goldsmith is National Sales Manager for ENVIRCO for 12 years and have been involved with Liberty Industry for 6 years. Les was introduced to the USP 797 concept over 16 years ago when NJ first implemented compounding code. He is a voting member on RP 0036 for Fan Filter Units and has high level contacts in clean room industry designs, construction, consulting, and product procurement

Michael H. Jones, PhD

For 25 years Mike Jones has held senior executive positions for various large scale certification and licensure testing programs, providing 10,000 to 250,000 examinations annually. He holds a PhD in Measurement and Program Evaluation from Florida State University. He is currently a Senior Psychometrician for Professional Testing Service and works in the Tallahassee Florida office. Professional Testing is based in Orlando Florida.

Nick Karlowsky

Nick has over 10 years' experience assuring the performance of critical environments. He has been involved with certification and validation of controlled environments since 2005. He is currently Testing Division Manager at Filtech, Inc. His duties include quality control of processes within certification of cleanrooms and biological safety cabinets. Recent activities have involved serving on the board of the Controlled Environment Testing Association (CETA), including Chair of the Registered Cleanroom Certification Professionals for Sterile Compounding Facilities (CETA's RCCP-SCF).

Doug Meacham

Douglas Meacham is second generation Test and Balance Engineer and partner with Kahoe Air Balance, Inc., overseeing the Cincinnati office. A graduate of Bowling Green State University, Mr. Meacham has over fifteen years of experience in the HVAC Test and Balance industry, including certification as a Test and Balance Engineer in 2009 and as a Test and Balance Technician prior to that. Mr. Meacham specializes in hospital and school systems, but has broad experience in the field. In 2014, Mr. Meacham was elected to serve as the Vice President of Zone II for the Associated Air Balance Council. When he is not working, Mr. Meacham enjoys golfing, camping, and other outdoor activities with his family.

continued on next page

Speaker Bios *(continued)*

Todd Urton

Mr. Urton has been involved in the testing and certification industry for 18 years serving in various capacities ranging from certification technician to quality management. He currently serves as Board of Director member for CETA, an examiner for CETA National Board of Testing, and is actively involved in various working groups for CETA's Application Guides as well as the Institute of Environmental Sciences and Technologies Recommended Practices. Mr. Urton is the primary instructor for the Agape Instruments "Advanced Certification" class for certification of Biological Safety Cabinets.

Tom Van Hassel

Tom Van Hassel, RPh, MPA, attended Ferris State University in Michigan, graduating in 1976, and received his MPA from Western Michigan University in 1982. Tom completed a pharmacy fellowship at the University of Pennsylvania Wharton School of Business in 1991. He was president of the Arizona Society of Health-System Pharmacists in 1997 and president of the Arizona State Board of Pharmacy in 2009. Tom is an adjunct professor of pharmacy at several colleges of pharmacy.

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>".



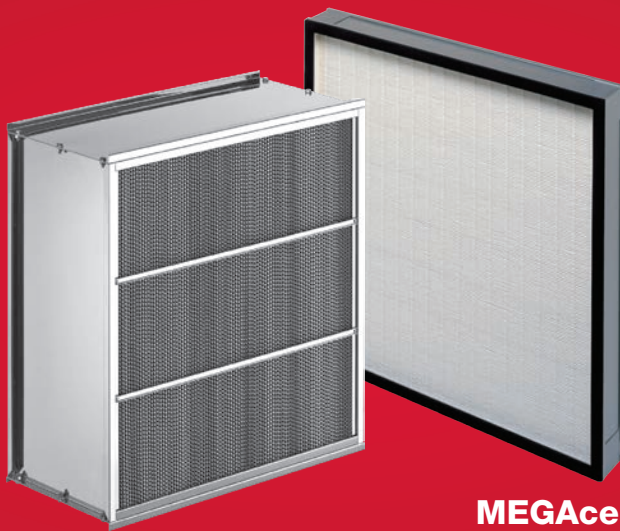


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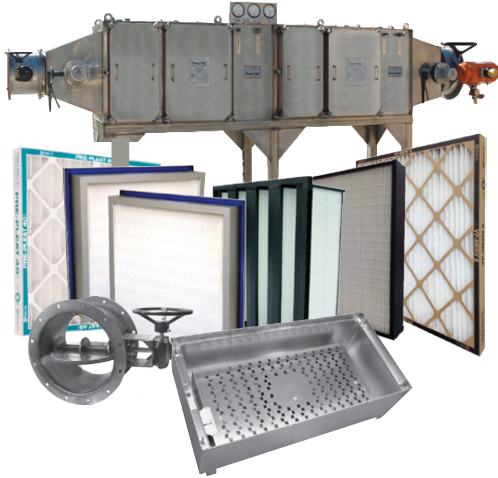
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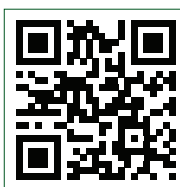




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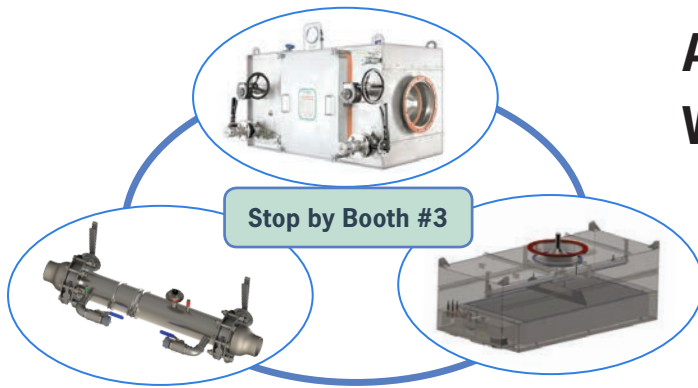
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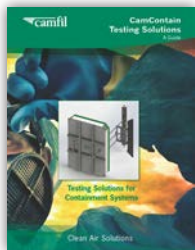
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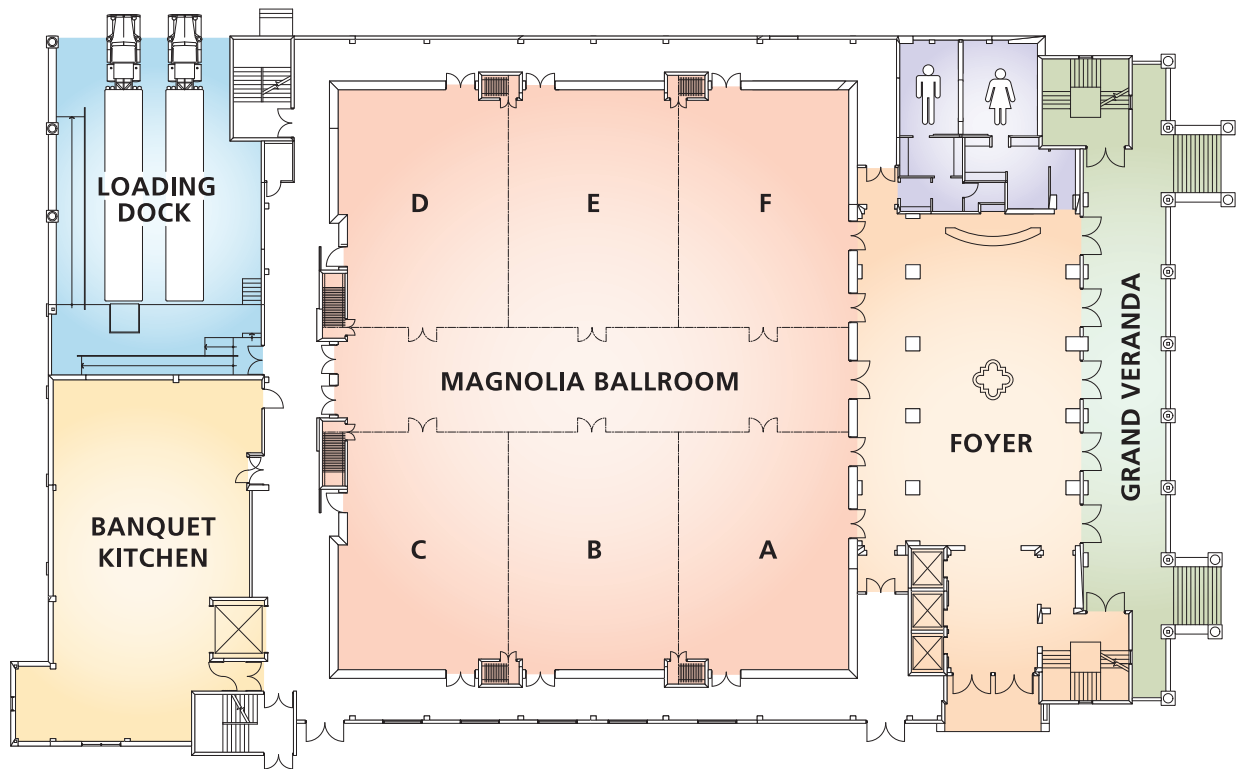
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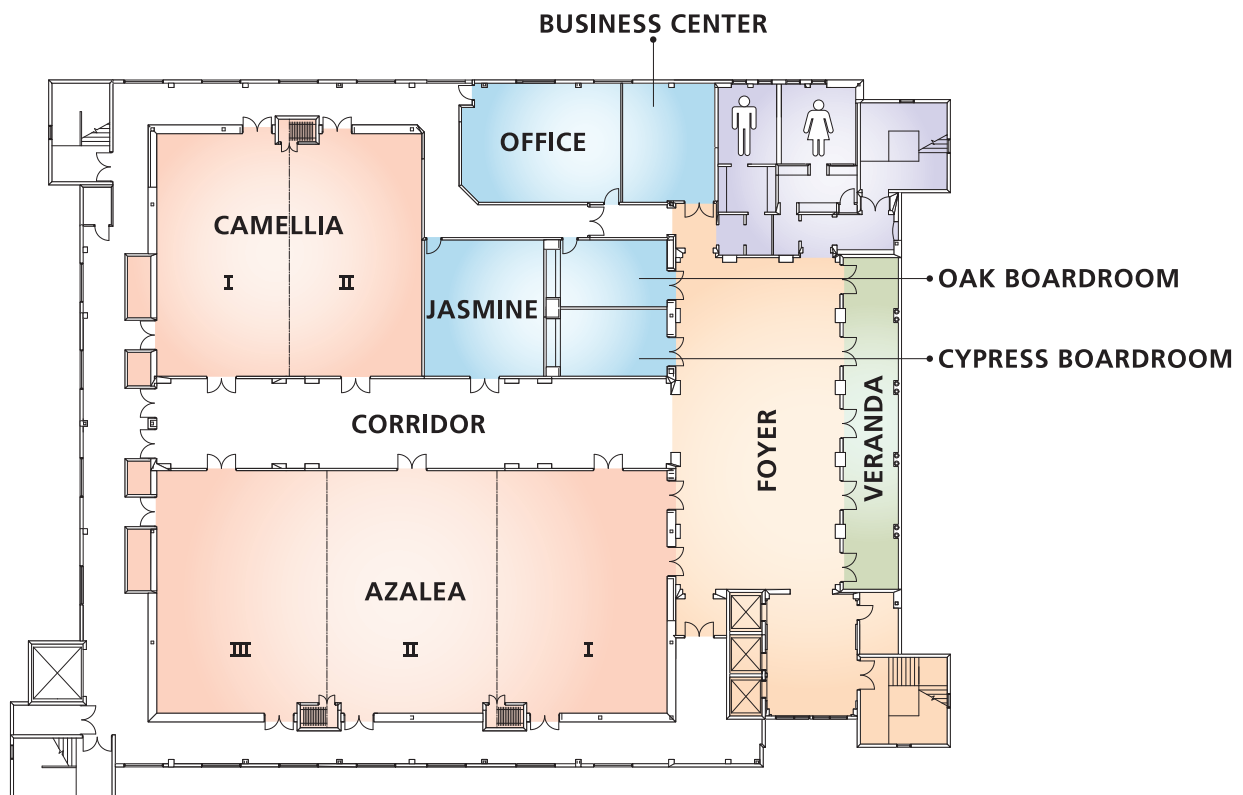
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