



26th Annual Controlled Environment Testing Association (CETA) Meeting
April 14-17, 2018

CETA

Controlled Environment Testing Association
Program and Exhibitor Information



SCHEDULE OF EVENTS

Thursday, April 12

CETA Board Meeting	3:00PM - 7:00PM	Boardroom 6
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Friday, April 13

Registration	7:00AM-5:30PM	Conference Center
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CNBT RCP-SCF Multiple Choice Exam	8:00AM-11:00AM	Bay 4
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CETA Series: Methods to Evaluate Fume Hood Operation and Challenge Containment Performance	1:00PM-5:00PM	Bay 5, 6
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Saturday, April 14

Registration	7:00AM-7:00PM	Conference Center
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Platinum Sponsor Update: Esco Technologies Inc.	8:00AM-10:00AM	Bay 3
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CNBT RCP-SCF Written Practical Exam	8:30AM - 12:00PM	Bay 4
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Platinum Sponsor Update: NuAire, Inc.	10:00AM-12:00PM	Bay 3
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CETA Series: Air, How to Hold It, How to Monitor It, and How to Pass It	1:00PM-5:00PM	Bay 4, 5, 6
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Exhibitor Setup	3:00PM-7:00PM	Bay 1, 2
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Opening Reception	7:00PM-9:00PM	Lakeview Terrace
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Sunday, April 15

Registration	7:00AM-4:30PM	Conference Center
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Breakfast/Exhibits	7:00AM-8:00AM	Bay 1, 2
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CETA Annual Meeting General Session	8:00AM-3:00PM	Bay 3, 4
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Meeting Welcome	8:00AM-8:10AM	Bay 3, 4	Wayne Copeland
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President's Address	8:10AM-8:25AM	Bay 3, 4	Nick Karlowsky
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Presentation: Health and Safety Risks faced by Certifiers when entering Health Care Facilities	8:25AM - 9:15AM	Bay 3, 4	Herschell Hitchcock
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Presentation: When You're Hot, You're Hot - Challenges and Considerations when Certifying Nuclear Pharmacies	9:15AM-10:15AM	Bay 3, 4	Michele Egberts
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Break	10:15AM - 10:45AM	Bay 1, 2
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Presentation: CA Compounding Regulations. What you should know as a Certifier, and why this applies to you	10:45AM - 11:30AM	Bay 3, 4	Christine Acosta
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Presentation: CNBT Update	11:30AM-12:00PM	Bay 3, 4	David Brande
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Lunch	12:00PM - 1:00PM	Bay 5, 6
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Presentation: USP Compounding Chapters Update and Equipment considerations in Sterile Compounding	1:00PM - 2:00PM	Bay 3, 4	Jim Wagner
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Presentation CAG 2.0 Making CAG's Great Again!	2:00PM - 2:30PM	Bay 3, 4
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Presentation: Adopting or Adapting? Handling Customer Data as it Relates to Current Industry Standards	2:30PM - 3:00PM	Bay 3, 4	Adam West
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Equipment Manufacturing Forum	3:00PM-6:00PM	North Cape, Kidd Island, Casco, Bay 6
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NSF Steering Committee	6:00PM-7:00PM	Shore Room Maren Roush
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SCHEDULE OF EVENTS

Monday, April 16

Registration	7:00AM-12:00PM	Conference Center	
Breakfast/Exhibits	7:00AM-8:00AM	Bay 1, 2	
CETA Annual Meeting General Session	8:00AM-11:45AM	Bay 3, 4	
Meeting Updates	8:00AM-8:10AM	Bay 3, 4	Wayne Copeland
Presentation: The FDA's role in CSP Facility Regulation and Inspection	8:10AM-9:00AM	Bay 3, 4	Jane Axelrad
Presentation: Why face velocity is inadequate to Verify Fume Hood Performance	9:00AM-10:00AM	Bay 3, 4	Tom Smith
Break	10:00AM - 10:20AM	Bay 1, 2	
Presentation: "A Look Back". A Past Presidents perspective on CETA then vs. CETA now	10:20AM-10:40AM	Bay 3, 4	Rene Soetens
Industry Updates: NSF / CETA Spec Guide	10:40AM - 11:00AM	Bay 3, 4	Terry Lewis Bill Peters
Presentation: Guiding your <797> Customer through the Investigation and Remediation of Environmental Monitoring Excursions	11:00AM - 11:45AM	Bay 3, 4	Abby Roth
Lunch (Boxed lunch)	11:45AM - 12:45PM	Bay 5, 6	
Wally Whitt Tournament (Boxed lunch at course for golfers)	12:00PM - 6:00PM	Resort Course	
I Don't Golf Activity Wine Tour or Zip Lining	1:00PM - 6:00PM	Travel Required	
Cocktails at the Dock	6:30PM - 7:00PM	Mish-An-Nock (Boat)	
Reception Cruise to Annual Banquet	7:00PM - 7:30PM	Mish-An-Nock (Boat)	
Annual Banquet	7:30PM - 10:00PM	Hagadone Event Center	

Tuesday, April 17

Registration	7:00AM-10:00AM	Conference Center	
Breakfast/Exhibits	7:00AM-8:00AM	Bay 1, 2	
CETA Annual Meeting General Session	8:00AM-10:00AM	Bay 3, 4	
Meeting Updates	8:00AM-8:10AM	Bay 3, 4	Wayne Copeland
Presentation: Prion Biology and Decontamination Methods	8:10AM - 9:00AM	Bay 3, 4	Greg Raymond
Presentation: Review of NSF / ANSI 49 - 2016 Annex G, What you should Know	9:00AM - 9:45AM	Bay 3, 4	Jason Kleintop
General Election & CETA Business Meeting	9:45AM - 10:00AM	Bay 3, 4	Nick Karlowsky
Meeting Adjourned	10:00AM	Bay 3, 4	
Exhibitor Breakdown	10:30AM	Bay 1, 2	
CNBT RCP-F Fume hood accreditation exam	10:30AM - 1:00PM	Bay 3, 4	
CETA Follow-up Board Meeting	11:00AM - 12:00PM	Boardroom 6	
CNBT RCP-SCF Exam Grading	12:30PM - 6:00PM	Boardroom 6	



Meeting Notes:

What do the stickers on my name badge mean?

GC means you're registered for the General Meeting and can attend the Opening Banquet, and all sessions and meals beginning Sunday morning.

FCS means you have registered to attend the Friday CETA Series from 1-5 PM.

SCS means that you have registered to attend the Saturday CETA Series from 1-5 PM.

AB means that you're either an exhibitor that purchased a banquet ticket for Monday evening or a guest with a banquet ticket for Monday evening.

Exhibitors/Sponsors without "GC" or "AB" can attend all meals including the Friday Opening Reception except for the Monday evening banquet but cannot attend sessions.

Registered guests are welcome to attend the Friday Opening Reception, but not the sessions.

**** Attendees should not record the sessions or take flash photography ****



Manufacturer Updates April 15, 2018 3:00-6:00 PM

Timing/ Room	North Cape	Kidd Island	Casco	Bay 6
3:00-3:30 PM	Baker	Esco Technologies Inc. (1 hour-long session - 2:30-3:30)	Thermo Fisher Scientific	Chattanooga Environmental Laboratory, LLC
3:30-4:00 PM	Baker	Esco Technologies Inc. (1 hour-long session - 2:30-3:30)	Thermo Fisher Scientific	Chattanooga Environmental Laboratory, LLC
4:00-4:30 PM	Holland Safety Equipment	PSC Climet	STERIS Corporation	Air Care Automation
4:30-5:00 PM	NuAire, Inc.	PSC Climet	STERIS Corporation	LABCONCO
5:00-5:30 PM	Hardy Diagnostics	Degree Controls, Inc	Kanomax	LABCONCO
5:30-6:00 PM	Germfree Laboratories, Inc.	Millpore Sigma	Kanomax	Unassigned

Controlled Environment Testing Association

OFFICERS

President

Nick Karlowsky (2019)
Filtech, Inc.

President Elect

Wayne A. Copeland (2020)
CEPA Operations, Inc

Secretary/Treasurer

Tony Caughron (2019)
TEC Services, Inc.

Past President

Todd Urton (2020)
Quality Cleanroom Consulting

EXECUTIVE OFFICE

Controlled Environment Testing Association (CETA)
Executive Director:
Brandi Gerew, CAE

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Raleigh, NC 27607

Phone: (919) 792-6339

Web site:

www.cetainternational.org

Email: info@cetainternational.org

DIRECTORS

Cary Binder (2019)

ENV Services Inc

Kimberly Coughlin (2018)

B&V Testing,
A Stericycle Company

Kym Faylor (2019)

Azzur Labs

Terry Lewis (2018)

Lewis Testing Services, Inc.

Chandler Papas (2018)

Pentagon Technologies

Jeff Serle (2019)

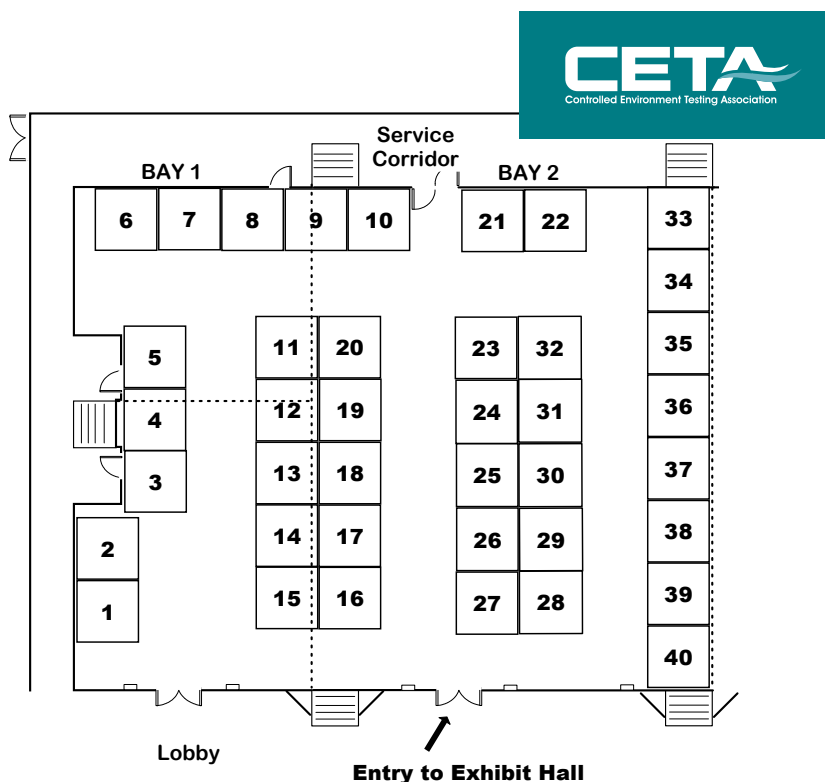
Germfree Laboratories

Shawn Windley (2019)

AAF Flanders

A SPECIAL THANKS TO OUR SPONSORS AND EXHIBITORS

Exhibitor	Booth Number	Exhibitor	Booth Number
AAF Flanders.....	1	Kanomax	21
PSC Climet.....	2	EMLab P&K.....	22
Shortridge Instruments, Inc.	3	Bioscience International, Inc.....	23
Filtration Group.....	4	Esco Technologies, Inc.	24
U.S. Micro-Solutions, Inc.....	5	Azzur Labs.....	25
MilliporeSigma	6	DRS Laboratories	26
Lighthouse Worldwide Solutions.....	7	EMSL Analytical, Inc.	27
Performance Assurance Systems	8	Kewaunee Scientific Corporation	28
Germfree Laboratories, Inc.....	9	Hardy Diagnostics.....	29
TEC Services, Inc.	10	Analytics Corporation.....	30
Baker.....	11	TSI Inc.	31
NSF International	12	ClorDiSys Solutions Inc	32
Chattanooga Environmental Laboratory, LLC	13	DFMZ Inc.....	33
ATI.....	14	Degree Controls, Inc.....	34
TBS Technologies, LLC	15	Thermo Fisher Scientific.....	35
Eagleson Institute	16	Lakeland Industries.....	36
CEPA Operations, Inc.	17	STERIS Corporation	37
LABCONCO.....	18	Nuaire.....	38
Holland Safety Equipment.....	19	AirCare Automation Inc.....	39
CAMFIL USA, Inc.	20	Aerobiology Laboratory.....	40
		CNBT	Unassigned



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VISIT OUR EXHIBITORS AT THE ANNUAL MEETING!

Booth 1: AAF Flanders

AAF Flanders is a world leader in air filtration products and understands the critical requirements of the biosafety industry. AAF is pleased to announce the availability of PAO compatible ePTFE HEPA filters, along with our ability to provide glass media HEPA filters, and Hi Temp HEPA filters.

Booth 2: PSC Climet

Climet Instruments manufactures portable a remote sensor airborne particle counters for continuous monitoring, also microbial air samplers. PSC PharmEquipment.com is Climet's manufacturer's representative, along with Esco downflow booths and isolators

Booth 3: Shortridge Instruments, Inc.

Manufacturer of AirData Multimeters and Air Balancing Accessories; also, HydroData Multimeters and Accessories.
www.shortridge.com

Booth 4: Filtration Group

Filtration Group is committed to product excellence, innovative solutions and customer service for leading Biosafety Cabinet manufacturers. Utilizing our proprietary technology Filtration Group custom engineers filter designs to meet the stringent performance requirements of the market. Filtration Group is the foremost source for Biosafety Cabinet Manufacturers.

www.filtrationgroup.com

Booth 5: U.S. Micro-Solutions

We are an ISO17025 compliant Environmental Microbiology Laboratory specializing in the analysis of bacteria and fungi from indoor environments, water, medical devices, and pharmaceutical sterile compounding settings (USP797). We provide culture analysis, equipment rental, and USP media. We are committed to providing exceptional quality, outstanding customer service, and competitive prices.

www.usmslab.com

Booth 6: 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. For more information, visit

www.emdmillipore.com and www.sigma-aldrich.com.

Booth 7: Lighthouse Worldwide Solutions

Lighthouse Worldwide Solutions is the world's leading supplier of real-time contamination monitoring systems and airborne particle counters. We offer the most complete line of contamination monitoring solutions available that include Airborne Particle Counts, Airborne Molecular Contamination Levels, Liquid Particle Counts, Electrostatic Charge, Temperature, Humidity, Organic Carbon Monitoring and much more.

<https://www.golighthouse.com/en>

Booth 8: Performance Assurance Systems

Port used to test the integrity of Hepa Filters

Booth 9: Germfree Laboratories

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.

Booth 10: 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.

www.tecservicesinc.com

Booth 11: Baker

For 60 years, The Baker Company has been at the forefront of engineering, testing and production of reliable laboratory contamination control equipment. Our products are built to order, with rigorous testing protocols and quality control measures that exceed industry standards. Our commitment ensures you – and your budget – will be pleased.

<https://www.bakerco.com/>

Booth 12: NSF International

For more than 40 years, NSF has maintained the most recognized and referenced standard worldwide for biosafety cabinet design, construction, performance and field certification. NSF evaluates and certifies biosafety cabinets to the requirements of NSF/ANSI 49. A list of all NSF Certified models can be found at www.nsf.org. In addition, NSF has an accreditation program for individuals who service biosafety cabinets in the field (field certification to Annex F of NSF/ANSI 49). The accreditation program includes written and practical examinations, along with continuing education requirements and a code of ethics. www.nsf.org

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Booth 13: Chattanooga Environmental Laboratory, LLC

Chattanooga Environmental Laboratory, LLC specializes in USP 797 testing of viable air, contact, and gloved fingertip samples. CEL is the leading U.S. distributor of the MicroBio Air Sampler. The MB offers a light-weight design with a sampling rate of 180 L/min at a competitive price. For more information, please visit

www.ChattaLab.com

Booth 14: ATI

Air Techniques is the leading designer and manufacturer of specialized testing equipment for HEPA filters, media, and filter cartridges. Air Techniques manufactures a comprehensive line of test equipment from small portable units for on-site certification up to the largest systems used by major producers and testing laboratories for testing filters.

Booth 15: TBS Technologies, LLC

Introducing the TBS Technologies patented TBS -1080 CD gas system: simple, easy to use, fits inside a BSC or any small enclosed space, portable (12 lbs), uses prepackaged reagents, automated process sequencing, large display screen, automatic neutralization of reaction mixture .

tbstechnologies.com

Booth 16: 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 17: CEPA Operations, Inc.

CEPA Operations, Inc. Testing, Certification and Repair services. HEPA Filter sales, parts and supplies for the certification industry. Your hard to find and custom parts expert.

www.cepatest.com

Booth 18: LABCONCO

Since 1925 Labconco has been manufacturing world class laboratory equipment including biosafety cabinets, fume hoods, water purification, glove boxes, blowers and other laboratory equipment.

Booth 19: Holland Safety Equipment

Holland Safety Equipment is the North American distributor for Temperature Electronics Ltd.'s fume hood and bio-safety cabinet airflow monitors on an OEM, reseller and end user basis. HSE also offers room pressure monitoring and data logging devices and smoke sources for airflow visualization. CETA Shormembers qualify for discount pricing.

www.hollandsafety.com

Booth 20: 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.camfil.com

Booth 21: Kanomax

Kanomax products provide precision measurement technology for fluids and particles. We contribute technological innovation and solutions for environmental management, indoor air quality testing, HVAC system testing, cleanroom monitoring and verification, lab control and workplace safety, airflow optimization, fume hood testing and diagnostics, sound and vibration analysis, and much more.

Booth 22: EMLab P&K

EMLab P&K is recognized as one of the leading commercial indoor air quality testing laboratories in North America with over 60 service and drop-off. We specialize in analyzing air and surface samples for mold, asbestos, bacteria, lead, radon and USP 797. We also carry a full line of IAQ products. Visit our newly redesigned website at www.emlab.com.

Booth 23: 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.

www.biosci-intl.com

Booth 24: Esco Technologies, Inc.

Esco represents innovative design with high quality since 1978. Esco Group is one of the largest global life sciences tools provider with sales in over 100 countries. Esco manufactures laboratory, medical and pharmaceutical equipment, such as Biosafety Cabinets, Laminar/PCR Hoods, Animal workstations, Cleanroom Components, Fume Hoods, and CO2/IVF Incubators.

Booth 25: Azzur Labs

Azzur Labs, an Azzur Group company, is a leader in analytical GxP compliant testing services for the pharmaceutical, medical device, food, and cosmetic industries. We provide expertise in every stage of the life cycle - from Discovery to Delivery™.

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Booth 26: DRS Laboratories

DRS Laboratories, Inc. is a supplier of Chlorine Dioxide Decontamination Equipment. 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 27: EMSL Analytical, Inc.

EMSL Analytical, Inc. is a nationally recognized, locally focused laboratory specializing in Microbiology, Legionella, USP <797>, Pathogens and more with over 40 laboratories across North America. For more information, please visit www.EMSL.com or call 800-220-3675.

Booth 28: Kewaunee Scientific Corporation

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: Hardy Diagnostics

"Hardy Diagnostics, an ISO 13485 certified company, manufactures and distributes products for microbiological testing in clinical, research, and pharmaceutical laboratories. We are a quality resource for USP <797> compliance solutions. Our product line includes microbial air samplers, media-fill test kits and environmental monitoring plates."

Booth 30: Analytics Corporation

Booth 31: TSI Inc.

TSI Incorporated is a leading supplier of instrumentation for certifiers. TSI's AeroTrak™ Particle Counters, VelociCalc™ Thermal Anemometers, DP-Calc™ Micromanometers, AirPro® Air Velocity Instruments, and EBT731 Capture Hoods 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 32: ClorDiSys Solutions Inc.

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 33: DFMZ, Inc.

Design Filtration Microzone Inc. is a leading innovator in the design, development and manufacture of quality environmental and particulate control solutions. Our equipment and cleanroom systems are designed to provide a high degree of product, personnel and/or environmental protection for all branches of industry.

www.dfmzgroup.com

Booth 34: Degree Controls, Inc.

Degree Controls is a leading airflow safety and alarm manufacturer, providing standard/custom controls for the critical containment industry. With application support to retrofit existing laboratories, degreeC works with certification companies to provide optimal alarm configurations/connectivity. The Rooster™ series provides auto-sash control, set-back, and auxiliary fan/valve control, utilizing simple touch-screen input.

Booth 35: Thermo Fisher Scientific

Thermo Fisher Scientific is the world leader in serving science. Our mission is to enable our customers to make the world healthier, cleaner and safer. Through our Thermo Scientific brand, we help customers accelerate innovation and enhance productivity. Thermo Fisher Scientific supplies innovative solutions for the world's controlled environment or health industries. With applications that span the controlled environment processes we provide a broad range of biological safety cabinets that support our customers' needs.

Booth 36: Lakeland Industries

CleanMax is single use cleanroom garment that is clean manufactured and compatible with ISO Clas 5-8 cleanrooms and all controlled environments. CleanMax is resistant to oils, bleach and 50% sodium hydroxide. It is also resistant to blood, body fluid, blood borne pathogens and viruses. Bound seams protect from breakthrough and strikethrough while adding to the strength and performance of the garment. CleanMax is comfortable yet durable. Special folds aid in gowning and encourage less handling and risk of contamination on the outer surface. Available in sterile and non-sterile options.

www.lakeland.com

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Booth 37: STERIS Corporation

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.

www.sterislifesciences.com

Booth 38: Nuaire

Nuaire manufactures high quality and innovative Life Science Laboratory products

Booth 39: AirCare Automation, Inc.

Cleanroom Monitoring and Control Systems for USP 797 and USP 800 Compliance

Booth 40: Aerobiology Laboratory

Aerobiology Laboratory Associates, Inc. is a woman owned, family run, environmental testing laboratory with expertise in microbiology and asbestos testing.

www.Aerobiology.net

**U.S. Micro-Solutions, Inc.**
An Environmental Microbiology Laboratory



Where Quality Counts!

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USP 797
MICROBIAL ANALYSIS
ISO 17025

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Bioaerosol • Surface • Personnel
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Equipment Rental
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www.usmslab.com

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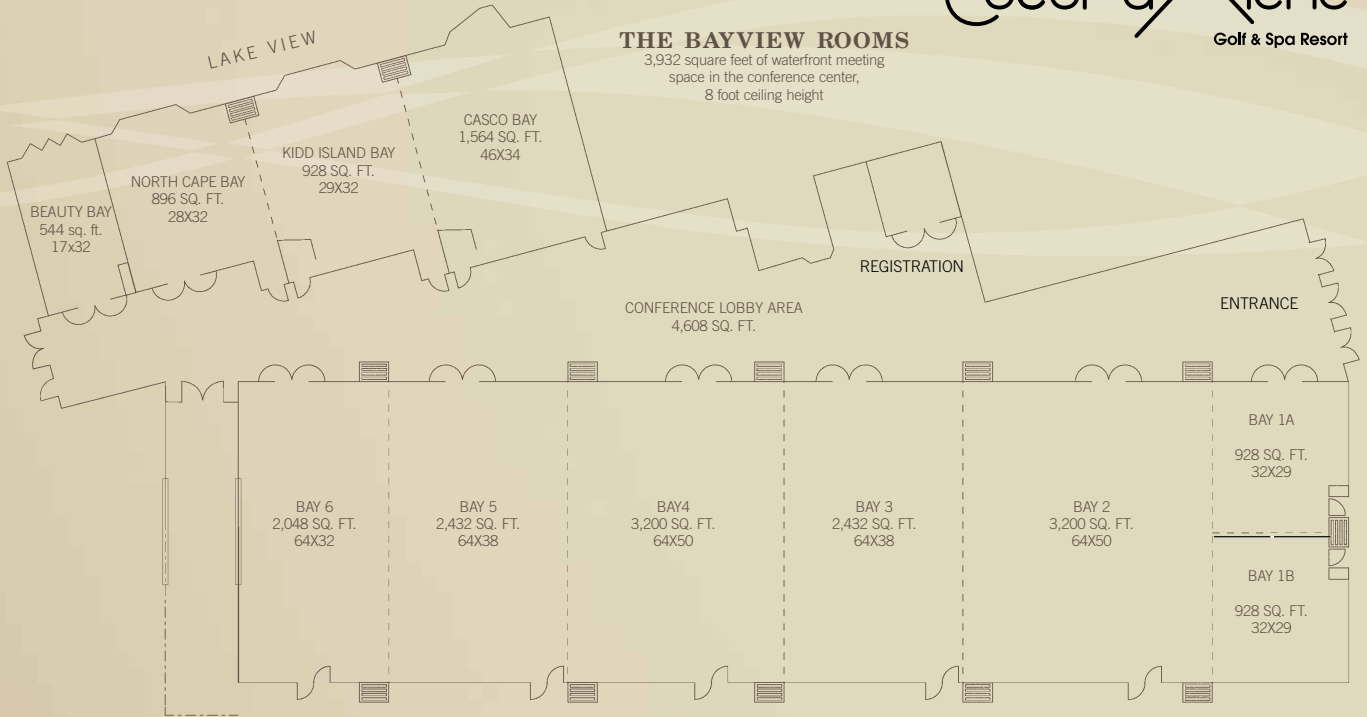
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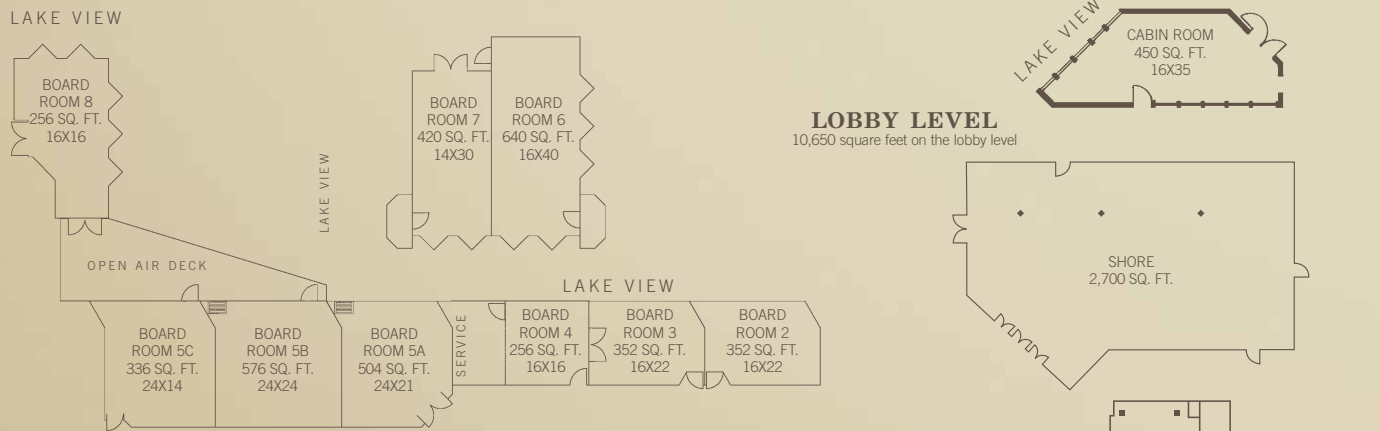


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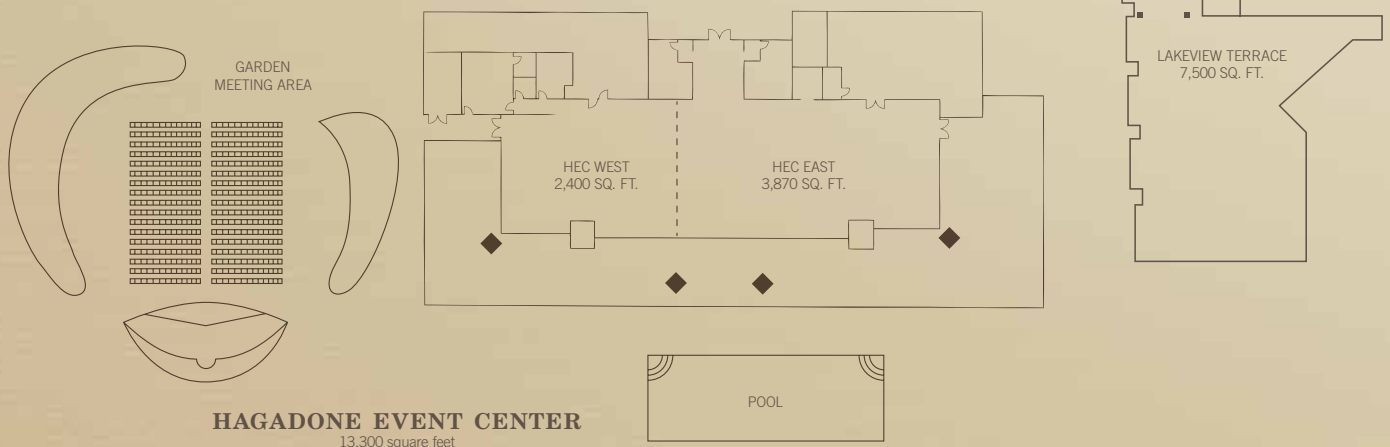
aafintl.com



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15,168 square feet in the conference center, 16 foot ceiling height
64x208 foot overall dimensions (Bay 1-6 Open)



THE SEVENTH FLOOR BOARDROOMS
3,692 square feet overlooking Lake Coeur d'Alene





SPEAKER BIOS

Christine Acosta

Christine Acosta is a Supervising Inspector with the CA Board of Pharmacy, where she provides guidance and directs investigative case plans and oversees investigations. Dr. Acosta trains the board's inspector staff, and provides consultation to the board's executive staff on complex enforcement and licensing activities. Dr. Acosta has been principally involved in the development of the board's compounding and sterile compounding regulations, and often serves as a subject matter expert for the board in testimony and in emerging policy of the board. Prior to joining the Board of Pharmacy, Dr. Acosta worked as a pharmacist-in-charge in a retail pharmacy, and as a clinical pharmacist in the inpatient setting.

Jane Axelrad

Jane A. Axelrad is a consultant on regulatory policy, oversight, and compliance issues affecting the Food and Drug Administration (FDA). Ms. Axelrad offers strategic and regulatory advice based on decades of experience at FDA establishing policy and developing and implementing groundbreaking legislation. For almost 25 years, Ms. Axelrad was the Associate Director for Policy in the Center for Drug Evaluation and Research (CDER) at FDA. In this position, she led multidisciplinary teams of scientists, technical experts and attorneys in addressing complex regulatory policy issues. In addition, from 1995-2012, she created and led the CDER Office of Regulatory Policy, which was responsible for writing regulations and guidance documents for the Center and providing policy advice to the Center Director and other senior staff. Ms. Axelrad is a skilled negotiator and was a critical member of FDA's negotiating team for four reauthorizations of the Prescription Drug User Fee Act (PDUFA). In addition, she negotiated with Congress and stakeholders during the development of other critical pieces of legislation including the Food and Drug Administration Modernization Act of 1997 (FDAMA), the Food and Drug Administration Amendments Act of 2007 (FDAAA), the Food and Drug Administration Safety and Innovation Act (FDASIA) (2012), and the Drug Quality and Security Act (DQSA) (2013). After enactment, Ms. Axelrad led many of the Center's activities to implement these laws. From 2012-2016, Ms. Axelrad was the Agency lead for the pharmacy compounding initiative where she led the development of numerous regulations and guidance documents to implement the drug compounding provisions of the DQSA. She also oversaw the agency's compounding inspection and enforcement efforts. Ms. Axelrad earned a JD from the Columbus School of Law, Catholic University of America, and a BA in Mathematics and Sociology from the

University of Michigan. Ms. Axelrad was the recipient of the Presidential Distinguished Executive Rank Award in 2015, the Presidential Meritorious Executive Rank Award in 2007 and 1998, the Secretary's Award for Distinguished Service, U.S. Department of Health and Human Services, in 2014, 2003 and 1998, the Food and Drug Law Institute Distinguished Service and Leadership Award in 2013, and numerous other individual and group awards.

Michele Egberts

Michele A Panichi-Egberts is a Radiation Safety and Compliance Officer for Nuclear Diagnostic Products, an independent nuclear pharmacy located in Cherry Hill, NJ. She is a Fellow of the Technologist Section of the Society of Nuclear Medicine and Molecular Imaging and a member of the SNMMI Committee on Radiopharmaceuticals.

Herschell Hitchcock

30 years Industrial Hygienist, Department of Defense Trained, CETA National Board of Testing Certified RCCP-SCF, Eagleson Institute - Certification of Sterile Compounding Facilities and Aseptic Isolators, 2013, Harvard School of Public Health - HEPA In-Place Filter Testing, 2011, Lab Safety - Aseptic and Hazardous Drug Compounder Education Competency, 2010 NSF 49 Accredited Biosafety Cabinet Field Certifier, 2009, AGAPE Biohazard Cabinet Field Certifier, 2008 Nuaire - Certification of Biological Safety Cabinet, 2007 Flow Science Product School, Nuaire Product School, Germfree Product School, past Certification as Certified Healthcare Safety Professional (CHSP), and Past Certification as Registered Environmental Assessor (California EPA)

Jason Kleintop

Jason Kleintop is the Director of Operations for DRS Laboratories, Inc. At DRS Laboratories, Jason coordinates projects involving space and surface decontamination for pharma, academia, research laboratories, and manufacturing facilities. He develops practical applications for the non-traditional decontamination application to ensure effective and successful results. He oversees the implementation and execution of the DRS manufactured equipment customer training program. After production and manufacturing of decontamination related equipment, Jason serves as Quality Assurance evaluating all aspects of the manufacturing process and final product for DRS customers.



SPEAKER BIOS

Jason Kleintop (continued)

Jason has 16 years of experience in the Decontamination and Certification industry. Prior to DRS Laboratories, Jason served as a Certification Manager for seven years overseeing and developing the certification and testing plan for customers' equipment, ensuring quality and accuracy of work as well as supervising and mentoring technicians.

Greg Raymond

Gregory Raymond is currently a research microbiologist/biochemist and manager of a prion laboratory at the Rocky Mountain Laboratories (RML) of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). Before that he did basic research on RNA biosynthesis in the microbiology, biochemistry and molecular biology department at the University of Wyoming where he was a graduate student for 3 years, then a research associate for 10 years. He has been researching prion diseases at NIH/RML since 1990. Prion diseases which are also known as transmissible spongiform encephalopathy (TSE) diseases include: Creutzfeldt Jakob disease (CJD) in humans; chronic wasting disease (CWD) in deer, elk and moose; bovine spongiform encephalopathy (BSE or "mad cow disease") in cattle, scrapie in sheep and goats; all of these are fatal. The goal of his research has been to gain an understanding of the basic biology of these unusual infectious agents such as: what exactly the infectious agent is, what makes it infectious, how does it propagate in a host, and how is it transmitted between individual animals and humans. He has also focused his research efforts in developing a simple, rapid, and accurate test for early diagnosis of prion diseases and on therapeutic interventions to prevent and possibly cure them. In his research he uses biochemistry, molecular biology, cell biology, microbiology and animal models. Through the years, he has written prion laboratory and animal standard operating procedures (SOPs) for BSL2 and BSL3 laboratories, participated in WHO (World Health Organization) advisory panels, CWD advisory groups, and is a contributor for the prion section of the current 5th edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL) and soon to be published 6th edition produced by the Centers for Disease Control (CDC) and the NIH. He developed and wrote prion biosafety SOPs for laboratory personnel using biosafety cabinets (BSCs) and BSC technicians that maintain BSC units at RML. He is an author on more than 60 peer reviewed research papers.

Abby Roth

Abby Roth is the Director of Microbiology at Clinical IQ, LLC., a health care consulting firm. She holds a Bachelor of Science

degree in Biology and a minor in Chemistry from York College of Pennsylvania. In 2014, she became a Certified Manager of Quality/Organizational Excellence through the American Society of Quality. Abby has over 14 years of experience in supporting the testing and consulting needs of the pharmaceutical, medical device and compounding industries. Her background in pharmaceutical microbiology includes extensive knowledge of environmental monitoring, including program development, sampling technique, sample analysis and data trending, as well as product testing. Abby also has experience in consulting on microbial contamination sources and remediation. She is currently serving as an expert committee member of the 2015 to 2020 USP Compounding Committee.

Tom Smith

Thomas C. Smith is the President and CEO of Exposure Control Technologies (ECT), Inc. Mr. Smith has worked for more than 30 years helping facilities provide safe, efficient and sustainable laboratories. He holds a Bachelor of Science in Mechanical Engineering from North Carolina State University and a Master of Science in Industrial Hygiene from the University of North Carolina. Mr. Smith has served as Chair of ASHRAE TC9.10 Laboratory Systems, Chair of the ANSI/AIHA Z9 Standards for Ventilation and Health, and been a member of the ASHRAE 110 committee since 1991. He serves on the Board for the International Institute of Sustainable Labs (I2SL) and was recently inducted into the Alumni Hall of Fame for the Mechanical and Aerospace Engineering Department at the North Carolina State University.

Rene Soetens

Rene Soetens is president and owner of Con-Test, Canada's national testing and certification company. He joined the industry in 1993 and has been active in promoting quality testing services ever since. He attended his first CETA meeting in 1994. He has served on the board of CETA in numerous capacities including a term as President.

Rene along with other board members played an active role in making sure that these Meetings were in fact educational in nature with the goal of enlarging the membership and improving the professionalism of the certification industry. Rene includes in his hobbies active involvement in politics and as can be seen shortly a love of the outdoors.

Jim Wagner

The president of Controlled Environment Consulting (CEC), has been involved in the Controlled Environment performance evaluation industry since 1979. His consulting

SPEAKER BIOS

includes design and evaluation of sterile compounding facilities, containment facilities and other engineering controls. Jim conducts international training on cleanroom and containment device certification. Prior to founding CEC, Jim was the President of Micro-Clean, a certification and validation company. Jim led the Controlled Environment Testing Association's (CETA) efforts to develop guidance documents for compliance with USP Chapter 797. He was a member of the USP Council of Experts for Compounding and an expert panel member for USP <800>. Jim is a current member of the USP Compounding Expert Committee responsible for revisions to USP <797>. Jim is a steering committee member for NSF/ANSI standard 49 Biosafety Cabinetry: Design, Construction, Performance, and Field Certification. Jim was a two-time president of the Controlled Environment Testing Association including being CETA's first president in 1991-92.

Adam West

Adam West has over 10 years of experience in the certification industry. He started his career with Agape Instruments Service, Inc., providing Field Certification

Services for 503A and 503B sterile compounding facilities and pharmaceutical and medical device manufacturers. Adam currently works in the Life Science Department of STERIS Corporation for Controlled Environment Certification Services, now branded as Micro Clean. He is a Field Certification Technician who specializes in viable environmental monitoring and remediation. Adam holds the Registered Cleanroom Certification Professional – Sterile Compounding Facilities (RCCP-SCF) certification and NSF-49 accreditation.



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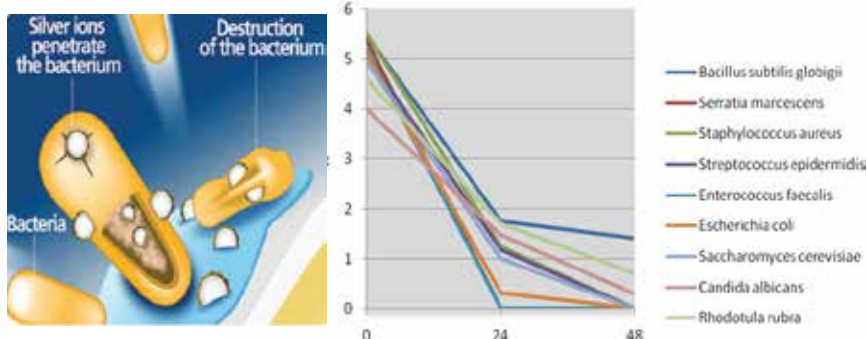
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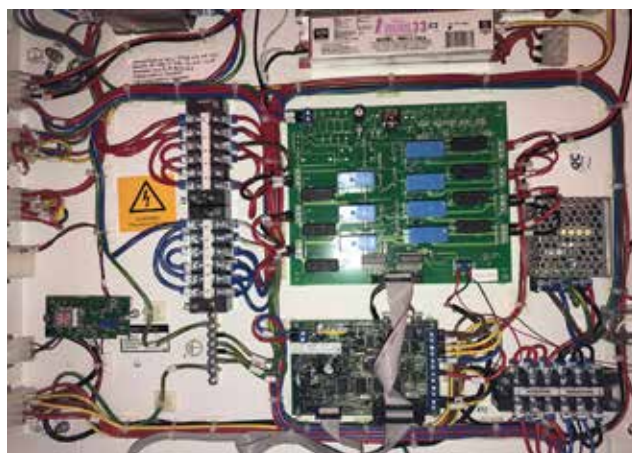
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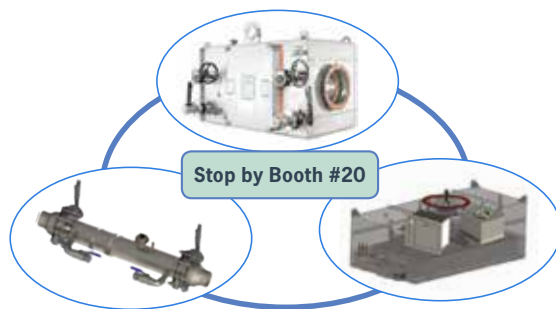
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