

Schedule of Events



Stirling D-E-F

Maren Roush

Inverness Alcove

Inverness Foyer

Inverness A

Thursday, April 20

3:00PM - 7:00PM

Stirling B

Friday, April 21

Registration	8:00AM-5:00PM	Stirling Foyer
RCCP-SCF		
Multiple Choice Exam	9:00AM-12:00PM	Stirling G-H
CETA Series #1:	I:00PM-5:00PM	Stirling D-E-F
Testing and Certification		Stirling B-C
of Non-Conventional Cor	Stirling East	

Saturday, April 22

Registration	8:00AM-7:00PM	Inverness Alcov
RCCP-SCF		
Written Practical Exam	9:00AM-12:00PM	Stirling G-H
Platinum Sponsor Update	10:00AM-12:00PM	Stirling West
CETA Series #2:	I:00PM-5:00PM	Stirling East
USP 797 Cleanroom Ope	Stirling B-C	
Testing, and Training		Stirling D-E
		Stirling O-P
		Shawn Windley
Exhibitor Setup	5:00PM-7:00PM	Inverness Foye
Opening Reception Luau	7:00PM-9:00PM	Island Pool

Sunday, April 23

Registration	7:00AM-4:00PM	Inverness Alcove
Breakfast/Exhibits	7:00AM-8:00AM	Inverness Foyer
CETA Annual Meeting General Session	8:00AM-2:30PM	Inverness A
Conference Welcome	8:00AM-8:05AM	Inverness A Nick Karlowsky
President's Address	8:05AM-8:15AM	Inverness A Todd Urton
Presentation: Your Role is Huuuge!	8:15AM-9:00AM	Inverness A Jim Welch

Learning Objectives:

- The importance of high reliability organizations in health security
- The growing global need for proven quality assurance
- How quality assurance is key to duty of care

Presentation: History of CETA

9:00AM-9:35AM Inverness A David Brande

- Learning Objectives: • Understand CETA's genesis
 - Learn more about the people who helped forge CETA's path
 - See some of the accomplishments of CETA over the past 25 years

	Sunday, April 2	(continued)		
Stirling B	Presentation:	9:35AM-10:15AM	Inverness A	
Suring D	ISO 14644-3 Update		G.Farquharson	
	Learning Objectives:			
	Changes from 2005	version.		
Stirling Foyer	• The DIS vote result a			
		v tests other than class	ification	
Stirling G-H	 Guidance on test fre 			
Stirling D-E-F	 Filter leak test option 		nd photometer	
Stirling B-C	 Other important test 			
Stirling East	Break	10:15AM-10:45AM	Inverness Foyer	
Stirling West				
Wayne Copeland	Presentation:	10:45AM-11:30AM	Inverness A	
.,	Certification of Compou		Jim Wagner	
	for Compliance with Cur	rent and Proposed Re	gulations	
	Learning Objectives: This presentation is a brea	ledoven the standards	and regulatory	
Inverness Alcove	expectations for compour			
	proposed standards and r		current and	
Stirling G-H		es of helpful and unhe	Inful certification	
Stirling West		ent and proposed com		
8		the certification proces		
Stirling East Stirling B-C				
Stirling D-E	 This session will also include strategies for certification professionals 			
Stirling O-P	•		I	
Shawn Windley	NSF / CETA Spec Guide	11:30AM-12:00PM	Inverness A	
		Jim Wagner, Maren Ro Jim Wagner - NSF Up		
Inverness Foyer		Maren Roush - NSF P		
Island Pool	Lunch	12:00PM-1:00PM	Inverness B	
	Presentation:	1:00PM-1:45PM	Inverness A	
Inverness Alcove	USP <797> and Beyond:	Chartere 1000 1000	Abby Roth	
Inverness Foyer	The Importance of USP (Learning Objectives:	_napters 1000-1999		
	e ,	and the latest revision	of LISP<797>	
Inverness A		apters in the USP, many		
		ed for information only		
Inverness A	The General Chapte	,		
Nick Karlowsky		oose of these chapters		
Inverness A	Specific information			
Todd Urton	and <1163 will be re			
Inverness A	Presentation:	1:45AM-2:10PM	Inverness A	
Jim Welch	CNBT Update	1.73/11-2.10111	David Brande	
-	-	2 20014 5 20014		
ns in health	Equipment	2:30PM-5:30PM	Stirling O-P	
	Manufacturer Forum		Stirling L-M-N	
ssurance			Stirling I-J-K	
			Stirling G-H	

NSF Steering Committee 5:30PM-6:30PM

Monday, April 24

Registration	7:00AM-1:00PM
Breakfast/Exhibits	7:00AM-8:00AM
CETA Annual Meeting General Session	8:00AM-12:00PM
General Session	

Schedule of Events



Monday, April 24 (continued)

Conference Updates

8:00AM-8:10AM

Inverness A Nick Karlowsky

8:10AM-8:45AM1 Inverness A

Are Today's Standards Really New and Improved? Vijayakumar R Learning Objectives:

- Contrast between necessary and just 'nice to have' standards
- What makes for durable standard
- Why filter new filter standards may not be really improved
- Why it is important to guestion not follow standards blindly

Presentation:

Presentation:

8:45AM-9:30AM Inverness A Revision of Annex I of the EU & PIC/S GMP G. Farguharson

Learning objectives:

- Integration of ISO 14644-1:2015 into Annex 1 5 micron particles and the impact on testing
- Air change rate calculation and use as a design tool source strength of contamination estimation and HVAC system tuning based on EM data

Presentation: Hazardous Drugs:

9:30AM-10:00AM Inverness A

Tim Hoggard

Inverness Foyer

Inverness A

Ed Balkovic

& Inverness B

Life Cycle and Environmental Surveillance

Learning objectives:

- Describe the life cycle of hazardous drugs in healthcare settings
- Identify primary routes of exposure to hazardous drugs.
- Explain hazardous drugs disposal process
- Review current practices for mitigation of hazardous drug exposure
- Review available environmental surveillance tools for hazardous drugs

Break

Presentation:

10:00AM-10:30AM

10:30AM-11:30AM Inverness A

Review of Current and Future Compounding Standards (CMS, USP and FDA) Eric Kastango

- To review and understand the history of pharmacy compounding and evolution of sterile compounding regulations
- •The presentation will also review some of the major compounding events that resulted in significant patient harm

11:30AM-12:00PM

Presentation:

Understanding Mold Contamination

in Clean Rooms

Learning Objectives

- Understand the sources of mold contamination
- Recognize mold presence and determine its source
- Design remediation strategies
- Controlling re-introduction

Lunch	12:00PM-1:00PM	Inverness Foyer
"I Don't Golf Activity" - Archery & Skeet Shoo	I:00PM-4:00PM ting	Edinburgh Lawn
Wally Whitt Memorial Golf Tourname	12:00PM-6:15PM ent	Copperhead Course Golf
Annual Banquet	7:00PM-10:00PM	Inverness Foyer

Tuesday, April 25

Registration	7:00AM-10:00AM	Inverness Alcove
Breakfast/Exhibits	7:00AM-8:00AM	Inverness Foyer
CETA Annual Meeting General Session	8:00AM-12:15PM	Inverness A
Conference Updates	8:00AM-8:10AM	Inverness A Nick Karlowsky

8:40AM-9:10AM

Presentation:

Working with a Contract Microbiology Lab:

From a Microbiologist's Perspective

Learning Objectives:

- Consideration of the overall lab operations
- Evaluation of facility and equipment conditions
- Assessment of staff experience and training
- Review of sample control and data integrity

Presentation:

9:10AM-9:45AM

Inverness A Jason Dobranic, Ph.D.

Inverness A

Ed Balkovic

Interpretation of Objectionable Organisms in Environmental Samples

Learning Objectives

- Understanding of what are "objectionable organisms", also known as "highly pathogenic microorganisms" in USP 797
- Determining the quantity and types of microbes that can trigger remedial action
- Better understanding on how microbial data can be interpreted from laboratory reports
- Trade-offs between a conservative-approach versus higher risk when defining if a microbe is objectionable in environmental samples

General Election & CETA Business Meeting	9:45AM-10:00AM	Inverness A Todd Urton
Exhibitor Breakdown	10:15AM	Inverness Foyer
CAG Working Groups: NEW CAG! CAG 010 Containment Ventilated Er	10:30AM-11:30AM	Stirling Boardroom Todd Urton
CAG Working Groups: CAG 008 Certification Ma		Stirling Boardroom Nick Karlowsky
Meeting Adjourned	12:15PM	
CETA Follow-up	12:30PM-2:00PM	Stirling

CETA Follow-up **Board Meeting** CETA/CNBT Exam Grading

12:30PM-2:00PM

8:00AM-3:00PM

2:30PM-8:00PM

Stirling B-C

Wednesday, April 26

CETA/CNBT Exam Grading Stirling Boardroom

Boardroom

Conference Notes:

Nametags:

The nametags are magnetic, so if you have a pacemaker, please go to the registration desk for a different name badge.

What do the stickers on my name badge mean?

GC means you're registered for the General Conference 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 I-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.



Manufacturer Updates April 23, 2017 2:30-5:30 PM

Timing/ Room	Stirling O-P-Q	Stirling L-M-N	Stirling I-J-K	Stirling G-H
2:30-3:00	Thermo Fisher Scientific	Holland Safety Equipment	Labconco	Air Techniques International
3:00-3:30	Thermo Fisher Scientific	Baker	Labconco	Air Techniques International
3:30-4:00	Degree Controls, Inc.	Baker	Bioscience International, Inc.	The Esco Group
4:00-4:30	Degree Controls, Inc.	TSI Inc.	Bioscience International, Inc.	The Esco Group
4:30-5:00	NuAire Inc.	TSI Inc.	Teknipure	Design Filtration Microzone
5:00-5:30	Kanomax USA	Germfree Laborato- ries, Inc.	Teknipure	Design Filtration Microzone

Controlled Environment Testing Association

OFFICERS

President Todd Urton (2020) Quality Cleanroom Consulting

> President Elect Nick Karlowsky (2019) Filtech, Inc.

Secretary/Treasurer Kym Faylor (2019) Azzur Labs

Past President Tony Caughron (2017) TEC Services, Inc.

EXECUTIVE OFFICE

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

3801 Lake Boone Trail Suite 190 Raleigh, NC 27607 Phone: (919) 792-6339 Web site: www.cetainternational.org Email: info@cetainternational.org

DIRECTORS

David Brande (2017) Cleanroom Project Management, Inc.

Cary Binder (2019) ENV Services Inc

Wayne A. Copeland (2020) CEPA Operations, Inc

Kimberly Coughlin (2018) B&V Testing, A Stericycle Company

Terry Lewis (2018) Lewis Testing Services, Inc.

Chandler Papas (2018)

Jeff Serle (2019) Germfree Laboratories

Shawn Windley (2019) AAF Flanders



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Bioscience International, Inc	
Camfil USA, Inc	6
The Esco Group	7
ClorDiSys Solutions Inc	
Air Techniques International	
Chattanooga Environmental	
Laboratory, LLC	10
NuAire Inc	
TSI Inc	
Filtration Group Corporation	13
EMSL Analytical Inc	14
TEC Services, Inc	
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Design Filtration Microzone	

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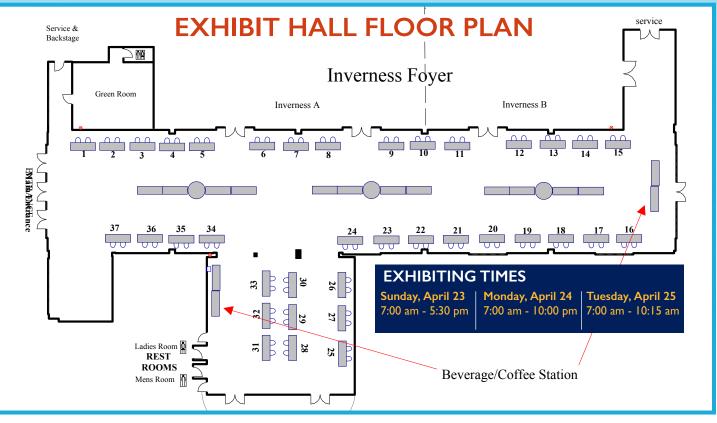
Exhibitor	Booth Number
Kanomax	19
_abconco Corporation	20
Thermo Fisher Scientific	
Sensocon, Inc	
Kewaunee Scientific Corporation	
Aerobiology Laboratory Associates Inc	
FBS Technologies, LLC	
CETA National Board of Testing (CNBT)	
ABSA International	
NSF International	
Shortridge Instruments, Inc	
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Visit Our Exhibitors at the Annual Meeting!

Booth I: APC Filtration Inc.

APC Filtration Inc. is an ISO 9001:2008 certified manufacturer providing over 34 years experience in custom made & designed air filters for global OEM's of industrial, commercial and domestic appliances and equipment.

www.apcfilters.com

Booth 2: 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 3: EMLab P&K

EMLab P&K is the leading commercial indoor air quality (IAQ) laboratory in North America, specializing in the analysis of air and surface samples for mold (fungi), USP797, bacteria, asbestos, legionella, and allergens. We maintain AIHA-LAP LLC and NVLAP accreditations with a goal of providing the highest quality analysis in the industry. www.emlab.com

Booth 4: Flow Sciences, Inc.

Flow Sciences' mission is to provide containment systems for laboratory, pilot plant and manufacturing areas. The products are designed to protect operators from exposure to hazardous particulates and vapors while performing delicate operations. The Flow Sciences' Team, with over thirty years experience in laboratory containment, is committed to finding containment solutions that meet your needs. www.flowsciences.com

Booth 5: Bioscience International, Inc.

Bioscience staff will be highlighting the well known SAS Active Air Sampler and its value in hood certification and ensuring USP 797 compliance.

www.biosci-intl.com

Booth 6: Camfil USA, Inc.

World leader in air filtration technology, Camfil offers state-of-theart 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 7: The Esco Group

The Esco Group is one of the largest global life sciences tools provider with sales in over 100 countries. The group is active in laboratory, medical and pharmaceutical equipment. Some of which are Biological Safety Cabinets, Laminar Hoods, CO2 Incubators, Ultra-low Temperature Freezers, Fume Hoods, IVF Incubators, Cleanrooms and Downflow Booths.

www.escolifesciences.us

Booth 8: 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 9: Air Techniques International

For more than 50 years, Air Techniques International (ATI) has defined the market in the measurement and detection of airborne particulate hazards and contaminants. ATI's workforce is comprised of a dedicated team of individuals committed to developing cutting-edge air characterization technologies; manufacturing reliable products used around the world in industries such as biosafety, cleanroom certification, flat sheet media, pharmaceuticals, and defense.

www.atitest.com

Booth 10: Chattanooga Environmental Laboratory, LLC

Chattanooga Environmental Laboratory, LLC is an A2LA accredited testing laboratory, specializing 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 our website or call 423-777-5220.

www.ChattaLab.com

Booth II: NuAire Inc.

Nuaire has been universally recognized as a leader in providing laboratory professionals with high quality and reliable products such as BioSafety Cabinets, CO2 Incubators, Laminar Airflow equipment, Animal Handling equipment, Centrifuges and Ultra-Low Freezers for the most demanding laboratory environments.

Booth 12: 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 13: Filtration Group Corporation

Filtration Group is the market leader in HEPA and ULPA filters designed for the Biosafety Cabinet manufacturers. Utilizing our Sentinel Pleat technology Filtration Group custom engineers 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. Whether it is a wood framed aluminum separator or an anodized aluminum minipleat product Filtration Group is the source for Biosafety Cabinet Manufacturers.

www.filtrationgroup.com

Booth 14: EMSL Analytical Inc.

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 15: 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 16: AAF Flanders

AAF Flanders is a world leader in high efficiency air filtration and containment products. We design and manufacture the highest quality products necessary for the medical, biological, pharmaceutical, and micro-electronics industries. We offer MEGAcel II ePTFE media filters, HTP High Temp filters, and filters for other critical applications. www.aafintl.com

Booth 17 & 18: Design Filtration Microzone

Our equipment and cleanroom systems are designed to provide a high degree of product, personnel and/or environmental protection for all branches of industry, including pharmaceutical and industrial/ commercial, as well as science and technology sectors. www.dfmzgroup.com

Booth 19: Kanomax

Kanomax offers professional grade testing instruments for laboratory environment testing and containment control applications. Our precision anemometer is designed for biosafety cabinet and fume hood performance tests. Our service department in New Jersey can accommodate your project requests with its quick turnaround time. www.kanomax-usa.com

Booth 20: Labconco Corporation

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.

Booth 21: 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.

www.thermofisher.com

Booth 22: Sensocon, Inc.

Sensocon, Inc. will be introducing the Siren Air Flow Alarm. The Siren is designed to monitor the airflow in bio-safety cabinets. http://www. sensocon.com/Series-AFA-Siren-air-flow-monitor.html **www.sensocon.com**

Booth 23: Kewaunee Scientific Corporation

Kewaunee Scientific Corporation supplies labs for healthcare, clinical, pharmaceutical, biotechnical, industrial, chemical, secondary schools, universities, and government facilities. Kewaunee manufactures casework, fume hoods, filtered fume hoods, biological safety cabinets, vertical laminar flow cabinets, systems, carts, work surfaces, and other laboratory related products. Made in USA for over 110 years. www.kewaunee.com

Booth 24: Aerobiology Laboratory Associates Inc.

Aerobiology Laboratory Associates, Inc. is an AIHA accredited testing laboratory. With 7 nationwide laboratory locations, we provide technical capabilities and outstanding levels of customer support by providing accurate, cost effective and timely results. We specialize in analysis of USP 61, 62, 797, and 800. Customize reports make your job easier.

www.aerobiology.net

Booth 25: 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 and automatic neutralization of reaction mixture.

www.tbstechnologies.com

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Booth 26: CETA National Board of Testing (CNBT)

The CETA National Board of Testing (CNBT) was established in 2008. The CNBT provides a nationally recognized accreditation program that tests certifier's competency in the field sterile compounding facility certification. Currently, the CNBT is developing a Fume Hood certification credential program to offer a credential specific to the testing and certification of fume hoods.

http://www.cetainternational.org/about-exams

Booth 27: 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 28: 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

Booth 29: Shortridge Instruments, Inc.

Shortridge Instruments, Inc. manufactures AirData Multimeters and Flowhoods for air balancing as well as provides calibration and service support for the Shortridge Instruments, Inc. product lines. **www.shortridge.com**

Booth 30: Teknipure

Teknipure is a manufacturer of consumables use to prevent contamination; including wipes, swabs, gloves, masks, mops and adhesive mats.

www.teknipure.com



Booth 31: Analytics Corporation

Analytics Corporation is an industrial hygiene and environmental testing laboratory in Ashland, Virginia. We have over 38 years of pharmaceutical testing experience with federal and local hospitals and businesses. Our 20,000+ sqft. facility is equipped for various testing services. www.analyticscorp.com

Booth 32: 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 members qualify for discount pricing. www.hollandsafety.com

Booth 33: U.S. Micro-Solutions, Inc.

We are an Environmental Microbiology Laboratory specializing in the analysis of microorganisms from indoor environments, medical devices, water, and pharmaceutical sterile compounding settings (USP 797). We are fully accredited and ISO 17025 compliant. We are committed to providing exceptional quality and outstanding customer service. www.usmslab.com

Booth 34: 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

Booth 35: Degree Controls, Inc.

Degree Controls, a leading airflow monitoring company, will be discussing the latest generation of Rooster Monitor I 00/200 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 36: DRS Laboratories, Inc.

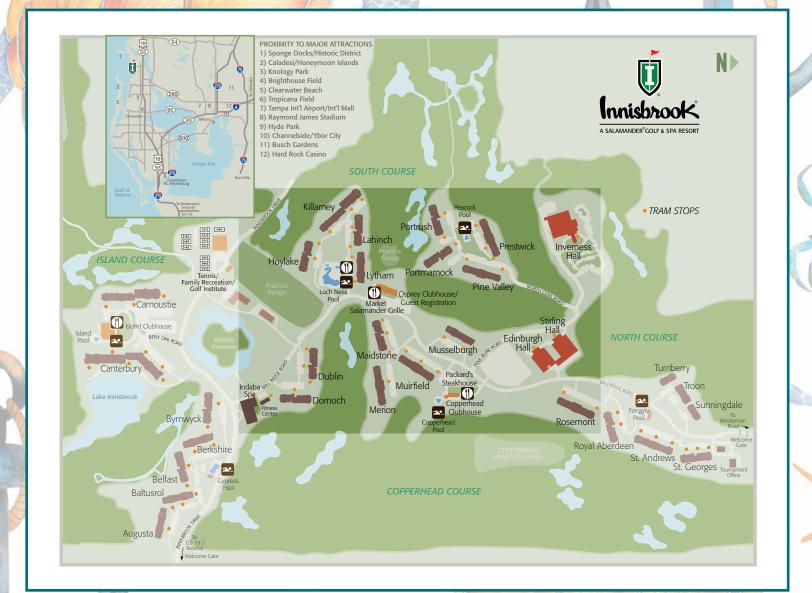
DRS Laboratories, Inc. is a supplier of Chlorine Dioxide Decontamination Equipment. Having explored alternative technologies to improve quality, timeliness, and cost of performing routine BSC decontaminations, DRS Labs has produced the first affordable, and portable device; including tools, procedures, and training. We also offer Decontamination Services in conjunction w/current certification contractors or independently.

www.drslaboratories.com

Booth 37: Baker

For more than 60 years, Baker has helped advance science, discovery and clinical care by pioneering innovative solutions for air containment, contamination control and controlled environments. Baker biological safety cabinets, clean benches, fume hoods, and pharmacy isolators provide unparalleled user and product protection for a variety of applications. **www.bakerco.com**

Welcome to Innisbrook - Where to Go!







Location/Time:

Innisbrook Resort and Golf Club -36750 US Hwy 19 N, Palm Harbor, FL 34683 April 21-25, 2017 Phone: (727) 942-2000

Closest Airport: Tampa International Airport (TPA) – 4100 George J Bean Pkwy, Tampa, FL 33607

Dress code:

Resort Business Casual - For men, shorts, jeans, or slacks paired with a t-shirt or polo shirt. Sneakers, tennis shoes, and sandals are acceptable, *but sleeveless shirts are not*. For women, a blouse with pants, jeans, a casual dress or a skirt is acceptable attire.

Weather:

Palm Harbor, FL weather in mid to late April averages a high of 82° and a low of 65° .

Things to do at Innisbrook:

- Golf (onsite): http://www.innisbrookgolfresort.com/golf/ innisbrook-courses/
- Tennis (onsite): http://www.innisbrookgolfresort.com/ activities/tennis
- Pools (onsite): http://www.innisbrookgolfresort.com/ activities/pools-beaches

Local Attractions:

Innisbrook Resort & Golf Club is centrally located to many beaches – including the renowned Clearwater Beach. Close by is also: Deep-sea fishing, Busch Gardens, the Tampa/St. Petersburg arts scene, and shopping in Tarpon Springs.

Some of the nearby attractions include:

- Historical Greek Village of Tarpon Springs 5 minutes
- Fred Howard Park and Beach 5 minutes
- Honeymoon Island Beach and State Park 10 minutes
- International Plaza 25 minutes
- Prime Outlets Ellenton 50 minutes
- Clearwater Beach 15 minutes
- Tampa Bay Downs 15 minutes
- Florida Aquarium 25 minutes
- Florida Orchestra 25 minutes
- Downtown St. Petersburg 35 minutes
- Downtown Tampa 40 minutes
- Salvador Dali Museum 40 minutes
- Hyde Park, Tampa 40 minutes
- Ybor City (Tampa Historic District) 45 minutes
- Busch Gardens 45 minutes
- The Museum of Science and Industry 45 minutes
- Derby Lane Greyhound Racetrack 55 minutes
- Tampa Greyhound Track 55 minutes
- Walt Disney World® 90 minutes

Onsite Dining/Evening Entertainment:

Innisbrook cuisine ranges from light, organic salads to robust steaks and seafood – all at fantastic value. The friendly staff at Market Salamander will even prepare custom picnic baskets for your day excursions. In the evening, the Osprey Bar, which overlooks golf greens and enjoys a spectacular sunset, provides a relaxing indoor and outdoor environment with live entertainment.

> Packard's Steakhouse

o Reservations: 727.942.5240. Serving only the finest aged Premium Beef steaks. Offering sumptuous Cold Water Lobster Tails and Fresh Day-Boat Floridian Fish finished with Chef's creative touches.

> Market Salamander Grillé

o Reservations: 727.942.5222. From health-conscious recipes to traditional Seasonal American Cuisine, the Market Salamander Grille Restaurant offers a variety of choices for all guests.

> Market Salamander

• Market Salamander is a unique market in Palm Harbor, Florida. Offering wholesome, chef-prepared and specialty foods, as well as specially flavored ice cream.

> Turnberry Pub

• Named after the legendary Scottish golf course, Turnberry Pub is the perfect restaurant in Palm Harbor for a fabulous breakfast buffet, a frosted mug of beer, and a sirloin burger or blackened grouper sandwich.

> The Grill at Loch Ness

• Relax in the beautiful Florida sun while dining poolside and sipping fabulous tropical-inspired frozen drinks.

> Osprey Sports Bar

o It's the perfect setting to relax with a cold beverage after a round of golf, grab a bite to eat with friends or catch the big game!

Conference Etiquette:

- Meeting behavior tips:
- o Show up on time.
- o During meetings, keep your attention focused on the speaker.
- o Don't fidget or squirm.
- o Ask questions that are relevant to the topic.
- o Never interrupt the speaker or someone else who is asking a question.
- o When you get up, push your chair in and pick up all your papers and personal belongings.
- o Thank the speaker, but don't monopolize his or her time.
- o Don't forget business cards!

Questions? Contact: CETA Executive Director, Brandi Gerew, CAE at info@cetainternational.org

Ed Balkovic, PhD

Dr. Balkovic is currently a Consulting Microbiologist. He also holds an academic appointment as an Adjunct Associate Professor in the Department of Cell & Molecular Biology at the University of Rhode Island. His experience includes 40+ years in the fields of Microbiology & Virology; 30+ years in the Biologics & Biopharmaceutical industries; and 20+ years at Sanofi Genzyme.

At Sanofi Genzyme, he served as a Subject Matter Expert (SME) Microbiologist. He established Genzyme's microbial identification lab, conducted investigations, risk assessments, special projects, and developmental technical training seminars throughout Sanofi. He has also conducted numerous studies evaluating new and improved methods for microbial detection and identification.

Dr. Balkovic received his doctorate degree in Microbiology and Immunology in the Influenza Research Center at Baylor College of Medicine, Houston, TX. He has held various positions in Contamination Control, Technical Support, Quality Control, Quality Assurance, Regulatory Affairs and Research & Development at both emerging biotechnology and established biopharmaceutical companies.

At the University of Rhode Island, Dr. Balkovic teaches in the areas of Clinical Microbiology & Virology, Vaccine Development, Emerging Infectious Diseases, Microbial Forensics, Biowarfare & Bioterrorism, Good Manufacturing Practices, and Biotechnology Product Development & Evaluation. He is also a Guest Lecturer in the Chinese American Biomedical Association's Cooperative Training Program with the Chinese Food and Drug Administration.

Dr. Balkovic is a member of the Parenteral Drug Association's (PDA) Science Advisory Board. He also serves on the Program Planning Committee for the PDA Global Pharmaceutical Microbiology Conference and served as the Conference Co-Chair in 2009 and 2010. He is Co-Chair of a PDA Task Force preparing a Technical Report on conducting Microbial Investigations. He is also the recipient of the 2017 PDA Distinguished Service Award.

David Brande

David Brande brings 32 years of experience in the cleanroom industry. David was a founder and President of Contamination Control Technologies, Inc., for 19 years. The company specialized in providing cleanroom and biological containment certifications, as well as international consulting services to the pharmaceutical, medical device and biomedical research industries until purchased by the Danish company Novo Nordisk Engineering (nne) in August of 2005. David left nne in mid 2007 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.

David has been certified as an:

• Accredited BioSafety Cabinet Field Certifier by NSF International, (1994-2004)

- Cleanroom Performance Testing Professional by NEBB (1994-2014)
- Qualified HEPA/ULPA Filter Tester by the IAFCA (1994)

David is an active member of Controlled Environment Testing Association (CETA) and International Society of Pharmaceutical Engineers (ISPE),

With CETA, David served as President from Oct 1995 to Feb 1997 and Secretary/Treasurer of the Board of Directors from 2012 until 2015. For past two years, David has served as the Committee Chair of the CETA National Board of Testing (CNBT) charged with writing, both written and practical, test questions for accreditation tests administered to technicians worldwide.

With ISPE he is a Past President of the Carolina South Atlantic Chapter and an active member of the HVAC-COP Steering Committee.

Dr. Jason Dobranic

Dr. Dobranic is an accomplished microbiologist with over 20 years of research and industry experience. Dr. Dobranic is the Vice President of Microbiology & Life Sciences for EMSL Analytical, Inc and has presented microbial issues at over 60 national and international speaking engagements. He has several industry-related articles published in trade magazines and appeared in a production of the Oprah Winfrey show as an expert on bacteria and indoor allergens.

Dr. Dobranic is currently a member of CETA, ASTM International, and the American Industrial Hygiene Association having served in the past as Chair of the Biosafety and Environmental Microbiology Committee and a member of their Analytical Accreditation Board. He is currently serving as a member of AIHA's LAPTechnical Advisory Panel. He is also the Chapter Director of the local Houston IAQA chapter and serves on boards for the ACAC and the EIA.

Gordon Farquharson, B.Sc.(Hons), C.Eng.

Gordon Farquharson, B.Sc. (Hons), C.Eng. is a Chartered Consulting Engineer with more than 35 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 with partnerships with PharmOut Pty Ltd, a consulting business based in Australia, FactoryTalk based in Thailand, and CM Plus Corporation of Japan.

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 him an ability to dovetail the

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Speaker Bios

Gordon Farquharson, B.Sc.(Hons), C.Eng. continued

differing regulatory requirements. 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 was Convenor of WG I and a UK expert working on the ISOTC209 and CENTC243 family of contamination control standards that provide the platform for contamination control standards that provide the platform for contamination control standards and practice in this millennium. He has worked with the EMA in London to help update and improve the cleanroom classification and monitoring requirements in Annex I of the EU and PIC/S GMPs and has contributed writing WHO's Pharmaceutical water GMP Guidance and the revision of the WHO GMP guidance on sterile products.

He is a founding member, management committee member, past Chairman, and Honorary Member of the UK Pharmaceutical & Healthcare Sciences Society (formerly Parenteral Society), and was 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 was a 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 cleanroom and isolator technology, as well as practical engineering interpretation of GMP philosophies.

Tim Hoggard

Tim Hoggard is currently the Clinical Specialist, Sterile Compounding at UF Health Shands Hospital, Pharmacy Services. He is responsible for development, implementation and execution of quality control procedures to confirm the safe operation of all sterile compounding facilities at UF Health Shands Hospital. Tim ensures ongoing compliance with applicable state and federal regulations related to sterile compounding. He develops and implements training programs and competency assessments to maintain technical expertise of compounding staff. Tim maintains a primary role in the comprehensive evaluation and comparison of vendors of outsourced sterile products for Shands Hospital.

Tim received his BS in Biology from the University of North Carolina at Wilmington, and BS in Pharmacy from the University of Georgia. He spent 13 years as a clinical staff pharmacist, and 17 years as Operations Coordinator, both at UF Health Shands Hospital. Tim has been in his current role since 2013.

Eric S. Kastango, M.B.A., B.S.Pharm., FASHP

President/CEO

Clinical IQ, LLC and CriticalPoint, LLC Madison, New Jersey

Eric S. Kastango, M.B.A., B.S.Pharm., FASHP, is president of Clinical IQ LLC, a health care consulting firm and CriticalPoint, LLC, a web-based education company.

Mr. Kastango received his Bachelor of Science degree in pharmacy from the Massachusetts College of Pharmacy and Allied Health Sciences and his Master of Business Administration degree from the University of Phoenix. He completed 65 hours of training in nuclear pharmacy at Purdue University and 80 hours of didactic training for the Six Sigma-Green Belt certification that he started with BD Medical Systems.

Eric received a coveted ISMP Cheers Award in 2015 for his work related to sterile compounding safety. He is one of four recipients of the 2013 Outstanding Service Award from the Massachusetts Society of Health-System Pharmacists and the 2014 recipient of the NABP Henry Cade Memorial Award that recognized his efforts and assistance to the states and NABP to address the compounding tragedy that occurred in 2012.

Since 1980, he has practiced pharmacy in a number of practice settings, including hospitals, community, and home care, in a number of different of roles, including the Corporate Vice President of Pharmacy Services for Coram Healthcare Corporation. He has also managed an FDA-registered cGMP manufacturing operation for Baxter Healthcare Corporation.

He is an active member and Fellow of the American Society of Healthcare Pharmacists and served on the USP Sterile Compounding Committee from 2005-2010 and 2010-2015 USP Council of Experts, Compounding Expert Committee until April 2013. In May 2013, USP recognized Eric and the members of Compounding Expert Committee with an Award for Outstanding Contribution to the USP Standards-Setting Process.

He has served on the USP Hazardous Drug Expert Panel since 2010. He is actively working with NABP and state boards of pharmacy to provide training to their sterile compounding inspectors. Eric served on the Expert Panel for ASHP Research & Education Foundation in the development of the 2015 Outsourcing Sterile Products Preparation Vendor Assessment Tool and ASHP's Insourcing Readiness Assessment Tool.

He is also the author of the 2004 ASHP Discussion Guide for Sterile Preparation: Summary and Implementation of USP Chapter 797, the ASHP Sterile Product Preparation CD-ROM: A Multimedia Learning Tool, the ASHP web-based 797 Compliance Advisor Gap Analysis Tool for USP Chapter 797. He assisted in the development of the CriticalPoint web-based educational series on Sterile Compounding and the Annual National USP <797> Compliance Survey now in its fifth year. Eric has over 200 invited national and international professional presentations on various pharmacy practice topics such as pharmacy compounding, patient safety, and quality systems.

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Abby Roth

Abby Roth is the Quality Director at Azzur Labs in Schnecksville, Pennsylvania. She has been with Azzur Labs since 2012 and has over 13 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 Compounding Committee.

R. Vijayakumar, PhD

Consultant in Chief - 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 several patents and 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 world wide. 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 is a Distinguished Visiting Professor at the Chinese Academy of Building Research and has been on the faculty of the short course on air and gas filtration at the University of Minnesota since its inception. He is a Fellow and a Distinguished Lecturer of ASHRAE He has taught courses in cleanroom designs for ASHRAE, and lectures around the world for them on various aspects of filtration and cleanroom designs. He has recently published an iBook on Aerosol Mechanics for the general user. He is a Fellow and past 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

Jim is the president of Controlled Environment Consulting (CEC), has been involved in the Controlled Environment performance evaluation industry since 1979. His consulting 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. Recently Jim led the Controlled Environment Testing Association's (CETA) efforts to develop guidance documents for compliance with USP Chapter 797. He is a current member of the USP Council of Experts for Compounding and an expert panel member for USP <800>. Jim is a steering committee member for NSF/ANSI standard 49 Biosafety Cabinetry: Design, Construction, Performance, and Field Certification.

James M "Jim" Welch

Jim Welch is the executive director of the Elizabeth R Griffin Research Foundation (ERG), a US-based 501c3 non-profit foundation dedicated to enhancing global health security through advocacy, engagement and support of effective management of biological risks in research and clinical environments. The Foundation works collaboratively with institutions, associations, philanthropic groups, private entities and government ministries around the world.

Educated at East Tennessee State University and the University of Tennessee, Jim serves as a key speaker, panelist and/or moderator in numerous national and global professional conferences, symposia, colloquia and webinars. He is an experienced instructor and facilitator in professional courses related to biosafety, biosecurity, leadership development, global health security, national and regional policy development, risk communication, strategy development and implementation, and organizational dynamics. He also works globally as a speaker and session moderator in cooperative risk reduction programs delivered through the United States Department of State and the United States Department of Defense.

As ERG's executive director, he is currently serves on the Global Health Security Agenda Consortium Steering Group, the Joint External Evaluation Alliance of the Global Health Security Agenda and as one of four NGO representatives on the Global Health Security Agenda Steering Group. He is a coordinator in the Eagleson / ERGF global occupational health colloquium for biological exposures and also for an annual global leadership summit of biosafety professionals. He has served as a member of the Law Enforcement and Veterinary International Conference (LEVIC) at INTERPOL, the Scientific Advisory Board of the National Biosafety and Biocontainment Training Program at the National Institutes of Health (NIH), International Scientific Committee of the Scientific Conference on CBRNE, board of directors of the International Federation of Biosafety Association (IFBA) and as a board member of the International Centre for Infectious Diseases (ICID).

Jim's professional memberships include ABSA International, American Association for Laboratory Animal Science (AALAS), the European Biological Safety Association (EBSA), Asia-Pacific Biosafety Association (A-PBA), African Biological Safety Association (AfBSA) and the International Veterinary Biosafety Working Group (IVBWG). He is a named honorary member of the Association of Primate Veterinarians and was the 2011 recipient of the John H Richardson Achievement Award from the American Biological Safety Association.

Jim is married and resides in Kingsport, Tennessee with his wife, Vikki. They have two children and four grandchildren.

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