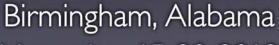


62nd Annual Biosafety and Biosecurity Conference

Birmingham - Jefferson Convention Complex





ABSA International (ABSA) was founded in 1984 to promote biosafety as a scientific discipline and serve the growing needs of biosafety professionals throughout the world. The Association's goals are to establish the global standard for biological safety, to provide a professional association that represents the interests and needs of practitioners of biological safety, and to provide a forum for the continued and timely exchange of biosafety information. ABSA accomplishes these goals through providing members and stakeholders expertise and resources through publications in the peer-reviewed journal *Applied Biosafety*; the ABSA website; sponsoring an conference event; training programs to inform members of regulatory initiatives, hazard recognition and management issues, risk communications; current biosafety publications; meetings and seminars; e-mail updates; training opportunities; and employment opportunities. Additionally, ABSA members receive "Members Only" web privileges where they have access to past issues of *Applied Biosafety*, and members can participate in a biosafety mentoring program.

What is Biosafety? The concept of biological safety (or biosafety) has paralleled the development of the science of microbiology and its extension into new and related areas including tissue culture, recombinant DNA, animal studies, molecular biology, synthetic biology, and biotechnology. The knowledge and skill gained by microbiologists necessary to isolate, manipulate, and propagate pathogenic microorganisms required parallel development of containment principles, facility design, and practices and procedures to prevent occupational infections in the workplace or release of the organisms to the environment.

What is a Biosafety Professional? A biosafety professional develops and participates in programs to promote safe microbiological practices, procedures, and proper use of containment equipment and facilities; stimulates responsible activities among workers; and provides advice on laboratory design.

Core Purpose: ABSA is dedicated to promoting and expanding biological safety experience.

Core Organizational Values: Leading the profession; collaboration and community; promote biosafety as a scientific discipline; absolute integrity; and high standards of excellence

ABSA Event Code of Conduct: ABSA International is committed to providing an environment that encourages the free expression and exchange of scientific ideas and promotes respectful treatment for all participants. All participants are expected to treat others with respect and consideration, follow venue rules, and alert ABSA staff or security of any dangerous situations or anyone in distress. ABSA International prohibits and will not tolerate any form of harassment or bullying at its events. Harassment is unwanted and unwelcome attention or other conduct that creates an environment where a reasonable person would feel unwelcome, intimidated, excluded, or abused. Harassment based on gender, race, religion, national origin, age, marital status, personal appearance, sexual orientation, gender identity or expression, disability, political affiliation, and any other personal characteristic is strictly prohibited. This policy applies to all attendees, speakers, exhibitors, contractors, volunteers, and guests at ABSA events. If a participant experiences or witnesses harassment, he/she should contact ABSA staff as soon as possible or contact security if they feel unsafe. All complaints will be responded to promptly and treated seriously and, to the extent possible, confidentially. ABSA expressly forbids any retaliation against individuals for reporting harassment. In the event that an individual knowingly provides false information regarding a harassment situation, ABSA may take similar disciplinary action. ABSA will accept and investigate all complaints of harassment and investigations will be conducted in an unbiased manner. All complaints will be responded to promptly and treated seriously and, to the extent possible, confidentially.

ABSA Inclusion Statement: In alignment with our core organizational values, ABSA encourages positive connections between biosafety professionals, scientists, governmental/nongovernmental organizations, and the public. It is our organization's policy to administer all activities without discrimination on the basis of age, gender, race, religion, sexual orientation, national origin, disability, marital/familial status, and veteran status. These practices extend to all aspects of ABSA's activities and to all roles within the association (e.g., member, ambassador, employee, mentor, sponsor, and vendor).

Contact Information Release: The generous support provided by exhibitors is significant to the success of ABSA Biosafety and Biosecurity Conferences. The exhibiting company's goal in participating in the conference is to interact with the attendee and to provide the most current information on their products and services. Attendees mailing addresses will be made available to the exhibitors who wish to mail information. This list will only contain name, full address, and affiliation (if provided) and email addresses. No phone numbers or fax numbers will be included.

Consent to Use Photographic Images: Registration and attendance at or participation in ABSA meetings and other activities constitutes an agreement by the registrant to ABSA's use and distribution (both now and in the future) of the registrant's or attendee's image or voice, without compensation, in photographs, video tapes, electronic reproductions and audiotapes of such events and activities.

62nd Annual Biosafety and Biosecurity Conference

Special Event

The Barber Motorsports Park was built by George Barber and includes the Barber Vintage Motorsport Museum, which has been named "World's Largest Motorcycle Museum" by the Guinness World Records. With its creative architecture and great attention to detail, the museum is home to over 1,400 motorcycles that span over 100 years of production. More than 650 bikes can be seen on any given day, and 200 different manufacturers from 20 countries are represented in the collection—from Harley-Davidson, Honda, and Indian—to Showa, DSK, and Cagiva. We hope you will join us for live music, a buffet of southern dishes (with vegetarian options), and some amazing rides.

Award Presentations

Monday, 8:25 am—Arnold G. Wedum Memorial Lecture Award

Tuesday, 8:05 am—Griffin Lecture Award

Tuesday, 10:50 am—Eagleson Lecture Award

Wednesday, 9:40 am—Richard Knudsen Award

Wednesday, 11:55 am—Arnold G. Wedum Distinguished Achievement Award

Wednesday, 11:55 am—Everett J. Hanel, Jr. Presidential Award

Wednesday, 11:55 am—John H. Richardson Special Recognition Award

Wednesday, 11:55 am—Scientific and Informational Poster Awards

Wednesday, 11:55 am—Hashimoto Award for Service and Honor

Wednesday, 11:55 am—Recognition of Certified Biological Safety Professionals and Registered Biosafety Professionals

Registration

The Registration Desk will be open Friday through Wednesday from 7:00 am - 5:00 pm.

Badge Policy

Badges must be worn at all conference events. There will be a \$25 badge replacement fee for lost or forgotten badges.

New Member Reception

The reception for new members and first-time conference attendees will be held Sunday from 5:30 - 6:30 pm.

Opening Reception

The Opening Reception will be held Sunday from 6:30 - 8:30 pm in the Exhibit Hall.

Hotel Information

The Sheraton Birmingham Hotel 2102 Richard Arrington Jr. Blvd, North

Birmingham, AL 35203 phone: 205-324-5000 room rate: \$164.00

Westin Birmingham

2221 Richard Arrington Jr. Blvd, North

Birmingham, AL 35203 phone: 205-307-3600 room rate: \$164.00

Exhibit Hall

The Exhibit Hall will be open on Sunday 6:30 - 8:30 pm for the Opening Reception and open on Monday and Tuesday during lunches and breaks.

Continental Breakfast

Breakfast will be available in the foyer Monday through Wednesday from 7:00 - 8:00 am.



ABSA International has been approved as a provider of continuing education programs in clinical laboratory science by the American Society for Clinical Laboratory Sciences (ASCLS), Professional Acknowledgment for Continuing Education P.A.C.E.® program.

For each professional development courses, contact hours will be based on 60 minutes of instructional time for each P.A.C.E.® contact hour. The maximum number of P.A.C.E.® contact hours to be credited for half-day courses is 3.50 contact hours and for full-day courses is 7.50 contact hours. Attendees have the opportunity to earn up to 17.0 contact hours by attending the entire scientific program. Attendance rosters must be signed in for each attended session that credit is requested for and the P.A.C.E.® certificate of attendance must be certified by ABSA staff at the registration desk at the end of your time at the conference.

Professional Development Courses

Visit www.absaconference.org for course availability.

Basic Level Courses

For those new to the profession or would like training in a particular topic.

Friday, November 15, 2019, 8:00 am - 5:00 pm

1. BSL-3 Operations and Management

J. Paul Jennette, MS, PE, RBP(ABSA), CBSP(ABSA), Cornell College of Veterinary Medicine, Ithaca, NY Carrie Smith, PhD, RBP(ABSA), CBSP(ABSA), USGS—National Wildlife Health Center, Madison, WI

This course will review the important aspects of the daily operation of a BSL-3 facility from two points of view; management of the facility and the daily operations. This assumes that you already have a facility built and have all required authorizations to work in it. The course will cover the different aspects you need to consider to operate a BSL-3 facility, such as: approval and training of a worker; maintenance support; occupational health issues; managing waste; maintenance of the HVAC and physical facility; periodic checks on the facility's systems; and emergencies of different types. Daily operations in a BSL-3 such as: understanding when it is safe to enter and when you need to evacuate; what to do when the ventilation fails; practical aspects of entry and exit procedures; practical tips on selection and use of personal protective equipment (PPE); safety considerations within the experimental SOPs; waste handling; facility cleaning; and how to have equipment repaired or serviced will be discussed. This course will be conducted in a way that allows for interaction and exchange of experiences between participants and instructors. This course will not cover regulatory aspects from any specific country.

Objectives:

- Describe the elements of BSL-3 Operations and Management, such as risk management, PPE, annual performance verification, emergency response, etc.
- Recognize institutional responsibilities from management to user
- Summarize the methods used to develop manuals, SOPs, and training

Suggested Background: Basic Risk Assessment and Biosafety Knowledge

Target Audience: All Safety Professionals

Friday, November 15, 2019, 8:00 am - 5:00 pm

2. International Biosafety, Biosecurity, and Biocontainment Challenges

William Arndt, PhD, Centers for Disease Control and Prevention, Atlanta, GA Natasha Griffith, MS, Centers for Disease Control and Prevention, Atlanta, GA Vibeke Halkjaer-Knudsen, PhD, Sandia National Laboratories, Albuquerque, NM

This course is intended to focus on international laboratory biosafety, biosecurity, and biocontainment features needed to support the implementation of a successful laboratory biorisk management program. This course will begin with a brief overview of common biorisk management implementation challenges and gaps often observed in locations such as Sub-Saharan Africa, Middle East, South Asia, and Southeast Asia. The instructors will share their experiences working in an international setting and on developing sustainable solutions to support the implementation of biorisk management best practices in a laboratory setting. Participants will share their experiences and challenges with everyone in the room and gain experience from instructors examples and others in helping to identify possible solutions to experiences or challenges shared. The course will include lecture, pictures of examples of laboratory biosafety, biosecurity, and biocontainment challenges from around the world, and small group activities analyzing case studies and developing alternate solutions. The goal of this course is to give participants confidence in using critical thinking skills to tackle biorisk management and biocontainment challenges in their respective facilities.

Objectives:

- Restate key laboratory biosafety, biosecurity, and biocontainment facility challenges and gaps
- Identify sustainable solutions to common biorisk management and biocontainment challenges and gaps
- Summerize how risk assessment and a risk-based decision strategy can be used to support the implementation of a sustainable laboratory biorisk management program

Suggested Background: Fundamentals of Biosafety

Target Audience: All Safety Professionals, Laboratory Workers, International Participants

Friday, November 15, 2019, 8:00 am - 5:00 pm

3. Building Biosafety Leaders

Michael Marsico, MS, Association of Public Health Laboratories, Silver Spring, MD Pandora Ray, MA, MPH, CPC, Association of Public Health Laboratories, Silver Spring, MD

In 2017, the Association of Public Health Laboratories (APHL) convened three Biosafety Leadership Workshops to facilitate the professional development of biosafety officers (BSOs) in state, local, territorial U.S. Affiliated Pacific Island public health laboratories. This multi-day workshop convened BSOs by region and provided a forum encouraging personal and professional growth with the overall goal to strengthen their leadership skills. The training included several group, interactive, and didactic exercises focused on: The Five Practices of Exemplary Leadership® Model (MICEE), Affinity Exercises, and Single Override Communication Objective (SOCO). Upon completion, participants gained an invaluable network and a broader skill set that directly benefited them and their work environment. Currently, APHL has condensed this multi-day training program into a complete one-day course. As a result of the ever-changing and increasingly complex environment, there needs to be biosafety leaders who embrace change, manage people, process efficiently, and anticipate future needs. Through skill development on leadership, project management, communications including: messaging and storytelling, building effective training programs, and implementing evaluation measures, the course will shape biosafety professionals into future leaders within the laboratory system.

Objectives:

- Describe the Leadership Challenge and MICEE Leadership Model
- Apply the elements of Single Overriding Communications Objective (SOCO) to deliver a message to laboratory management
- Identify work preferences that contribute to team dynamics and the management of relationships, information, decision making, and organization

Suggested Background: None

Target Audience: All Safety Professionals

Friday, November 15, 2019, 8:00 am - 12:00 pm

4. Facility Commissioning and Certification: Using the WHO Lab Biosafety Manual

Joby Evans, PE, CAC, CxA, Georgia Engineering LLC, Atlanta, GA

Luis Alberto Ochoa Carrera, MS, Institute for Epidemiological Diagnosis and Reference (InDRE), Mexico City, Mexico Laboratory commissioning and certification are identified in the World Health Organization's Laboratory Biosafety Manual as quality assurance processes for the biocontainment laboratory. These processes are not always understood by biosafety professionals. Many biosafety professionals are, at times, spectators and bystanders in the commissioning and certification process of their facilities. The biosafety officer will benefit by having a fundamental understanding of the commissioning and certification process and the resulting documentation. This understanding should allow them to articulate the engineering control data they require from their commissioning agent and how to use that data in the certification process. The certification requires the understanding of the personal protective equipment and the administrative controls. This course will review the process of laboratory certification; documentation, investigation, review of operational documents, testing, and reporting. This knowledge allows the biosafety professional to understand how the certification process verifies and documents laboratory readiness and when to know it is ready for safe and reliable operation based on the guidelines and the accepted criteria. The instructors will present some of the commonly encountered issues observed in developed and developing countries; how the issues are identified, and present some specific means and methods to mitigate the issues. The understanding of these processes and their interrelation assist the biosafety professional to confidently bring the laboratory into full operation to perform the scientific program.

Objectives:

- Identify the skills and knowledge required for regular recommissioning and certification process in containment labs
- Summarize the data outputs and meaning, and how the certification process maintains a safe and reliable laboratory facility
- Identify and propose practical solutions to the encountered issues observed during the inspection, commissioning, and certification process

Suggested Background: Fundamentals of Biosafety, Principles and Practices of Biosafety

Target Audience: All Safety Professionals, Facility Operations and Maintenance Personnel

Friday, November 15, 2019, 1:00 pm - 5:00 pm

5. Introduction to the CEN Workshop Agreement (CWA15793)

Rawan B. Khasawneh, Jordan University of Science and Technology, Irbid, Jordan

In some international communities, there is a growing need to develop a robust laboratory biorisk management system. A recognized comprehensive guideline is required to be applied in countries who are in the process of implementing the system. In this course, participants will become familiar with the CWA 15793 as a voluntary biorisk management system approach that applies internationally, agrees with quality management, environmental and occupational health management systems, and does not contradict with standards or legislation. CWA 15793 will be converted to the new ISO standard 35001, the commitment to follow the CWA 15793 will enable participants to effectively assess, mitigate, and monitor the laboratory biosafety and biosecurity risks, using the concept of continual improvement through the PDCA (Plan-Do-Check-Act) principle in organizations that handle biological agents and/or toxins, regardless of type, size, and biological agents. The CWA 15793 has comprehensive requirements participants can use as a framework for training, raising awareness, and supporting lab certification, accreditation, audit, and inspections. The course will begin with an introduction to terms, advantages of the CWA 15793, and a brief introduction to the major sections including: planning, policies, implementation and operation, checking and corrective actions, followed by a discussion about how to initiate implementation to improve laboratory biorisk management system and the expected challenges.

Objectives:

- Distinguish the CWA 15793 as an international reference document for laboratory biorisk management requirements
- Recognize the main domains of and how to initiate using the CWA 15793 to improve overall lab biorisk management system
- Conduct a self-audit to determine current adherence to the CWA 15793 and identify priorities

Suggested Background: Fundamentals of Biosafety

Target Audience: New Biosafety Professionals, All Safety Professionals, International Participants

Saturday, November 16, 2019, 8:00 am - 5:00 pm

6. Engineering for the Biosafety Professional Part I

Juan Osorio, IE, World BioHazTec Corporation, Rockville, MD

Theodore Traum, PE, CCP, DGCP, World BioHazTec Corporation, Rockville, MD

Brynte Johnson, RBP(ABSA), CBSP(ABSA), SM(NRCM), World BioHazTec Corporation, Rockville, MD

Proactive biosafety professionals need to be involved and knowledgeable in the operation, maintenance, and certification of their containment facilities and building systems. The biosafety professional may be called upon to participate in the planning, design, and validation of a new biocontainment laboratory or renovation of an existing facility. The biosafety professional's training and experience is usually limited to the sciences and they often lack the knowledge of basic engineering principles. This course is intended to fill the gap by providing basic engineering principles that are useful in the planning, design, construction, maintenance, and operation of a BSL-3 or high-containment facility. In order for the biosafety professional to participate in these activities; a foundation of engineering fundamentals, a developed set of skills to ask questions in engineering terms, and the confidence to question the answers are needed. There will be step-by-step slide presentations on planning, design, and quality assurance. Some of the exercises will require calculations (calculator recommended).

Objectives:

- Discuss engineering principles, design, and construction process of a BSL-3 laboratory in order to identify potential problems before construction begins
- Identify the phases and strategies of BSL-3 laboratory design and construction
- Describe the elements of a BSL-3 laboratory quality assurance program

Suggested Background: None

Target Audience: All Safety Professionals, All Biosafety Professionals, Facilities Personnel

Saturday, November 16, 2019, 1:00 pm - 5:00 pm

13. Introduction to Biosafety in the Clinical Setting

Daniel Eisenman, PhD, RBP(ABSA), CBSP(ABSA), SM(NRCM), Advarra, Research Triangle Park, NC

The clinical setting poses a different environment than research laboratories. This course provides foundations for applying biosafety concepts in the clinical setting. Topics covered include common issues and lessons learned pertaining to: clinical facilities including pharmacies, laboratories, clinics, infusion areas, ORs and waste disposal facilities; PPE, disinfection, risk assessments and safety practices in the clinical setting; speaking biosafety to doctors, nursing staff, pharmacy staff, infection prevention and control, diagnostic microbiology lab personnel and hospital EHS staff; applying NIH Guidelines and the *BMBL* to the clinical setting; gaps in oversight of research safety for clinical trials. The course will close with a focus on clinical trials including: the role of an IRB and how it can overlap with an

IBC; the process for investigational products to obtain FDA approval to be deemed as safe and effective therapeutics; and the evolving regulatory environment in the U.S. for biologics such as vaccines, regenerative medicines and gene therapy. The course is designed to be highly interactive with discussions, surveys, and team exercises.

Objectives:

• Apply biosafety principles in the clinical setting

• Perform risk assessments and identify gaps in occupational safety in the clinical setting

• Discuss the regulatory oversight for clinical trials and the developmental process for investigational products

Suggested Background: Fundamentals of Biosafety

Target Audience: All Safety Professionals, Laboratory Workers, Research Administrators, Clinical

Professionals

Saturday, November 16, 2019, 1:00 pm - 5:00 pm

14. Emotional Resiliency in High-Risk Environments

Lisa Orloff, World Cares Center—Resiliency Advisors, New York, NY

Traumatic events have the power to overwhelm normal coping abilities of individuals and groups. Emotionally charged, high-stress jobs can have a negative impact on individuals if they are not aware of the risks or coping skills. Research shows that training can reduce the impact that disasters, disaster work and high-stress environments have on those that function within them. Fortunately, resiliency is not a trait that is inherited, each person has the ability to build their own resiliency. This course is the first step on your road to resilience and building resilient teams. As a result of participating in this interactive course, participants will take part in role play activities demonstrating the objectives of the course.

Objectives:

- Identify the emotional risks related to disaster and high-stress work environments
- Recognize the signs and symptoms of disaster and high-stress work environment related stress
- Increase the ability to respond safely and effectively in disaster response and high-stress work environments
- Describe the techniques to address emotional stress

Suggested Background: None

Target Audience: All Safety Professionals

Sunday, November 17, 2019, 8:00 am - 5:00 pm

15. Shipping Infectious Substances Certification Course

Eric Cook, MPH, CBSP(ABSA), Sandia National Laboratories, Albuquerque, NM

This course is appropriate for those who have some experience with infectious substance handling or shipping, but may not have been certified within the past three years. The course utilizes group discussions and interactive exercises focused on the essential areas of infectious substance shipping. Participants will have the opportunity to mark, label, package, and complete documentation for a variety of infectious substances shipments (Category A, Category B, and Exempt Patient Specimens). Participants will review applicable regulations with a focus on IATA. This course is appropriate for those responsible for packaging, marking, and labeling shipments of all categories of infectious substances, dry ice, and liquid nitrogen. A final written certification exam will be administered. Participants must score at least 80% in order to be certified.

Objectives:

- Classify biological materials for shipping purposes as either Category A, Category B, Exempt, or not regulated based on the principles of risk assessment
- Demonstrate how to package, mark, label, and document shipments for infectious substances, Category A, Category B, and dry ice
- Complete a written exam to qualify for infectious substance shipping certification

Suggested Background: None

Target Audience: All Safety Professionals, Laboratory Workers, New Biosafety Professionals

Intermediate Level Courses

For those with basic knowledge or would like to learn more.

Saturday, November 16, 2019, 8:00 am - 5:00 pm

8. Disinfection, Sterilization and Inactivation: A Practical Guide for the Biosafety Professional

Althea Treacy, PhD, National Institutes of Health, Bethesda, MD

Antony Schwartz, PhD, CBSP(ABSA), SM(NRCM), Duke University, Durham, NC

This course will provide biosafety professionals with a strong foundation in disinfection, sterilization, and inactivation that will directly benefit them in carrying out their responsibilities. Course discussion will be on the history and current regulatory context of disinfection, sterilization, inactivation, validation strategies, quality assurance tests for each topic, and analysis of the factors that influence the effectiveness and potency of different treatment methods will be given. Subsequent material will cover the mechanisms of disinfection, sterilization, and inactivation, including chemical structures and classes of disinfectants sterilants and inactivation agents. Further discussion will describe the selection of appropriate methods and identification of associated safety hazards. Utilizing proven practices and procedures, participants will be led through a facilitated discussion leading to the development of standard operating procedures for executing sterilization, disinfection, or inactivation at their institution. Throughtout the course, participants will participate in didactice modules and hands-on exercises in small groups.

Objectives:

- Identify and restate mechanisms of disinfection, sterilization, and inactivation
- Select appropriate disinfectants and sterilants and appropriately evaluate inactivation methodologies
- Choose the appropriate validation and quality assurance test for method of disinfection, sterilization, or inactivation

Suggested Background: Fundamentals of Biosafety, Micro/Molecular Biology 101, Principles and Practices of

Biosafety

Target Audience: All Biosafety Professionals, Laboratory Workers

Saturday, November 16, 2019, 8:00 am - 5:00 pm

9. Emerging Technologies in Agricultural and Plant Sector: Biosafety and Biosecurity Challenges and Risk Management

Aparupa Sengupta, PhD, RBP(ABSA), University of California—Merced, Merced, CA Luis Alberto Ochoa Carrera, MS, Institute for Epidemiological Diagnosis and Reference (InDRE), Mexico City, Mexico Global food security and enhancement of food quality has been a pressing issue worldwide. Recent advent of powerful technologies like gene editing tool CRISPR/Cas9 have the potential of bringing unprecedented global impact in different industries starting from novel bioenergy production, new therapeutic intervention in medical world to biodiversity conservation. In the agricultural sector, these technologies have contributed significantly towards food security, reduction in pesticide use and greenhouse gas emissions, and in improvement of occupational safety in both industrialized and developing countries over the last two decades. Although extremely beneficial, these technologies are certainly not risk-free. They could be used for nefarious acts, such as bioweapon development to create new pathogenic organisms to render vaccines ineffective. These technologies may also have off-target effects, such as tumor suppressor gene silencing during cell culture experiment, or potential of changing biodiversity and invasion and disruption of local agricultural system by exotic or transgenic species. Since, outbreak of diseases, bioweapons, and emerging technology transfer of knowledge knows no borders, the beneficial use of the technology can become challenging in terms of biosafety and biosecurity, if the risks are not understood and addressed appropriately. The course will also include new emerging technologies, applicable to the agricultural and plant biotechnology field, where an appropriate risk assessment and communication strategies are imperative for preventing accidents from occurring or re-occurring.

Objectives:

- Identify and implement the different regulations related to agricultural and plant biosafety/biosecurity when reviewing institutional research protocols
- Evaluate and conduct a risk assessment of the potential impact of using emerging technologies and gene editing in agriculture and plant projects
- Identify and manage risk with the fast-evolving scope of research, especially with the use of CRISPR/Cas9 technology

Suggested Background: Fundamentals of Biosafety, Risk Assessment, Micro/Molecular Biology 101

Target Audience: All Safety Professionals, Experienced Biosafety Professionals, Laboratory Workers

Saturday, November 16, 2019, 8:00 am - 5:00 pm

10. Keeping it Going: Maintaining and Improving a Select Agent Program Over the Long-Term

Amy Vogler, PhD, RBP(ABSA), Northern Arizona University, Flagstaff, AZ Shelley Jones, MS, RBP(ABSA), Northern Arizona University, Flagstaff, AZ

Keeping a Select Agent program going can be difficult, especially in the face of ever-changing regulatory requirements and limited resources. Long-established procedures may suddenly become unacceptable, interrupting research, and frustrating laboratorians. Likewise, a single unexpected adverse event can put an entire program at risk. Being prepared to deal with such changes and events is critical to maintaining a robust program. Anticipating future challenges can prove even more advantageous, elevating a good program to a great program. A proactive approach can minimize the impact of new requirements and reduce duration and frequency of "crises" sparked by sudden, unexpected requirements or events. This course will explore strategies for maintaining and improving an existing Select Agent program, including strategies for anticipating and responding to new requirements. Strategies will be based on the instructors' experience with their institution's program with additional input solicited from class participants during open discussions. Topics will include the history of the Select Agent program; effective oversight practices; efficiently meeting ongoing requirements; reporting, responding to, and analyzing incidents; a series of suitability program case studies; implementation of the recent inactivation requirements, including strategies for investigating inactivation "failures;" and inspection preparation and response. The course will consist of topical presentations followed by group discussions aimed at facilitating application of presented strategies to participants' individual programs and providing a platform to capitalize on participants' collective experience.

Objectives:

- Identify strategies for efficiently maintaining a Select Agent program in good standing with ongoing requirements
- Review a series of suitability program case studies and identify strategies for dealing with potential suitability concerns in accompanying exercises
- Summarize new inactivation requirements and identify successful strategies for compliance

Suggested Background: Building a Select Agent Program: Safety, Compliance, and Efficiency **Target Audience:** All Safety Professionals, Select Agent Program Safety Professionals

Saturday, November 16, 2019, 8:00 am - 12:00 pm

11. Building and Sustaining a Biohazard Accident Investigation Program in the Microbiology Laboratory Sharon Master. PhD. Masthead Lab Solutions. Albuquerque. NM

Biohazard risk management is critical to a safe workplace. Conducting an investigation after a biohazard event is critical for effective risk management. However, there is limited guidance on this within the realm of biosafety. This course will educate participants on how to appropriately conduct all stages of an accident investigation, including root cause analysis, thus enabling them to build an effective investigation program at their laboratory. Through the use of real life scenarios and workbook exercises, participants will be able to identify a lab accident, a near-miss, and an exposure. Through the use of examples and real life scenarios from a clinical microbiology setting, participants will also learn tips and tricks to recognize laboratory-acquired infections. This course will help reinforce concepts, build, establish, and strengthen laboratory investigation programs resulting in more robust risk management programs.

Objectives:

- Develop and establish an accident investigation program
- Differentiate, using scenarios, between a near miss and an exposure
- Recognize a laboratory-acquired infection

Suggested Background: None

Target Audience: All Biosafety Professionals, Laboratory Workers

Saturday, November 16, 2019, 8:00 am - 12:00 pm

12. Case Studies in Biocontainment Emergencies

David Harbourt, PhD, RBP(ABSA), CBSP(ABSA), SM(NRCM), U.S. Army Medical Research Institutes of Infectious Diseases, Fort Detrick, MD

It is important that biosafety professionals understand how to respond to emergency response situations that could affect operations in containment laboratories. Biosafety professionals need to be able to understand how their facility and personnel function during normal operations to aid in preparation for significant events. It is also vital for biosafety professionals to know who the key decision makers are in their facility for situations that could potentially result in disruptions to operations. By understanding how their facility is intended to function, who the key decision makers are and the critical information that is needed during emergency scenarios, biosafety professionals can help ensure that they are prepared when situations arise in the future. This course is intended to cover some basics of emergency response situations along with the features of a containment laboratory that may be affected during an emergency. This course will go over important questions that biosafety and safety professionals need to be able to answer about their facility to help prepare them for emergencies. The course will be separated into two sections with the first covering the key questions of each of the facility components to include HVAC, plumbing, electrical failures,

and potential occupational exposures. The second part of the course will cover a series of case studies based on real world emergency response situations in biocontainment laboratories. Individuals will be expected to work in groups to help solve each of the case studies and at the end of the course, the instructor will discuss how the emergency was handled in real time along with lessons learned.

Objectives:

- Restate the basics of emergency response and how they relate to biocontainment laboratory operations
- Identify potential system vulnerabilities in a biocontainment laboratory
- Summarize lessons learned from case studies and apply them to their own facility if applicable

Suggested Background: Fundamentals of Biosafety, Risk Assessment, BSL-3 Design and Operations, Principles and

Practices of Biosafety

Target Audience: All Biosafety Professionals, All Safety Professionals

Sunday, November 17, 2019, 8:00 am - 5:00 pm

16. Articulating the Value of Your Biosafety Program

Robert Emery, DrPH, CBSP(ABSA), University of Texas Health Science Center at Houston, Houston, TX Scott Patlovich, DrPH, CBSP(ABSA), University of Texas Health Science Center at Houston, Houston, TX

A recurrent challenge for biosafety professionals is the ability to garner necessary program resources. The basis for this difficulty is that on a good day in the world of biosafety "nothing happens," so upper management may not fully appreciate or understand all of the effort that went into making "nothing happen." Biosafety professionals experience difficulty in this regard because many in the profession have received intensive training in the biological sciences, but little or no training in the area of program management. This course will focus on key management techniques that can be used within biosafety programs to help improve stakeholder understanding of the program and activities, which, in turn, can result in the provision of necessary programmatic resources. Numerous real world examples of successful applications of the techniques discussed will be displayed for review and discussion.

Objectives:

- Identify biosafety programmatic measures and metrics that can be easily captured and communicated
- Recall techniques used for displaying biosafety data in ways that others can readily understand and value
- Describe how basic safety and biosafety programs work together to avoid duplication of efforts and improve safety and client satisfaction levels

Suggested Background: None

Target Audience: All Safety Professionals, All Biosafety Professionals

Sunday, November 17, 2019, 8:00 am - 5:00 pm

17. Operationalizing Biosecurity: An Intensive, Scenario-based Biosecurity Threat Assessment

Lauren Richardson, DVM, DACVPM, Merrick & Company, Greenwood Village, CO

Ryan Burnette, PhD, Merrick and Company, Greenwood Village, CO

Stephen Goldsmith, DVM, Federal Bureau of Investigation, Washington, DC

Biorisk management programs should be implemented at any institution where the release, loss, or theft of biological material could result in serious negative consequences, such as harm to workers, the outside community, damage to institutional reputation, and/or financial/legal actions. This course provides an opportunity for biosafety professionals and program managers to identify threats, risks, and vulnerabilities; develop strategic and tactical interventions; apply these biosecurity concepts; and design a plan for implementation of these interventions in a tabletop scenario. The scenario will allow participants to explore mechanisms and logistical challenges for assessment and implementation of a biosecurity program, and will demonstrate the importance of an integrated approach to biosecurity as a complement to existing biorisk programs. Participants will be given a hypothetical scenario and will work together to develop an integrated plan. Participants will identify stakeholders; assess biosecurity threats, risks, and vulnerabilities at the organizational level; determine potential mitigation strategies; prioritize activities and strategies; and develop a strategy for communication of needs to organizational leadership and relevant stakeholders. As a part of this, participants will apply the Five Pillars of Security (physical, personnel reliability, material control, transportation, and information security) as a framework for building an integrated security program (ISP). Participants will gain a deeper knowledge of the application of biosecurity assessment, ISP implementation, and strategies for integration into their existing programs.

Objectives:

- List stakeholder roles in biosecurity planning and assessment as part of a comprehensive biorisk management program
- Recognize, assess, and develop mitigations for risks, threats, and vulnerabilities to protect biological materials
 and other laboratory assets from unauthorized access, loss, theft, misuse, diversion, or intentional release
- Develop strategies for prioritization and communication of needs associated with implementing an integrated biosecurity plan

Suggested Background: Principles and Practices of Biosafety

Target Audience: All Biosafety Professionals, Risk Management Professionals

Sunday, November 17, 2019, 8:00 am - 5:00 pm

19. Sustaining an Effective Biological Safety Program Utilizing all Tools within EHS and Beyond

Maya Nair, PhD, RBP(ABSA), University of North Texas Health Science Center, Fort Worth, TX

Antony Schwartz, PhD, CBSP(ABSA), SM(NRCM), Duke University, Durham, NC

Increasingly, biological safety professionals are faced with managing biological safety programs with limited resources and less than ideal number of staff. Additionally, with the ever-changing regulatory and technological landscape, more and more responsibilities are added to biological safety office's oversight. This course will focus on identifying effective strategies for developing, managing, and sustaining a biological safety program with available resources. Throughout the course, instructors will focus on three Rs (Regulatory, Regional, and Realistic) and how these principles can maximize the use of resources and help focus the biosafety professional's time and energy into efforts that sustain the biological safety program. Participants will analyze ways other EHS programs intersect with biological safety and how these common pathways can be "exploited" for resources and efficient use of an institution's budget. Participants will discuss strategies on how to maintain a high-level of user engagement and compliance in the program. The three Rs will be used as a guide to prioritize resources for identifying changes in regulations, navigating institution-specific issues, and setting realistic goals for successful outcomes. Some of the tools reviewed in this section of the course will include inspection checklists, entity plans, emergency response procedures, and ideas on being prepared for the unexpected. Case studies and interactive group exercises will be used to reinforce concepts shared by the instructors and to learn from each other on how best to maximize our resources.

Objectives:

- Identify strategies and tools for maintaining a biosafety program with available resources and in good standing with current regulations
- Analyze and apply the three Rs strategy for a sustainable biosafety program
- Discuss strategies on how to maintain a high-level of user engagement and compliance in the program

Suggested Background: None

Target Audience: All Safety Professionals, All Biosafety Professionals

Sunday, November 17, 2019, 8:00 am - 12:00 pm

21. Biocontainment Laboratory Operations

John Henneman, MS, RBP(ABSA), Kansas State University, Manhattan, KS

Miguel Grimaldo, MEng, University of Texas Medical Branch—Galveston, Galveston, TX

J. Paul Jennette, MS, PE, RBP(ABSA), CBSP(ABSA), Cornell College of Veterinary Medicine, Ithaca, NY

This course will discuss key insights and share instructor expertise in biocontainment facility planning, start-up, and operations from an operator's point of view. We often hear from some of the best of architects and engineers on how to build a biocontainment laboratory, but what about their competency, have they ever operated a laboratory to evaluate their own design process? Where did they learn their craft? During the course, a discussion of the detailed questions to ask the design/construction team, the steps to follow, and lessons learned during all the stages of building or renovating a biocontainment facility. The course will conclude with a discussion on planning and requirements to implement scientific operations.

Objectives:

- Summarize lessons learned in the design, construction, and start-up of a biocontainment facility
- Identify the questions to ask when selecting the facility design, construction, commissioning, and operations teams
- Recall the plans and requirements needed to initiate scientific operations

Suggested Background: Fundamentals of Biosafety, Risk Assessment, BSL-3 Design and Operations, Principles and

Practices of Biosafety

Target Audience: All Safety Professionals, Engineers, Architects, Operations Managers

Sunday, November 17, 2019, 8:00 am - 12:00 pm

22. HGT Studies: Biosafety, Infection Control, and Pharmacy Safety Considerations

Edward David, MPH, RBP(ABSA), Celgene Corporation, San Diego, CA

This course will outline regulatory and safety challenges in conducting human gene transfer research and offer strategies to address them. This course will cover basic regulatory and risk assessment for human gene transfer studies, and expand on the practical aspects of conducting such studies including identifying key stakeholders such as the IBC, IRB, Infection Control, and Pharmacy, and how to coordinate safety activities between each group. The course will outline some of the differences between biosafety, infection control, and hazardous drug safety and how each can work together to achieve desired outcomes. The course will examine case studies that highlight some of the challenges one might encounter in the real world.

Objectives:

- Describe regulatory framework for human gene transfer research and perform basic risk assessment
- Identify key stakeholders for conduct of human gene transfer research and strategies to coordinate activities between them
- Summarize real world pitfalls for human gene transfer research through examination of case studies

Suggested Background: Fundamentals of Biosafety, Risk Assessment, Principles and Practices of Biosafety

Target Audience: All Safety Professionals, All Biosafety Professionals

Sunday, November 17, 2019, 8:00 am - 12:00 pm

23. Biosecurity in Academic Institutions

Timothy Key, MD, MPH, University of Alabama—Birmingham, Birmingham, AL Justin Roth, PhD, University of Alabama—Birmingham, Birmingham, AL Judith McBride, MSPH, MT(ASCP), CIH, University of Alabama—Birmingham, Birmingham, AL Rani Jacob, PhD, MPH, University of Alabama—Birmingham, Birmingham, AL

Mark Sawyer, BA, Federal Bureau of Investigation, Birmingham, AL

Due to the innovative and open nature of academic research, institutions are vulnerable to a variety of security threats, diversion or release of agents, export control, loss of equipment or intellectual property, and unauthorized research. This course will provide the participants with ways to identify biosecurity threats common to academic institutions, information to help them identify risks present on their campus, and tools to help them mitigate these risks. The course will be team taught by professionals having expertise in biosafety, occupational medicine, and governmental enforcement. A discussion will be held about the roles and responsibilities of various positions in the institution, basic security components such as: access control, agent inventory, reporting, interface with enforcement authorities, and training; mitigation strategies including: research ethics, physical, and cyber security plans, and developing a robust culture of safety.

Objectives:

- Identify biosecurity threats at academic research institutions
- Perform a biosecurity risk assessment
- Apply biosecurity risk mitigation strategies in a table top drill setting

Suggested Background: Fundamentals of Biosafety, Risk Assessment, Principles and Practices of Biosafety

Target Audience: All Safety Professionals, Laboratory Workers, Law Enforcement, Research Administrators

Sunday, November 17, 2019, 1:00 pm - 5:00 pm

24. Evolving Role of IBCs in the Oversight of Human Gene Transfer

David Emery, PhD, Clinical Biosafety Services, Wildwood, MO

There has been a recent explosion in the number and diversity of human gene transfer clinical trials, as well as FDA-approved therapies based on recombinant DNA. This has been accompanied by a serial reduction in the oversight of human gene transfer clinical trials by the National Institutes of Health (NIH), to the point that such trials are no longer subject to review by the NIH Recombinant DNA Advisory Committee, or required to even be registered with the NIH. The transition of gene transfer technologies from the laboratory to the clinic, and the replacement of biosafety oversight of human gene transfer from the NIH to the institutional level, has fundamentally changed the roles and responsibilities of Institutional Biosafety Committees at large and small institutions around the country. This course will provide an overview of the current status of human gene transfer research and FDA-approved clinical applications, review the biosafety risks unique to the application of gene transfer in the clinical setting, and outline the evolving regulatory environment for both clinical research and clinical applications that make use of gene transfer technologies. This will include an overview of the evolving changes in the NIH Guidelines involving the biosafety oversight of human gene transfer clinical trials at the national and institutional levels, and how local Institutional Biosafety Committees are evolving to meet new demands. This will include a review of the regulatory requirements surrounding the use of gene therapy drugs approved by the FDA in clinical trials and in clinical practice. Case studies and group discussion will be used to amplify the take home messages.

Objectives:

- Restate the risks and challenges associated with human gene transfer
- Identify the categories and risk groups of biological agents used in human gene transfer
- Identify the key regulatory roles of IBCs in the oversight of human gene transfer research

Suggested Background: Micro/Molecular Biology 101, Institutional Biosafety Committee Basics **Target Audience:** Experienced Biosafety Professionals, Clinical Professionals, IBC Administrators

Sunday, November 17, 2019, 1:00 pm - 5:00 pm

25. Flow Cytometry and High Speed Cell Sorting—Biosafety, Testing, and Validation

Geoffrey Lyon, MPH, Yale University, New Haven, CT

Flow Cytometry is a staple of both academic and biotechnology research. This course will help differentiate the between flow cytometers (analyzers) and cell sorters and identify the different biosafety concerns with analyzers and sorters. It will discuss the current ISAC Cell Sorter Biosafety Standards; including risk assessment, sorter selection, facility design, and methods of aerosol containment. Participants will review the different aspects of biosafety that need to be considered when looking at laboratories with stand alone equipment verse core facilities. There will be discussion of the new and evolving types of cell sorters and the safety features included, the various methods that have been used to test the aerosol containment of cell sorters and their associated biosafety cabinets. A review of the most recent paper for a bead based test, Novel Impactor and Microsphere-Based Assay Used to Measure Containment of Aerosols Generated in a Flow Cytometer Cell Sorter, Cytometry Part A, 18 December 2018 will be conducted.

Objectives:

- Discuss and clarify the basic concepts and differences between flow cytometry and cell sorting
- Describe the current ISAC Cell Sorter Biosafety Standards and the caveats to consider when managing a core facility or a stand alone laboratory
- Discuss the history of aearosol containment testing along with the latest ISAC standard for testing AMS and BSC cabinets associated with cell sorters

Suggested Background: Risk Assessment, BSL-3 Design and Operations, Principles and Practices of Biosafety **Target Audience:** All Safety Professionals, New Biosafety Professionals

Sunday, November 17, 2019, 1:00 pm - 5:00 pm

26. Institutional Biosafety and Biosecurity—Enhancing Oversight Through Effective Governance

Kathryn Harris, PhD, RBP(ABSA), National Institutes of Health, Bethesda, MD Michelle McKinney, MS, CBSP(ABSA), National Institutes of Health, Bethesda, MD

Kevin Ramkissopn, PhD, National Institutes of Health, Bethesda, MD

This course will discuss the importance of ensuring institutions have a robust and comprehensive biosafety and biosecurity governance structures in place. Information will be provided about the activities of the Federal Experts Security Advisory Panel (FESAP) related to strengthening biosafety and biosecurity practices and oversight. In this course, participants should be prepared to engage in discussions, information sharing, interaction, and sharing of best practices that institutions can employ to enhance biosafety and biosecurity programs. There will be small group discussions centered around a case study involving a biosafety incident occurring at an institution subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), which illustrates the importance of institutional biosafety oversight and how inadequate local oversight can result in significant problems.

Objectives:

- Identify the activities of the Federal Experts Security Advisory Panel (FESAP) related to strengthening biosafety and biosecurity practices and oversight
- Describe the tools and best practices that institutions can employ to strengthen their biosafety and biosecurity programs
- Summarize the requirements for reporting incidents under the NIH Guidelines and the importance of ensuring robust and comprehensive biosafety and biosecurity governance structures are in place

Suggested Background: Background knowledge with IBCs and IREs; knowledge of U.S. biosafety and biosecurity

research oversight

Target Audience: Experienced Biosafety Professionals, PIs, IBC and IRE members and others involved in life

science research oversight

Sunday, November 17, 2019, 1:00 pm - 5:00 pm

27. Managing an Efficient BSL-3/ABSL-3 Facility Shutdown

Colleen Driskill, RBP(ABSA), CBSP(ABSA), SM(NRCM), University of Massachusetts Medical School, Worcester, MA James Gardner, University of Massachussetts Medical School, Worchester, MA Kim West, BS, University of Massachussetts Medical School, Worchester, MA

This course will focus on BSL-3/ABSL-3 facility shutdowns, deliver and convey real world information, examples, and knowledge to participants from experiences in the operation and oversight of a BSL-3 laboratory. There will be a review and discussion of real world shutdown scenarios, descriptions of how contractors, vendors, and tradesmen can work in conjunction with the facilities, and examples of what has and has not worked well. Forms and procedures will be reviewed to assist with the coordination, scheduling and efficient organization of shutdowns, repairs, and facility reverification. Interactive exercises will provide reinforcement for participants to practice instituting the tools discussed. Instructors bring a variety of interesting viewpoints from different professional perspectives regarding shutdowns and

will discuss the BSL-3 Annual Facility Reverification process. Instructors will speak to unique experiences with validating controls, alarms, and issues that have been experienced with various HVAC equipment. Specific examples of BSL-3 facility-related incidents the instructors have experienced associated with shutdowns, root cause identification, actions taken, and lessons learned will be discussed. Other important factors of safety and compliantly operating a BSL-3 lab will be reviewed, such as risk assessments for facility repairs and maintenance work.

Obiectives:

- Describe procedures for facility shutdowns for BSL-3 and or ABSL-3 lab facilities and provide examples for efficient, safe, and orderly completion of repairs, preventative maintenance and or facility re-verification
- Identify key standard operating procedures, policies, and forms that provide guidance for orderly and efficient shutdowns of BSL-3 labs
- Describe real world BSL-3 facility related problems and incidents and offer examples of how these types of issues can be avoided

Suggested Background: Fundamentals of Biosafety, Principles and Practices of Biosafety

Target Audience: All Biosafety Professionals, Laboratory Workers, BSL-3 Facility/Engineering Professionals

Advanced Level Courses

For those with experience or looking for a challenging course.

Saturday, November 16, 2019, 8:00 am - 5:00 pm

7. Advanced Risk Assessment

Chad Austin, PhD, CBSP(ABSA), SM(NRCM), University of Texas Health Science Center—Houston, Houston, TX Anne-Sophie Brocard, PhD, RBP(ABSA), CBSP(ABSA), University of Texas Medical Branch—Galveston, Galveston, TX Brandon Hatcher, PhD, GlaxoSmithKline, Vaccines R&D, Rockville, MD

In this advanced and interactive course, participants will evaluate a variety of challenging scenarios based on actual research protocol submissions and real world events from multiple risk perspectives. Participants will work in teams to conduct risk assessments on a diverse selection of scenarios that will include multiple systems used in research as a research project progresses from discovery, to cell culture, to small animal models using recombinant materials, and human clinical trials. Risk assessments will focus on the likelihood of exposure and the severity of consequences from exposure to the multitude of hazards encountered in increasingly complex research as well as the surprises that may come across the biosafety officer's desk. Participants will be challenged to consider additional risks aside from infection and how best to mitigate them. Participants should have a thorough understanding of pathogenic microorganisms, rDNA principles, other infectious substances and the link between biosafety, risk assessment, and risk mitigation for this advanced course. There is an emphasis on the interactive nature of the risk assessment process and differing views of risk tolerance will be considered; participants should be prepared to participate in discussions and bring interesting or difficult examples of interest to them to discuss with the class.

Objectives:

- Prioritize risks based on the likelihood and consequences of an occurrence
- Identify risks requiring mitigation and mitigation strategies to minimize the unacceptable risks
- Identify institutional and external partners to help implement mitigation strategies
- Evaluate mitigation strategies for effectiveness, adjust strategies as warranted

Suggested Background: Fundamentals of Biosafety, Risk Assessment, Micro/Molecular Biology 101, Principles &

Practices of Biosafety

Target Audience: Experienced Biosafety Professionals, Laboratory Workers

Sunday, November 17, 2019, 8:00 am - 5:00 pm

18. Gene Editing and Risk Assessment: Application to IBC Protocol Review

Jessica McCormick-Ell, PhD, RBP(ABSA), CBSP(ABSA), SM(NRCM), Rutgers University, Newark, NJ

Gene editing technologies have been used for decades by scientists in the field of molecular genetics and recombinant DNA technology. Recently, with the discovery of CRISPR-Cas 9 gene editing, this field has expanded and the ease to manipulate genes has changed significantly. There are multiple methods for editing genes and many times they are used together. Biosafety officers, although experts in safety and biorisk assessment, may need additional information in regards to the scientific and technical side of this new technology in order to understand the risks of a protocol more completely in order to provide adequate risk management recommendations. This course is designed to provide a brief, but detailed, overview of basic gene editing technologies such as plasmid based systems, RNA interference, viral vectors, CRISPR Cas9 technology and gene drives. After brief discussion of these technologies, participants will review a proposed project as it may be presented to the IBC. Participants will be expected to review, discuss risks and

benefits, and be able to propose alternative ways for the research to be conducted in a safer manner. The goal of this course is to provide participants with comprehensive background knowledge of various gene editing and recombinant DNA technologies commonly used so they will be able to ask pertinent questions during protocol review. Additional details about off-targeting issues and streamlined protocol exercises will be offered. The course has been modified to reflect new technologies and previous participant comments.

Objectives:

- Describe the different types of gene editing technologies including viral vectors, RNAi and CRISPR/Cas9
- Explain why and how these technologies are used together in a research project
- Restate the topics and questions needed to assess the risks of gene editing research proposals

Suggested Background: Risk Assessment, Micro/Molecular Biology 101

Target Audience: All Biosafety Professionals

Sunday, November 17, 2019, 8:00 am - 12:00 pm

20. Advanced Topics in Animal Research for Biosafety Professionals: Hazard Identification, Risk Assessment, and Practical Control Strategies

Susan Harper, DVM, DACLAM, DACVPM, USDA Agricultural Research Service, Beltsville, MD Lesley Colby, DVM, DACLAM, University of Washington, Seattle, WA

This course will provide participants with a variety of advanced scenarios and interactive exercises that demonstrate the range of biological and other (chemical, radiological, and physical) hazards routinely encountered in animal-based research including those inherent to animals and those associated with commonly utilized procedures and select specialized equipment. Participants will be guided through strategies for identifying potential hazards, assessing the magnitude and extent of induced risks, and developing effective and cost-efficient control measures to protect the safety of workers, animals, and the environment. The course employs "real world" examples to improve understanding of animal program operations and to facilitate the exchange of ideas and the development of constructive partnerships between safety professionals and key animal program representatives for optimizing safety program outcomes.

Objectives:

- Review basic hazard identification and risk assessment techniques as they apply to research involving live animals
- Learn how to incorporate effective hazard and exposure control strategies into animal protocol design and research facility management procedures
- Identify ways that safety professionals can work constructively with animal program personnel to address common research safety issues

Suggested Background: An Introduction to Animal Research for Biosafety Professionals: Oversight, Accreditation,

and Collaborative Groups

Target Audience: All Biosafety Professionals, All Safety Professionals

Opening Reception

The Opening Reception will be in the Exhibit Hall on Sunday, November 17 from 6:30 - 8:30 pm.

Scientific Program

	Monday, November 18, 2019		
7:00 - 5:00 pm	Registration		
7:00 - 8:00 am	Continental Breakfast in Foyer		
9:00 - 4:00 pm	Vendor Exhibits		
8:00 - 8:15 am	Welcome and ABSA International President's Address Master of Ceremonies Dee Zimmerman, Galveston, TX		
8:15 - 8:20 am	Local Arrangements Committee Welcome Debra Sharpe, MPH, RBP(ABSA), Sharpe Solutions International, LLC, Birmingham, AL		
8:20 - 8:25 am	Scientific Program Committee Welcome Jessica McCormick-Ell, PhD, RBP(ABSA), CBSP(ABSA), SM(NRCM), Rutgers University, Newark, NJ		
Session I	Arnold G. Wedum Memorial Lecture Award Introduction: Claudia Gentry-Weeks, PhD, Colorado State University, Fort Collins, CO		
8:25 - 9:30 am	Biosafety in Clinical Laboratories Michael Pentella, PhD, D(ABMM), University of Iowa College of Public Health, Iowa City, IA		
9:30 - 10:00 am	Exhibits, Posters, and Coffee Break		
Session II	A Focus on Human Gene Therapy		
10:00 - 10:20 am	Moderator: Justin Roth, University of Alabama—Birmingham, Birmingham, AL The US Regulatory Environment is Evolving to Accommodate a Coming Boom in Gene Therapy Research		
10:20 - 10:40 am	Daniel Eisenman, PhD, RBP(ABSA), CBSP(ABSA), SM(NRCM), Advarra, Research Triangle Park, NC Viral-mediated Gene Therapy and Genetically Modified Therapeutics: Occupational Safe Drug Handling in a Health System Pharmacy Jill E. Blind, PharmD, Nationwide Children's Hospital, Columbus, OH Biosafety Challenges with the Use of Viral-mediated Gene Therapy in a Healthcare Setting Alex M. Brown, BS, The Research Institute at Nationwide Children's Hospital, Columbus, OH		
10:40 - 11:00 am			
Session III	Behavior Enhancing Compliance		
11:00 - 11:20 am	Moderator: Betsy Matos, PhD, RBP(ABSA), CBSP(ABSA), Iowa State University, Ames, IA Biosafety Critical Task Analysis as a Means to Mitigate Human Failure in a High-Containment Facility		
11:20 - 11:40 am	Anna E. Lawton, BSc, The Pirbright Institute, Pirbright, Woking, United Kingdom Managing Goal Conflicts in a Biomedical Research Laboratory Viji Vijayan, RBP(ABSA), Duke-NUS Graduate Medical School, Singapore, Singapore		
11:40 - 12:00 pm	Transitioning from Lagging to Leading Indicators: How a Near Miss Program is Changing Safety Culture		
12:00 - 1:30 pm	Monica Lurtz, PhD, WuXi AppTec, Philadelphia, PA Exhibits, Posters, and Lunch		
Session IV 12:30 - 1:30 pm	Poster Session Presenters must be available during the session.		
Session V	Invited Speaker Introduction: Anthony Troiano, PhD, RBP(ABSA), Environmental Health & Engineering, Inc.,		
1:30 - 2:30 pm	Newton, MA Making Your Biosafety Message Stick! Robert Emery, DrPH, CBSP(ABSA), University of Texas Health Science Center at Houston, Houston, TX		
4.4	Housion, IA		

2:30 - 3:00 pm	Exhibits, Posters, and Coffee Break	
Session VI	Emerging Issues in Biosafety Moderator: Michele Howard, Centers for Disease Control and Prevention, Atlanta, CA	
3:00 - 3:20 pm	Moderator: Michele Howard, Centers for Disease Control and Prevention, Atlanta, GA Risk Assessment and Facility Containment for Research with Gene Drive Arthropods Sheryl Major, University of California—San Diego, San Diego, CA	
3:20 - 3:40 pm	Prion-like Proteins: Implementation of IBC Oversight Susan Vleck, PhD, RBP(ABSA), Stanford University, Stanford, CA	
3:40 - 4:00 pm	Microbial Aerosols in the Modern Microbiology Laboratory Allan Bennett, MSc, Public Health England, Porton Down, Salisbury, United Kingdom	
Section VII	Interesting Topics in Biosafety Moderator: Larry Mendoza, RRP(ARSA), Virginia Commonwealth University, Richmond, VA	
4:00 - 4:20 pm	Moderator: Larry Mendoza, RBP(ABSA), Virginia Commonwealth University, Richmond, VA Differences in BSO Roles in the Pharmaceutical Industry Versus Academic Laboratories Rebecca McGirr, MS, RBP(ABSA), Sanofi Pasteur Limited, Toronto, Ontario, Canada	
4:20 - 4:40 pm	Liquid Nitrogen Storage in a High-Containment Laboratory—Why AAHL is Moving Away from It Shane Riddell, CSIRO-Australian Animal Health Laboratory, Geelong, Victoria, Australia	
4:40 - 5:00 pm	Utility of the Incident Command System in Laboratory Emergency Management Kaci VanDalen, MS, National Institutes of Health, Bethesda, MD	
5:00 - Close	Members' Business Meeting Door prizes will be awarded—must be present to win.	

Tuesday, November 19, 2019		
7:00 - 5:00 pm	Registration	
7:00 - 8:00 am	Continental Breakfast in Foyer	
9:00 - 4:00 pm	Vendor Exhibits	
8:00 - 8:05 am	Welcome Master of Ceremonies David Gillum, MS, RBP(ABSA), Arizona State University, Tempe, AZ	
Session VIII 8:05 - 8:15 am	Griffin Lecture Award Introductions: Caryl Griffin, MSN, MDiv, Affiliate Elizabeth R. Griffin Program, Kingsport, TN Julie Fischer, PhD, Elizabeth R. Griffin Program, Georgetown University Medical Center, Washington, DC	
8:15 - 9:15 am	Medical Center, Washington, DC Laboratory Biosafety: The Leader's Role David Franz, DVM, PhD, Former Commander, US Army Medical Research Institute of Infectious Diseases, Gettysburg, PA	
Session IX	Biosecurity Moderator: Shelley Jones, MS, RRP(ARSA), Northern Arizona University, Flagstoff, A7	
9:20 - 9:40 am	Moderator: Shelley Jones, MS, RBP(ABSA), Northern Arizona University, Flagstaff, AZ Evaluating the Effectiveness and Sustainability of Responsible Conduct of the Life Sciences Training in Pakistan Mashaal Chaudhri, MPH, Fogarty International Center at the National Institute of Health, Bethesda, MD	
9:40 - 10:00 am	Keeping International Synthetic Biology Safe and Secure: The iGEM Experience	
10:00 - 10:20 am	Piers D. Millett, PhD, iGEM Foundation, Cambridge, MA Cyberbiosecurity: New Intersections and Technologies Stephen M. Lewis, MS, Merrick & Company, Greenwood Village, CO	
10:20 - 10:50 am	Exhibits, Posters, and Coffee Break	

Session X 10:50 - 11:50 am	Eagleson Lecture Award Introduction: Mary Ann Sondrini, Eagleson Institute, Sanford, ME The Challenge of Arthropod Biocontainment in the Non-model Organism World: Mosquitoes, Gene Drive, and Beyond Zachary Adelman, PhD, Texas A&M University, College Station, TX	
11:50 - 1:20 pm	Exhibits, Posters, and Lunch	
Session XI 12:20 - 1:20 pm	Poster Session Presenters must be available during the session.	
Session XII	Regulatory Updates Moderatory Valnage Rengaraian PhD IM PRD(ARSA) Emery University Atlanta CA	
1:20 - 1:40 pm	Moderator: Kalpana Rengarajan, PhD, JM, RBP(ABSA), Emory University, Atlanta, GA Update from the NIH Office of Science Policy	
1:40 - 2:00 pm	Kathryn L. Harris, PhD, RBP(ABSA), National Institutes of Health, Bethesda, MD USDA APHIS PPQ Containment Facilities and Pest Permits Overview	
2:00 - 2:20pm	Gregg Goodman, MS, US Department of Agriculture—APHIS PPQ, Riverdale, MD Enhancing Partnerships to Promote Biosafety and Biosecurity Patricia Delarosa, PhD, RBP(ABSA), CBSP(ABSA), US Department of Health & Human Services, Washington, DC	
2:20 - 2:50 pm	Coffee Break, Posters, and Exhibits	
Session XIII	Global Interest Topics Medianter Design Word DDD(ADSA) Floride Atlantic University Desa Detay Florida	
2:50 - 3:10 pm 3:10 - 330 pm	Moderator: Darlene Ward, RBP(ABSA), Florida Atlantic University, Boca Raton, FL Development and Implementation of a Ladderized Biosafety Training Program at the Research Institute for Tropical Medicine of the Department of Health—Philippines Plebeian Bautista Medina, MS, Research Institute for Tropical Medicine, Muntinlupa, Philippines Biosafety and Biosecurity Measures in the Epidemiological Surveillance of Rabies Virus and Other Lyssaviruses in Mexico	
3:30 - 3:50 pm	Luis Alberto Ochoa Carrera, MS, Institute for Epidemiological Diagnosis and Reference (InDRE), Mexico City, Mexico Proposals to Mitigate the Risk of Deliberate Contamination of Blood Transfusion Components in Tunisia Adam Ben Nasr, MS, Faculté de Pharmacie de Monastir, Monastir, Tunisia	
Session XIV	Public Health M. J. J. D. M. J. D.	
3:50 - 4:10 pm	Moderator: Dawn Wooley, PhD, RBP(ABSA), CBSP(ABSA), Wright State University, Dayton, OH Implementation of WHO Global Action Plan III Containment Certification for US Poliovirus Type 2 Laboratories	
4:10 - 4:30 pm	Christy Ottendorfer, PhD, Centers for Disease Control and Prevention, Atlanta, GA Enhancement of Biosafety and Biosecurity in Tanzania Through Surveillance, Risk Assessment, and Identification of Select Agents in Bushmeat Robab Katani, PhD, Penn State University, University Park, PA	
4:30 - 4:50 pm	Adapting Laboratory Level Biosecurity Measures to Support Systems-Level Awareness, Prevention, Response, and Recovery Efforts of Infectious Disease Samantha Dittrich, MPH, Merrick & Company, Arlington, VA	
6:00 - 10:00 pm	Banquet at the Barber Motorsports Museum	

	Wednesday, November 20, 2019		
7:00 - 5:00 pm	Registration		
7:00 - 8:00 am	Continental Breakfast in Foyer		
8:15 - 8:20 am	Welcome Master of Ceremonies President-Elect: TBD		
Session XV	Biosafety Program Best Practices Moderator: Noman Siddiqi, PhD, RBP(ABSA), Harvard School of Public Health, Boston, MA		
8:20 - 8:40 am	Small Actions Bigger Impact: Training Brings In-house Solution for Biosafety Issues Saeed Khan, PhD, Dow University of Health Sciences, Karachi, Pakistan		
8:40 - 9:00 am	Scavenging for Biosafety: How a Game Can Increase Program Awareness and Buy-in R. Allen Helm, PhD, RBP(ABSA), CBSP(ABSA), University of Chicago, Chicago, IL		
9:00 - 9:20 am	Implementing a Comprehensive Import Permit Program at a Large University Aristea Lubar, BS, University of California—San Diego, La Jolla, CA		
9:20 - 9:40 am	Providing a Safe Lab Environment for Pregnant and Immunocompromised Laboratorians Leyma P. De Haro, PhD, City of Albuquerque Environmental Health and Safety, Albuquerque, NM		
Session XVI 9:40 - 10:10 am	Richard Knudsen Award Introduction: Frank Novembre, PhD, RBP(ABSA), Baylor Scott & White Research Institute, Temple, TX Presenter: TBD		
10:10 - 10:30 am	Coffee Break		
Session XVII	Biosafety Stewardship		
10:30 - 10:50 am	Moderator: Kaci VanDalen, MS, National Institutes of Health, Bethesda, MD Beyond the Lab: Increasing the Visibility of Biosafety and Biosecurity Daniella A, Biotela MS, University of Wisconsin, Milwayless Milwayless WI		
10:50 - 11:10 am	Danielle A. Rintala, MS, University of Wisconsin—Milwaukee, Milwaukee, WI Laboratory Leadership Service: Fostering a Culture of Safety Through Risk Management Training and Practice Shaniece Theodore, PhD, Centers for Disease Control and Prevention, Atlanta, GA		
11:10 - 11:30 am	Developing and Teach a Biosafety Class Robert P. Ellis, PhD, CBSP(ABSA), Colorado State University, Fort Collins, CO		
11:30 - 11:50 am	Establishing Yale's Biosafety Stewardship Program Shumin Bian, PhD, CSP, Yale University, New Haven, CT		
11:55 - 1:30 pm	Honor Awards and Special Recognition Luncheon Presenter: Dee Zimmerman, Galveston, TX Arnold G. Wedum Distinguished Achievement Award Everett J. Hanel, Jr. Presidential Award John H. Richardson Special Recognition Award Scientific and Informational Poster Awards Hashimoto Award for Service and Honor Recognition of Certified Biological Safety Professionals and Registered Biosafety Professionals Presenters: Thomas Boyle, RBP(ABSA), Rowan University, Stratford, NJ Su-Hwi Hung-Cunliffe, PhD, RBP(ABSA), CBSP(ABSA), Lansdowne, PA		

Session XVIII	Let's Focus on Engineering Controls
1:35 - 1:55 pm	Moderator: Kelly Flint, RBP(ABSA), CBSP(ABSA), National Institutes of Health, Frederick, MD Don't Get Steamed About Autoclaving: Case Studies and Recommendations Claudia Gentry-Weeks, PhD, Colorado State University, Fort Collins, CO
1:55 - 2:15 pm	Technical and Animal Preparation Parameters During Performance Qualification for Successful Steam Sterilization of Large Animal Carcasses Jan Schinköthe, Friedrich-Loeffler-Institut, Greifswald Insel Riems, Germany
2:15 - 2:35 pm	BSC Mythbusters: Can 2+ People Work in a BSC Safely? Kara Held, PhD, Baker, Sanford, ME
2:35 - 2:55 pm	Novel Validation Method for Evaluating Biocontainment of Cell Sorting Flow Cytometers Benjamin Fontes, MPH, CBSP(ABSA), Yale University, New Haven, CT
3:00 - 3:20 pm	Coffee Break
Session XIX	BSL-3/BSL-4
3:20 - 3:40 pm	Moderator: Cristine Lawson, PhD, RBP(ABSA), US Department of Defense, Fort Detrick, MD Validation and Utility of a Bleach-based Chemical Effluent Decontamination System (CEDS) for Biocontainment Laboratories David Harbourt, PhD, RBP(ABSA), CBSP(ABSA), SM(NRCM), US Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD
3:40 - 4:00 pm	Spores or Not Spores, 'Tis the Question: Considerations for Biological Verification and Technical Feasibility of Room Fumigations Daniel Kümin, PhD, Basler & Hofmann AG, Esslingen, Switzerland
4:00 - 4:20 pm	Large-scale Decontamination and Decommissioning of a Vintage High-Containment Effluent Decontamination System (EDS), Planning Through Execution Fahim Manzur, MS, Plum Island Animal Disease Center, Orient Point, NY
4:20 - 4:40 pm	Risk Mitigation and HEPA Filtration Systems: Emerging Issues at the Microbiological Level Nikki Goss, MS, AAF Flanders, Jeffersonville, IN
4:40 pm	Close of Conference Master of Ceremonies President-Elect: TBD

Future Conferences

ABSA International's 1st Biosecurity Symposium

May 12-15, 2020 • The Renaissance Depot Hotel, Minneapolis, MN

63rd Annual Biological Safety Conference

October 30—November 4, 2020 • JW Marriott Phoenix Desert Ridge, Phoenix, AZ

USDA ARS 6th International Biosafety & Biocontainment Symposium

February 1-4, 2021 • Baltimore Marriott Waterfront, Baltimore, MD

64th Annual Biological Safety Conference

October 22-27, 2021 • Raleigh Convention Center, Raleigh, NC

65th Annual Biological Safety Conference

October 14-19, 2022 • Wisconsin Center, Milwaukee, WI

USDA ARS 7th International Biosafety & Biocontainment Symposium

February 6-9, 2023 • Baltimore Marriott Waterfront, Baltimore, MD

Registration Form 62nd Annual Biosafety and Biosecurity Conference November 15-20, 2019

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Friday, November 15, 2019 1. BSL-3 Operations and Management 2. International Biosafety, Biosecurity, and Biocontainment Challenges 3. Building Biosafety Leaders 4. Facility Commissioning and Certification 5. Intro to the CEN Workshop Agreement	Saturday, November 16, 2019 6. Engineering for the Biosafety Professional—Part I 7. Advanced Risk Assessment 8. Disinfection, Sterilization, Inactivation 9. Emerging Technologies in Agriculture and Plant Sector 10. Keeping it Going 11. Building and Sustaining a Biohazard Accident Investigation Program 12. Case Studies in Biocontainment Emergencies 13. Intro to Biosafety in the Clinical Setting 14. Emotional Resiliency in High-Risk Environments	Sunday, November 17, 2019 15. Shipping Certification Course 16. Articulating the Value of Your 17. Operationalizing Biosecurity 18. Gene Editing and Risk Assessment 19. Sustaining an Effective Biological 19. Sustaining and High Speed 19. Sustaining 19. Sustaining 19. Sustaining 19. Sustaining 19. Sustaining 19. Sustaining and High Speed 19. Sustaining

egistration for two 4-hour courses on the same day will include lunch.

Badge Policy: Badges must be worn at all conference events. There will be a \$25 badge replacement fee for lost or forgotten badges.

Conference Cancellation Policy: Cancellations received before October 4, 2019—85% refund; cancellations received between October 4 and 18, 2019—50% refund; cancellations received after October 18, 2019—no refund.

to the ABSA International Office to receive the Affiliate Member discount.









AVAILABLE RESOURCES

GENERAL BIOSAFETY

Serves as a starting template for Biosafety Professionals

ANIMAL BIOSAFETY

Videos describing the procedures animal handlers should follow when working at ABSL-1, -2, or -3

BLOODBORNE PATHOGENS

Starting point for administrators creating a BBP Exposure Control Program

ABSA International Training Tools/Resources Committee

ABSA International's Training Tools/Resources Committee is soliciting submissions via the ABSA International website. Our goal is to provide tools, templates, and resources to those who provide training in biosafety or closely-related areas.

You may contribute by:

- 1. Sending us resources you are willing to share here. These can be placed on the public site for full access or on the members-only area for access only by ABSA members. Your content will be reviewed prior to posting.
- 2. Letting us know what types of resources you might find useful. The Training Tools/Resources Committee will gather suggestions and look into what resources are currently available as well as make recommendations for development of appropriate tools.
- 3. Submitting feedback with the user evaluation form for each resource you use.



Biosafety Buyer's Guide www.biosafetybuyersguide.org

ABSA International launched the Biosafety Buyer's Guide to connect supplier partners with members and biosafety professionals. The Guide features biosafety and biosecurity related companies, services, and consultants. The Biosafety Buyer's Guide offers biosafety professionals easy access to ABSA International's partners' products and services. The Guide offers Basic Listings (company contact information), Highlighted Listings (company contact information and logo), and Banner Ads. Listings and Banners are posted for 12 months.



Categories

- Architects
- Biocontainment
- Biodecontamination
- Biosafety Cabinets
- Biosafety Consultants
- Certifiers
- Decontamination
- Engineers
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- Modular Laboratories
- Monitoring
- Packaging and Shipping
- Personal Protective Equipment
- Software
- Sterilization
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- Veterinary
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To add your products or services to the Biosafety Buyer's Guide, contact Karen Savage at karen@absaoffice.org. Download an application at http://biosafetybuyersguide.org/pdf/ABSA BiosafetyBuyersGuideApplication.pdf.



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