

The Age of Auditing, February 3-4, 2015
Speaker Bios

General Session Speakers:

Alan Dittrich, PhD, President, Massachusetts Society for Medical Research

Dr. Dittrich has been president of The Massachusetts Society for Medical Research since September, 2002. At MSMR he is responsible for tracking legislation that might affect animal research for the six New England states, for outreach to the public and the media on issues regarding animal research, and for presentations to member and non-member groups on a variety of topics pertinent to the animal research community.

He is also the treasurer of States United for Biomedical Research, an affiliation of organizations that focus on advocacy for and education about biomedical research

Prior to MSMR, Dr. Dittrich was director of prospect development in the Office of Development at Brown University, and before that he had a nearly two-decade career in marketing, marketing communications and advertising, principally for healthcare and technology companies. In his first career, Alan was a teacher.

He attended the California Institute of Technology and graduated from Williams College with a degree in Mathematics and English. He earned his master's degree in English literature and his doctorate in American literature from Brandeis University. He has published non-fiction, fiction and editorial.

Raven Caitlin, CPA, CIA, CFSA, Raven Global Training and The Institute of Internal Auditors, Inc.

Raven Catlin is an internationally recognized expert and speaker in Internal Auditing. Leveraging her 17 years of auditing, consulting, and training experience, Raven provides on-site training and conference presentations. Training participants gain valuable skills and motivation to achieve success.

Raven is VCU graduate. Before starting Raven Global Training, Raven was a Consultant at Experis and a Senior Manager at Protiviti. She held internal audit positions with Freddie Mac, Bank of America, and Philip Morris. Raven is an active member of the IIA and a contributing author to IIA's CIA Learning System. Go to http://ravenglobaltraining.com/about_us for a full bio.

Sonja T. Chou, VMD, MS, DAACLAM, Executive Director of Veterinary Sciences and Animal Welfare, WuXi App Tec (Suzhou)

Scout earned her Bachelor of Science degree in biochemistry/cell biology from the University of California, San Diego in 1995, and her V.M.D. degree from the University of Pennsylvania, School of Veterinary Medicine in 2000. She then completed a post-doctoral training program in laboratory animal medicine and received a Master of Science degree in Comparative Medicine from the University of Washington in 2004. She worked in different business segments within Charles River until 2011, including Animal Welfare and Training, Genetically Engineered Models

and Services, Phenotyping Services, Discovery and Imaging Services, and Preclinical Services. In addition to supporting research efforts within North America and China, she also worked as a consultant to support animal care and use programs at select academic institutions in New England area. Scout became a Diplomate of the American College of Laboratory Animal Medicine in 2005 and remains active within several professional organizations that support responsible animal use in research, testing, and teaching. In August of 2012 Scout joined WuXi AppTec and currently serves as the Executive Director of Veterinary Science and Animal Welfare.

Betty Goldentyer, DVM, USDA, APHIS, Animal Care

Dr. Betty Goldentyer is the Director of Animal Welfare Field Operations for the Animal Care Program of the United States Department of Agriculture, Animal Plant Health Inspection Service. Dr. Goldentyer has been with the Animal Care Program for 25 years. She was a field inspector for dealers, exhibitors and research facilities in Wisconsin, an Animal Care Specialist supervising inspectors in the southeast US and the Director for tin Raleigh since 1997. Before joining APHIS, Dr. Goldentyer practiced in a small animal clinic and a large humane society in the Chicago area. She is a graduate of the Tufts University School of Veterinary Medicine.

Christopher Scull, PhD, GLP Manager, Memorial Sloan Kettering Cancer Center

Dr. Scull earned an undergraduate degree in Chemistry and a doctorate in Pathology from the University of North Carolina, and completed postdoctoral training at Columbia University. He holds additional certifications in project management and regulatory affairs. His biomedical experience includes patient care, research in the laboratory and animal care experience. Dr. Scull also has drug development experience within both academia and biotech startups, and in his current position he advises and supports investigators in a variety of preclinical development topics in order to help bring new drugs to the clinic.

At Memorial Sloan Kettering Cancer Center, Dr. Scull is currently establishing a new facility for conducting GLP-compliant preclinical studies, and has designed and secured the required laboratory and animal housing facilities. As the GLP Manager, he is responsible for validating and maintaining all equipment, conducting staff GLP training, preparing for FDA audits, and serving as the Study Director for all GLP-compliant laboratory and animal studies. These studies, which are subject to FDA audit, will be submitted to the FDA in support of IND applications for first-in-human clinical trials.

Track 1 – Due Diligence/External Auditing Speakers:

Shameen A. Afif-Rider, BS, LATg, CPIA, RAC, Medimmune

Ms. Afif-Rider has over 16 years of experience in the laboratory animal environment, with a substantial focus on animal welfare compliance for the last 10 years. One of her current responsibilities is assessing external laboratory facilities to ensure they meet the standards for use set forth by AstraZeneca/Medimmune.

Donna Goldsteen, BS, CMAR, CPIA, RLATG, Senior Manager, Laboratory Animal Resources, Medimmune

Ms. Goldsteen has over 30 years of experience in the laboratory animal management field. She has worked in the government, CRO and private pharmaceutical industry. She supports the external animal welfare auditing program using her extensive knowledge of animal welfare regulations and animal facility management.

Pam Huber, Director for Client Services, Marshall BioResources

Ms. Huber has twenty years of experience in the laboratory animal breeding industry with specific focus on client services and customer satisfaction. Her experience includes direct involvement with client audits of our facilities and processes. She also served as a trained ISO internal auditor to ensure compliance with company established goals, processes, and measures.

Amber Lange, B.S. RLATG, Exec. Director, Laboratory Animal Services, Novartis Institutes for Biomedical Research

Amber Lange has worked in the fields of laboratory animal science for 28 years. She has worked for Bristol-Myers Squibb, Millennium Pharmaceuticals, and for 20 years with Novartis Pharmaceuticals Corporation. In her current role as Executive Director, Scientific Operations/Laboratory Animal Services, and manages the Laboratory animal Sciences Department, including Animal Care and Veterinary Care, in support of over 100 scientists in Research and Preclinical Safety. In this position, she is responsible for all aspects of facility operations including renovation projects, capital purchase submissions, compliance with local and Federal regulations and guidelines, building and computer system validation, third party oversight, and investigator training programs.

John Sancenito, President, Information Network Associates, Inc. (INA)

John J. Sancenito is the President of Information Network Associates, Inc. (INA); an international risk management, investigative and corporate consulting firm headquartered in Harrisburg, Pennsylvania. INA offers a variety of services, including intelligence based risk management, physical security consulting, investigations, digital forensic analysis, forensic accounting.

Mr. Sancenito's professional background includes more than 28 years of combined law enforcement and private investigation experience. He is a former County Detective with the Cumberland County Pennsylvania District Attorney's Office.

Mr. Sancenito has particular expertise in research laboratory security practices and benchmarks. He has consulted internationally on physical security design, policies and procedures, and security countermeasures. He has performed physical security assessments at laboratories throughout the United States and Europe. He has considerable knowledge on the topics of animal rights extremism and considered one of the leading experts on the topic.

Track 2 & 3 – PAM/Internal auditing and Training Speakers:

Melinda Bruns, MS, CPIA, RLATG, RVT, Quality Improvement Specialist, The Ohio State University

Ms. Bruns's focus is in leading and facilitating Post Approval Monitoring (PAM) activities. She also provides educational outreach and training to the research community.

Prior to her current position, Melinda had developed and led the PAM program at the University of Cincinnati. Her career began there as a laboratory technician. Then she moved into the role of a protocol and animal colony manager for research laboratories that supported studies related to cardiovascular disease and cancer models.

Melinda is a registered veterinary technician who graduated from the Veterinary Technology Program at University of Cincinnati and also attained a Bachelor degree in Biological Sciences. Her diverse background in animal care, both clinical and research experience, has allowed her to serve as a resource to the research community; identify educational needs for improving laboratory animal programs; and foster a positive environment to achieve compliance.

Chris Charlebois, BS, LATG, Associate Director, Global Research Compliance, Merck & Co

Ms. Charlebois received her degree in Veterinary Technology from Mercy College in Dobbs Ferry, NY. In her current position, she leads a team of auditors conducting internal audits for Post Approval Monitoring, controlled substances, QA oversight, laboratory notebooks and IACUC investigations. Chris and her team also support external audits of vendors and CROs.

Her career began as an animal care technician supporting toxicology studies. She soon moved into management at both academic and pharmaceutical establishments. As the manager for Veterinary Services at The Rockefeller University in New York City, Chris and her team supported discovery research studies. In addition to Operations Manager responsibilities for vivaria at Wyeth, Sterling Drug and Albany Medical College, Chris has also served as an IACUC coordinator. After a diverse career in the laboratory animal industry, Chris is well prepared for her current role in compliance.

Ms. Charlebois originates from the Adirondack Region of New York State near Lake George. She currently lives in Royersford, Pennsylvania with her husband of 24 years and 2 cats, Arnold and Cole. She has 2 children in college, Ephraim (22) and Anna (18) and is enjoying the "empty nest" phase of her life.

Jennifer Davis, DVM, DAACLAM, Compliance Liason Veterinarian, Office of Animal Welfare, University of Pennsylvania

Dr. Davis conducts post-approval monitoring (PAM) of IACUC protocols and research laboratory practices, and provides leadership in implementing a strategic and collaborative direction for the PAM process at Penn. While the Compliance Liaison group works with all Penn

investigators, her focus is geared more towards higher risk studies (e.g., USDA covered species, more invasive surgical procedures, etc.). Jennifer arrived in Philadelphia after completing a residency in laboratory animal medicine at Emory University in Atlanta, GA. Prior to her residency, Jennifer worked in private practice, primarily in emergency medicine and critical care, as well as worked in a cardiovascular research laboratory at the Medical University of South Carolina.

Odessa Giardino, MS, CVT, RLATG, Head of Education and Quality Assurance, Research Animal Resource Center (RARC), Center of Comparative Medicine and Pathology, Weill Cornell Medical College and Memorial Sloan Kettering Cancer Center

Ms. Giardino has an MS degree in biology and is a board-certified veterinary technician and a laboratory animal technologist certified by the Association for Laboratory Animal Science (AALAS). Ms. Giardino has extensive experience in the development and implementation of training programs and regulatory compliance in laboratory animal science. In her current position, she has primary responsibility for ensuring institutional compliance with federal, state, and local regulations and provides regulatory training and support to the Institutional Animal Care and Use Committees at Weill Cornell Medical College and Memorial Sloan-Kettering. Her special interests include research into models of neuropathology and drug metabolism, and the development of novel surgical models.

Cheryl Lees, MS, LATg, Senior Specialist, Animal Welfare Compliance, Merck & Co. Inc.

Cheryl Lees received her B. S degree in Biology from Millersville University and her Masters from Temple University's QA/RA graduate program. Ms. Lees began her career at White Eagle Toxicology Labs and joined Rhône-Poulenc Rorer's/Aventis Toxicology Department within Preclinical Safety Evaluation. Ms. Lees has eleven years GLP experience conducting pre-clinical studies and has participated in the validation and implementation of several data acquisition systems. In 2001, Ms Lees joined Merck's GLP QA group auditing and inspecting all areas within Safety Assessment and participating in FDA inspections. In 2010, Ms Lees joined Merck's Animal Welfare Compliance organization as a Post Approval Monitor ensuring compliance with government regulations, IACUC approved protocols and internal policies and procedures as compared to in-life activities and supporting documentation. On a personal note, Ms Lees has 2 daughters, enjoys vacationing at the beach, gardening, walking her dog and watching football.

Jordan Publico, B.S, RLATg, RQAP-GLP, ILAM, Senior Quality Assurance Auditor, Charles River Insourcing Solutions

Jordan Publico has twelve years of experience working various positions in multi specie facilities in the Commercial, Academic, and Government arenas. He obtained his bachelor degree from the University of Maryland (GO TERPS!) with the focus on laboratory animal management, stays current with his LATG registration, and is also a Registered Quality Assurance Professional in

Good Laboratory Practice. He has over six years of experience as the QA auditor for Charles River, and performs scheduled site visits with the focus on animal welfare and employee safety. As an animal research advocate he also currently holds the position of President for the National Capital Area Regional Chapter for the Society of Quality Assurance (NCARSQA), judges at high school science fairs, gives talks at grade school career days, and anything else he can do to promote Animal Research.

William Singleton, DVM, DACLAM, President, Animal Care Training Services

William Singleton is a board certified laboratory animal veterinarian. He received his Veterinary Degree from Tuskegee University in 1991. He spent 5 years as a Clinical Veterinarian at Southwest Foundation for Biomedical Research in San Antonio Texas. He served as the Veterinary Manager at Aventis Pharmaceuticals for 5 years and later went on to be the Associate Director of Clinical Care and Training at the University of Pennsylvania. William's passion for developing others and aptitude for training led to the creation of Animal Care Training Services (ACTS) in 2007. ACTS is committed to improving the quality of animal care and wellbeing through technical training and professional development.

Emi Yano, PMP, B.Ed, Quality Assurance Analyst, Research Oversight and Compliance Office, University of Toronto

Emi Yano is a Quality Assurance Analyst in the Research Oversight and Compliance Office at the University of Toronto (UofT), Canada. She has worked in the field of animal research regulations for eight years.

At UofT, Emi led the redevelopment and implementation of the university's Post-Approval Review (PAR) program. She conducts Quality Assurance Visits as part of the PAR program and manages the development of Standard Operating Procedures.

Previously, Emi worked at the Toronto Centre for Phenogenomics, where she co-created and coordinated the post-approval monitoring program. She orchestrated the initial and ongoing development of the training program and managed the animal ethics review process.

Emi is also a Project Management Professional and is pursuing a Master of Education. Outside of work, she enjoys going on adventures (both real and imaginary) with her one year old son.