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The New Paradigm: "Inspections During COVID"

PDA Parenteral Drug Association
Southern California Chapter

COME JOIN US FEBRUARY 17th | 4:00 - 6:00pm!

PDA Members Free | Non-PDA Members $25



Conducting and Hosting Remote GLP Audits

Ms. Angela Bazigos, CEO of Touchstone Technologies, Inc.
Karine A. Lux, BS, LAT of The Jackson Laboratory
Aaron Rose, Sr Program Manager at The Jackson Laboratory

How do you handle east to west coast remote audits? Join the discussion of handling a document audit, the onsite audit, and the communications with an East Coast company. Successful ways to use the onsite auditor to get the information to the East Coast company and how a west coast company handled being audited remotely. While the East Coast company was able to do a document audit, they still wanted a 'boots on the ground' person for the onsite audit.
This GLP remote audit discussion will include Angela Bazigos (the Auditor), Dr. Aaron Rose (Lab Director) and Ms. Karine Lux (Senior Manager, Quality Systems Initiatives).
In addition to the discussion, 2 publications created from this remote audit will be provided to attendees.

Good Laboratory Practice Facilities Continuity in a Pandemic

Dr. Kimberley Buytaert-Hoefen, Director of Pre-Clinical Consulting of Azzur Group

The COVID-19 pandemic has changed the world that we live in. Strict restrictions have been enforced in order to reduce the impact of the pandemic. These restrictions may interfere with working practices in test facilities conducting GLP studies. Deviations from standard operating procedures and study plans due to the pandemic should be documented, investigated and mitigated based on risk. The impact of the imposed restrictions on test facility operations including non-study specific activities and QA inspections should also be assessed and be included in the evaluation of the GLP status of studies. In response to the pandemic, FDA regulators are modifying their GLP facility and study reviews. This presentation will review best practices for operating GLP facilities and handling regulatory interactions in the time of COVID-19.

For questions about this event, please contact:
Sheba Zaman, President, SoCal PDA Chapter, zaman@socalpdachapter.org, 949-735-7227
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Speaker Bios:

Ms. Angela Bazigos is the CEO of Touchstone Technologies Inc. She has degrees in Microbiology and Computing and 40 years of experience in the Drugs, Biologics, Medical Devices, Healthcare & Food. Her experience combines GxP regulations in Quality Assurance, Regulatory Compliance, Clinical Trial Science, Auditing, Information Technology, Project Management, Clinical Lab Science, Microbiology, Food Safety & Turnarounds. Past employers / clients include Royal Berkshire Hospital, Roche, Novartis, Genentech, PriceWaterhouseCoopers, Veracyte and other Medical Device Companies, Stanford Hospital & Baylor College of Medicine. She consults to pharma, biotech, medical device and food companies as well as provides due diligence for investors. Past Positions include Chief Compliance Officer, Director of QA and MIS Director. She also co-authored & prototyped 21 CFR 11 guidance with FDA and commented on GAMP5 and FDA guidance documents. Co-authored Computerized Systems in Clinical Research w/ FDA & DIA Patent on speeding up software compliance. Quoted in Wall Street Journal for using training to bring regulatory compliance to the Boardroom includes training for Society of Quality Assurance. Comments / collaborates with FDA on new guidance documents. Adjunct Professor at UC Berkeley. Vice President of Pacific Regional Chapter of Society of Quality Assurance. Stanford's Who's Who for Life Sciences.

Karine Lux serves as the Senior Manager, Quality Systems Initiatives with her primary focus on leading and facilitating measurable operational and process improvements projects with a quality focus. Karine joined The Jackson Laboratory in 2003, focusing on and obtaining AAALACi accreditation and OLAW assurance for the (then) new Sacramento site. During her tenure at JAX, Karine held multiple roles in addition to the Quality position, including In Vivo Research Services Manager (outsourced nonclinical services), interim Environmental Health and Safety Services Manager, and IACUC Chair. Prior to joining The Jackson Laboratory, Karine gained her management, operational, research and regulatory experience with management and research positions Scios, Inc, ALZA Corporation, and In-Vivo Technologies, Inc. Karine holds a Bachelor of Science degree in Animal Science from University of California at Davis and is LAT certified.

Aaron Rose serves as the Senior Program Manager for The Jackson Laboratory Invivo Services. His role focuses on customer experience, strategic product management, and sales analysis. Aaron joined The Jackson Laboratory in 2015 as a technical information scientist focused on helping researchers understand and find the right mice for their scientific need. He has also served as a project scientist and study director in In Vivo Services. Prior to joining The Jackson Laboratory, Aaron worked as a post-doctoral researcher and co-founded a biotech, Biologic Hawaii Inc. Aaron holds Bachelor degrees in Chemistry and Molecular Biology from Humboldt State University and a Ph.D in Molecular Biology from The University of Hawaii at Manoa.

Dr. Kimberley Buytaert-Hoefen obtained a Bachelor's degree in Psychology at the State University of New York at Binghamton and then went on to complete her Master's and Doctorate degrees in Neuroscience at the University of Colorado at Boulder. She completed two post-doctoral fellowships at the University of Colorado Health Sciences Center where she specialized in embryonic and adult stem cell research. In 2005, she entered private industry with a position as a Lead Scientist at Navigant Biotechnologies. In 2009, she accepted a position as a Consumer Safety Officer at the FDA, where she specialized in pharmaceutical inspections with an emphasis on biotechnology and sterile processing.

Since 2016, as a Consultant, Dr. Buytaert-Hoefen specializes in Biologics, Gene and Cellular therapies. She assists companies with the authoring of regulatory documents, interactions with regulatory agencies and GLP, GCP and GMP regulatory compliance.

Dr. Kimberley Buytaert-Hoefen recently joined Azzur Group as Director of Pre-Clinical Consulting.

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