ISPE Boston Area Chapter Presents:

GAMP Forum:

The use of Innovative Technologies like SaaS, AI/ML and Blockchain in regulated environments

Thursday, January 16, 2020
1:00 pm to 7:30 pm

Royal Sonesta
40 Edwin H Land Blvd
Cambridge, MA 02142

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PROGRAM SUMMARY:

The afternoon will begin with a plenary discussion, featuring a number of industry experts, about the upcoming draft Computer Software Assurance draft guidance from FDA's CDRH division This is widely envisaged as a mandate from FDA to rigorously apply risk management to computer validation activities, and designing 'right size" assurance that software used to support quality decisions can be relied on, while encouraging innovation and optimization of computer software solutions.

The rest of the afternoon will split into two parallel tracks; One will focus on validation of software, how to design a risk based approach, best practices to audit Software as a Service providers, and practical examples of validating SaaS solutions in a regulated environment.

The second track will examine new technologies and how they might be advantageous in Life Science companies. Sessions will include an introduction to Artificial Intelligence and Machine Learning to cover what it is, what it is not, and how to approach leveraging it in regulated environments. Complimenting this, you will have the opportunity to understand the core concepts of blockchain technologies, such as the role and needs for distributed ledgers, and hear practical use cases and lessons learned from industry projects. This track session will conclude with some live demos and online tools to help visualize both these concepts.

PROGRAM AGENDA:

1:00 - 1:30 pm	Registration	
1:30 - 2:15 pm	Plenary Session: **Computer Software Assurance: Paradigm Shift** - Shana D Kinney, REGENXBIO; Khaled Mousally, Compliance Group; Ken Shitamoto, Gilead	
	CSV and Cloud Track TRACK	**Technology Track**
2:30 - 3:15 pm	**CSV 101: Just What Does "Risk Based" CSV Mean?** –Lorrie Vuolo-Schuessler, Syneos Health	**The Use and Compliance of Artificial Intelligence (AI) in the Pharma/Biotech Industry** – Eric Staib, Genpact PVAI
3:15 - 3:45 pm	**Break**	
3:45 - 4:30 pm	**Compliant Computer System Validation in an "as-a-Service" World** – Jimmy Hughes, bluebird bio	**Blockchain Applications in Pharma** – Jamey Canterbury, EY
4:30 - 5:15 pm	**Auditing XaaS Suppliers for GxP Applications** – Stephen Ferrell, Compliance Path	**Blockchain and AI Demonstrations** – James Canterbury, EY; Eric Staib Genpact, PVAI
5:15 - 7:30 pm	**Networking Reception**	

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WHO SHOULD ATTEND:

This afternoon session will be of interest to quality and IT professionals dealing with validation of software in regulated environments, from both the medical device and pharmaceutical life sciences environments.

PRESENTATION ABSTRACTS:

Plenary Session: Computer Software Assurance: Paradigm Shift

Shana D. Kinney, REGENXBIO Inc.
Khaled Moussally, Compliance Group
Ken Shitamoto, Gilead

In an effort to harmonize with international standards, the FDA (CDRH) announced in their FY 2019 Proposed Guidance Development list to release a new draft guidance "Computer Software Assurance for Manufacturing, Operations, and Quality System Software," that aligns with the current quality systems regulation ISO 13485. Hear directly from members of the FDA/industry collaborative team on the scope of what this guidance may entail and from individuals who have already implemented the FDA's proposals.

The Use and Compliance of Artificial Intelligence (AI) in the Pharma/Biotech Industry

Eric Staib, Vice President of Quality and Compliance, Genpact PVAI

The pharma/biotech industry is increasingly relying on software to automate many functions previously performed by humans. As our computer systems become more integrated and data sets become more robust, computer science is advancing our ability to learn from that data and draw conclusions about what might, or should happen next. We are now reaching a point where these algorithms are sophisticated enough to begin making decisions for us in the form or artificial intelligence (AI). This presentation will highlight how AI is being used in industry and how/what companies are doing to ensure its compliance with predicate rule and the latest regulatory guidance on data integrity (DI).

CSV 101: Just What Does "Risk Based" CSV Mean?

Lorrie Vuolo-Schuessler, Senior Director of Quality Assurance, Syneos Health

Whether new to computer system validation or a seasoned validation professional this presentation will provide insight on the importance of applying a risk based approach to computer system lifecycle activities by appropriately scaling activities and deliverables.

For years, GAMP® and regulatory guidance have emphasized the need to scale all lifecycle activities and the associated documentation according to risk. The risk based approach should take into account data integrity, product quality, and patient safety. While many companies say they have a risk based approach, often risk is not effectively identified or managed throughout the system and data lifecycles. It is important, therefore, to think, both logically and critically, about the potential risks to the business processes, the system, and the data to effectively identify, mitigate, and control risk.

Blockchain Applications in Pharma

Jamey Canterbury, Principal, Risk Advisory, Ernst Young

Blockchain technology is beginning to take hold in Life Sciences; there are a number of successful pilots and several production solutions that address industry issues ranging from DSCSA Saleable Returns to Clinical Trial Management. This session will introduce the core concepts of blockchain technologies and share practical use cases/lessons learned from industry projects.

Compliant Computer System Validation in an "as-a-Service" World

Jimmy Hughes, Sr. Manager, Computer Systems Validation, bluebird bio

The presentation will discuss the growing landscape of SaaS applications available and in use in pharma and the challenges associated with those. We will review key differences in implementing, validating, operating, and managing hosted applications and the vendors that sell them, from setting up a system development life cycle program, to understanding the importance of vendor qualification, to testing, to setting up appropriate operational controls, like risk-based change management and periodic review. We will discuss the differences between traditional on-premise systems validation as opposed to the needs of hosted system qualification.

Auditing xaaS suppliers for GxP

Stephen Ferrell, Managing Director - Americas, Compliance Path

Cloud delivered GxP applications are rapidly replacing locally deployed applications as the norm. This presentation will focus on the questions to ask and technical considerations for engaging XaaS providers to ensure high performance and fully compliant service delivery.

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SPEAKER BIOGRAPHIES:

Jamey Canterbury, Principal, Risk Advisory, Ernst Young

James is a Principal in EY's Risk Advisory practice and a leader within EY's global blockchain team. He helps his clients understand new technologies and how they might be applied to solve real-world problems. Specifically, for blockchain he works to educate clients on the new technology and designs solutions to capitalize on the benefits of a blockchain network when designing efficient, transparent, and trusted solutions. He has 15 years of experience helping biopharma companies find innovative answers to the challenges created by operating in a highly regulated industry. Before blockchain, he primarily managed projects that span from interpreting FDA regulations to privacy & security to financial controls. James holds a BS in Industrial Engineering from Penn State University and is a Certified Information Systems Auditor. He currently sits on the board of the NJ chapter of ISPE, is the secretary for the Global GAMP Steering Committee, and leads the GAMP blockchain special interest group.

James Canterbury is a Partner in Ernst & Youngs Risk Advisory practice where he works with the global blockchain team to development technology solutions for Life Sciences companies. James is also on the board of directors for the global GAMP steering committee as part of the International Society of Pharmaceutical Engineers

Stephen Ferrell, Managing Director - Americas, Compliance Path

Mr. Ferrell is a recognized expert in regulatory compliance in the Pharmaceutical, Medical Device and Biotech space. Mr. Ferrell was co-founder of CompliancePath Ltd, a Scottish and US Compliance services company that support regulated clients all around the world. Mr. Ferrell has held executive and senior level management positions with a number of technology firms in the Life Sciences.

Stephen has implemented Quality Management Systems at several companies at both the corporate and divisional level and has hosted and conducted countless audits across the GxP disciplines, ISO13485 (inclusive of IEC62304/ISO14971), ISO27001, SOC 1 & 2, EHNAC and FEDRAMP.

Mr. Ferrell represents the Scottish Life Sciences Association in the USA and was a signatory on the historic 'Turnpike agreement' which created collaborative channels for US & Scottish Life Sciences companies to share knowledge and expertise. Mr. Ferrell is a member of the ISPE GAMP Steering committee, Co- Chair's the Cloud Special Interest Group and was the project lead for the ISPE GAMP IT Infrastructure Control and Compliance Guide published in August of 2018.

Jimmy Hughes, Sr. Manager, Computer Systems Validation, bluebird bio

Jimmy Hughes is Senior Manager of Computer System Validation at bluebird bio in Cambridge, MA, and has over 10 years of experience in Quality, Validation, and Engineering in the biopharmaceutical industry, with 5 years specifically focused on Computer System Validation. In his role at bluebird, Jimmy manages a team of validation engineers and helps ensure that the company's computer systems are delivered and operating effectively and compliantly. Jimmy holds a BS from Tufts University and has previously been an active member of ISPE Boston Chapter's Educational Planning Committee (EPC).

Shana D. Kinney, Validation Manager, REGENXBIO Inc.

Validation Manager with 13 years' progressive experience in the biosafety testing, molecular diagnostic medical devices, and gene therapy industries. Served as validation engineer, quality engineer, software quality assurance, and computer systems validation engineer. Currently working at REGENXBIO Inc. as Sr. Manager, Computer Systems Validation building a CSV program for a rapidly growing startup. Co-author of the ISPE Good Practice Guide for IT Infrastructure and member of the ISPE GAMP Americas Steering Committee. Certified by ASQ as a Six Sigma Green Belt, Software Quality Engineer, and Quality Engineer. Bachelor's degree in Applied Mathematics and Master's in Applied Statistics.

Khaled Moussally, Quality/IT Executive, Compliance Group

Khaled is a Quality / IT executive who partners with Life Science and Medical Device industry clients to provide solutions to their IT / Engineering quality and compliance related challenges. After spending over 27 years in IT, Manufacturing and Quality, 19 years of which at Baxter Healthcare, Khaled understands the regulated environment and is able through his deep experience and valuable network to provide his expert advice. Khaled is a contributing participant of the MDIC "Case for Quality Initiatives" and an active member of the "FDA CSV Industry team" and "Co-Author" of the FDA draft guidance "Computer Software Assurance (CSA) for Manufacturing, Operations, and Quality System Software". Khaled has presented in many seminars along with the FDA & Industry leaders on how to reduce time and cost in validating software by applying CSA Draft guidance.

Ken Shitamoto, Gilead

Ken Shitamoto leads the IT quality engineering function at Gilead Sciences, which performs software quality assurance (testing), validation, and infrastructure qualification. He is a multi-disciplined professional with extensive experience in quality engineering, quality management, project management, audits, and software development. He has been in the biopharmaceutical space since 1993 and has worked on the manufacturer (GXP), vendor (GCP), and consulting sides of the business. He is an active member of the FDA-Industry team working on Non-Product Computer Systems Assurance.

He holds a BA Molecular Cell Biology and MS Computer Science and from UC Berkeley and San Jose State University respectively. He is an avid supporter of the American Lung Association, and Ken and his daughter have raised over 130K dollars to fight lung disease.

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Eric Staib, Vice President of Quality and Compliance, Genpact PVAI

Eric is currently the Vice President of Quality and Compliance for Genpact PVAI. He has more than 25 years of pharmaceutical industry experience in various GXP areas including direct experience and leadership for quality systems development/management, software quality engineering, information technology and computer systems validation. He holds a Bachelor of Science degree from James Madison University in Biology, a Master of Science degree from Temple University in Quality Assurance & Regulatory Affairs, a graduate certificate from Lehigh University in Project Management, and an MBA from Drexel University in Pharmaceutical Management. Eric was previously the Chair of the GAMP Americas Steering Committee for ISPE, and currently Co-chairs an AI/ML Special Interest Group (SIG). He has presented at numerous industry conferences in addition to having published and contributed to several concept papers, magazine/journal articles, and good practice guides.

Lorrie Vuolo-Schuessler, Senior Director of Quality Assurance, Syneos Health

Lorrie Vuolo-Schuessler is the Senior Director of Quality Assurance, Computer Systems Quality and Data Integrity at Syneos Health. She has extensive experience in the pharmaceutical industry with particular emphasis on computer systems quality and data integrity. She has presented at many industry conferences on computerized system validation and data integrity.

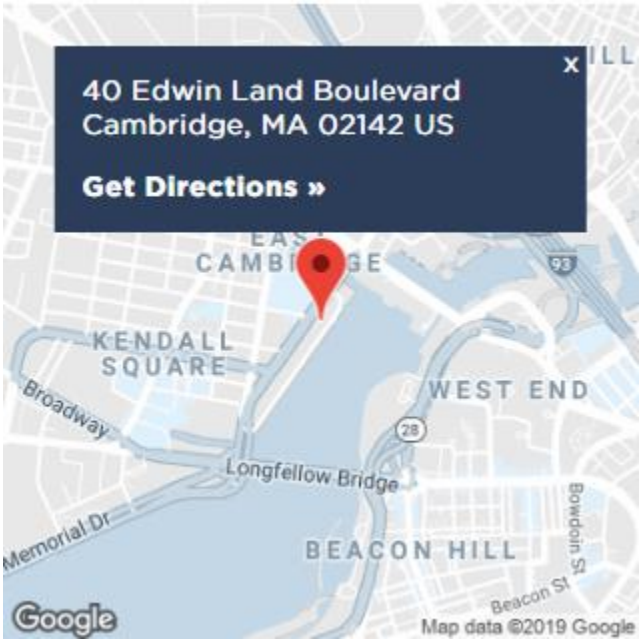
Lorrie is the Chair of the GAMP Americas Steering Committee, a member of the GAMP Global leadership team, and Co-Chair of the GAMP Data Integrity Special Interest Group which recently created the ISPE GAMP RDI Good Practice Guide: Data Integrity – Manufacturing Records. She contributed to the development of both the ISPE GAMP Guide: Records and Data Integrity and the ISPE GAMP RDI Good Practice Guide: Data Integrity – Key Concepts. Additionally, she served as the leader of the GAMP Laboratory Special Interest Group driving the development of the GAMP Good Practice Guide: A Risk-Based Approach to GxP Compliant Laboratory Systems Second Edition (2012). She is also an active member of the SQA Computer Validation & Information technology Compliance Specialty Section.

MEETING MANAGER:

Heather Longden, Waters Corporation

DIRECTIONS AND PARKING:

Click here for door to door directions.



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PROGRAM SCHEDULE:

1:00 – 1:30 PM	Registration
1:30 – 2:15 PM	Plenary Session
2:30 – 5:15 PM	Concurrent Breakout Sessions
5:30 – 7:30 PM	Networking Reception

REGISTRATION FEES:

	Registration by 1/9/2019	Registration After 1/9/2019
☐ Members	$125	$135
☐ Young Professional Members	$65	$75
☐ Nonmembers	$195	$210

REGISTRATION IS NOW OPEN ONLINE!

Don't waste time filling in the form! Register online at www.ISPEBoston.org/Events.
Pay by credit card OR check.

Name: _____ Title: _____

Do you wish to opt out of being listed on the attendee roster?: ☐

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