VIRTUAL EVENT

APRIL 13-15, 2021

Computer Systems Validation & Software Assurance Week

The Trusted Source in Mastering Regulatory Updates, Evaluating Cutting-Edge System Integration Methodologies and Discovering Latest Digital Innovations

Unparalleled Perspectives from Industry Experts

Conference Co-Chairs:

Senthil Gurumoorthi
Director
GILEAD SCIENCES

Ken Shitamoto, MS
Senior Director, IT
GILEAD SCIENCES

Distinguished Speakers:

Geetanjali Abbi
Associate Director, CS Validation
ALKERMES

Daniel Caparrós
Head of Global Data & Digital Quality
MERCK KGAA, DARMSTADT, GERMANY

Pritam Khade
Director, Global Quality Compliance
ALLERGAN INC

Dan Matlis
President
AXENDIA

Michelle Miller
Director, Global Validation & GQO Training
ILLUMINA

Raechelle Raimondo
Former Executive Director, Global IT Systems Assurance and Compliance
ALLERGAN

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INSTITUTE OF VALIDATION TECHNOLOGY
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informa connect

ABOUT THIS VIRTUAL EVENT

Backed by two decades of industry insights and educational training, this gold standard event is driven by the regulatory expectations of today and the technologies of tomorrow. With the rising digital transformation and timely regulatory updates, it is imperative to gain the proper training on adapting to the new "normal."

Join the experts at *COMPUTER SYSTEMS VALIDATION & SOFTWARE ASSURANCE WEEK* for updates, strategies and comprehensive takeaways to bring back to your organization and ensure a successful 2021 and beyond. This event is not to be missed!

SURVEY RESULTS:

A SURVEY OF YOUR COLLEAGUES FOUND:

Only 7% feel they understand FDA's CSA Expectations and Proposed Draft very well

TOP 5 CONCERNS IN IT AND COMPUTER SYSTEMS VALIDATION:

1. Creating Documentary Records for Compliance
2. Risk-Based Assurance Activities
3. Testing
4. Data Integrity Lapses
5. Human Error

Ready to join your fellow thought leaders and subject matter experts in accessing the most trusted resource for validation and compliance professionals in FDA regulated industries?

IVT Network provides unmatched regulatory and industry guidance. Members access peer-reviewed journals and archives, training videos and on-demand education, weekly podcasts on industry best practices and emerging technologies, as well as the benefit of networking with an established collection of peers. Plus, Gold Membership includes access to all online training materials and receives discounts on virtual and live conference attendance fees. Learn more today!

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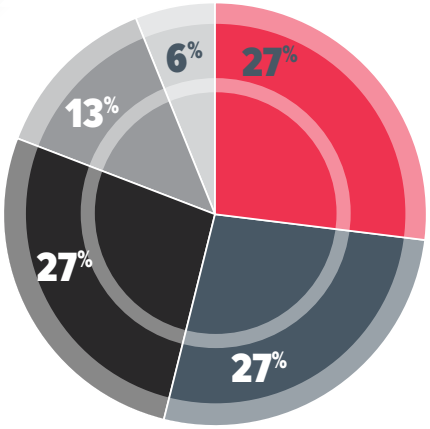
AUDIENCE SNAPSHOT

LIFE SCIENCES AUDIENCE BREAKDOWN BY TITLE



- **Quality / QA / QC** 27%
- **CSV / Validation** 27%
- **IT / IS / Systems / Software** 27%
- **Compliance / Regulatory** 13%
- **Engineer** 6%

CORE AUDIENCE

BIO/PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURERS

Also including representatives from:

- **CMO/CRO**
- **Technology/Solutions Providers**
- **Consumer Goods**
- **APIs/Chemicals/Materials**

CONSISTENTLY ACCLAIMED BY ATTENDEES

WHAT PREVIOUS ATTENDEES HAD TO SAY ABOUT IVT QUALITY AND VALIDATION CONFERENCES

"I was impressed with the quality of the presenters — Very knowledgeable and so down to earth, that by sharing their experiences make you feel, 'you're not alone.' You will learn a lot!"

"I really enjoyed the presentations and getting updated with what is happening in the industry."

"Really great conference with a lot of helpful content to refine our validation program."

"Very satisfied that I was able to connect up with those in my industry and get back on top of topics that are important in this area. Also really appreciated the pre-recorded sessions that I could watch whenever I wanted to."

LIVE CONTENT AGENDA. YOUR TIME. REAL TIME.

*Tentative Agenda, Subject to Speaker Availability

During **Computer Systems Validation and Software Assurance Week,** experience live presentations, interactive sessions and networking events. Any timeframe below that does not have a session listed is a great time to network and enjoy our on-demand sessions.

Day One: Tuesday, April 13, 2021

*Please note all times are listed in EST

10:30-10:45 AM	LIVE **Informa Connect's Welcome and Co-Chairs' Opening Remarks** *Elise Wyatt, Conference Producer,* **Informa Connect – IVT Network** *Ken Shitamoto, MS, Senior Director, IT,* **Gilead Sciences** *Senthil Gurumoorthi, Director,* **Gilead Sciences**
10:50-11:50 AM	LIVE **PANEL** **Excellence and Next Generation Approaches to Quality System Monitoring and Analysis – Perspectives in Innovation** This session reflects on the current landscape, team challenges from the past year and key issues that will continue to shape this vibrant industry and what that means for quality and validation professionals in the year ahead. The Keynote Panel comes during a pivotal time in 2021 as companies continue to pilot tremendous change and uncertainty, while striving to innovate. • Reflections on current landscape – Data and process driven strategies for improving data quality – Challenges in data governance programs and policies – Understanding sources of bad data – Roles in data governance and data quality • Navigating Team Challenges – Missing data, data consistency and data integrity – Data security and speed of data delivery – Defining metrics and reporting strategies • Outlook on Key Issues – Establishing digitally enabled facilities using real-time analytics for agility in meeting ever-changing markets – Speed and efficiency using digitization, automation and online testing – Using predictive capabilities to ensure highest levels of quality and control **Moderator:** *Michelle Miller, Director, Global Validation,* **Illumina** **Panelists:** *Daniel Caparrós, Head of Global Data & Digital Quality,* **Merck KGaA, Darmstadt, Germany** *Nuala Calnan, Ph.D., Chief Executive Officer,* **BioPharm Excel Ltd;** *Founder,* **The Quality Risk Management Institute (QRMi)** *Alyce Deegan, MBA, PMP, CQA, Life Sciences Leader*
11:50 AM-12:00 PM	TAKE TIME TO STRETCH

STAY CONNECTED AND JOIN THE CONVERSATION

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12:00-12:50 PM

LIVE **PANEL DISCUSSION**

The CSA Revolution

In this session you will achieve a better understanding of the intent and scope of the FDA's Computer Software Assurance guidance, while gaining insight into CSA's relationship to other existing regulations. Learn to apply to critical thinking and risk-based principles as part of the lifecycle strategy in support of data integrity. Plus, hear why you should stop focusing on regulatory risks over the more important patient safety.

- Understand FDA's CSA Guidance in the Context of Current Regulations and GAMP®
- Discover first steps — CSV Migration to CSA and Modern Testing
- Uncover ways in which automation can improves Data Integrity
- Hear how CSA promotes better use of data for the benefit of the patient safety and product quality

Conversation Contributors: *Ken Shitamoto, MS, Senior Director, IT,* **Gilead Sciences**
Senthil Gurumoorthi, Director, **Gilead Sciences**
Ray Murphy, Principal Software Quality Engineer, **Boston Scientific**
Khaled Moussally, Executive Vice President, Quality, **Compliance Group**
Francisco (Cisco) Vicenty, Program Manager – Case for Quality, **FDA**

1:00-1:30 PM

LIVE

The Future is Coming: Software Validation Automation

- Discover how to take your validation to the next level - CSA and more
- Discuss the digital transformation — it is not only paperless validation
- Explore new technology to automate your SaaS validation and risk identification processes
- Learn how to avoid SaaS validation risks

Ido Raz, Validify Chief Executive Officer, **Validify**

1:30-2:10 PM

TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND CONTENT

2:10-2:15 PM

Content Highlight *presented by :* Kneat

2:15-3:00 PM

LIVE

Quality Agreements for Computer SaaS

- Explore the scope of vendors for which QA's should be established
- Evaluate risk-based approach to quality agreements for computer SaaS
- Discuss roles and responsibilities
- Identify Quality Agreement vs Commercial Agreement and discuss General Quality requirements
- Learn how to roll this process out operationally for existing vendors

Geetanjali Abbi, Associate Director, CS Validation, **Alkermes**

3:10-3:55 PM	LIVE **Risk-Based Approaches to CSA** • Focus on effort with quality impact • Discuss reduction of duplication and non-value added testing processes • Learn to effectively leverage supplier documentation *Sara Levy, CSV and Data Integrity Manager,* **Pluristem Therapeutics**
4:05 PM	TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND DIVERSITY AND INCLUSION PODCASTS

Day Two: Wednesday, April 14, 2021

**Please note all times are listed in EST*

10:30-10:45 AM	LIVE **Day Two Kick-Off** *Ken Shitamoto, MS, Senior Director, IT,* **Gilead Sciences**
10:50-11:50 AM	LIVE **PANEL DISCUSSION** **The Digital Transformation** • Explore organization-wide digital transformation initiatives • Discuss firsthand experiences of point solutions to platforms transitions • Learn about the shift to cloud computing and cloud-first approach **Conversation Contributors:** *Dan Matlis, President,* **Axendia** *Paul Hurlocker, Vice President, Platform Solutions & Engineering at the Center for Machine Learning,* **Capital One** *Samuel Cheemakoti, GMP Head, IT Systems for OTC Drugs,* **Beiersdorf** *Ron Scharadong, Senior Director, Technology Quality – CSV,* **Johnson & Johnson**
12:00-12:45 PM	LIVE **Evaluate and Assess Computer Validation Audits** Independent inspections of computer solutions under regulatory control identify process, data, and staff procedural performance against industry-standard compliance objectives and expectations. It is beneficial for both the auditors and organizations under audit to have an approved audit findings evaluation and assessment plan available to determine successful computer solution artifacts and to bridge compliance gaps. *Leslie Lighton-Humphreys, IT SQA & CSV Manager,* **AmerisourceBergen**
12:45-1:45 PM	TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND CONTENT
1:45-2:15 PM	LIVE **Minimize Audit Risk & Submission Timelines with Managed Hosting & Validation** • Share challenges you may face when upgrading your clinical trial analytics environment • Learn how the d-wise Accel environment addresses these challenges and provides turn-key validation for your stats programming team • Hear from Biotech and CRO leaders who have benefited from this approach *Ali Dootson, Director of Consulting,* **d-wise** *Phil Loucks, Client Manager,* **d-wise**

2:15-2:25 PM	**TAKE TIME TO STRETCH**
2:25-2:55 PM	LIVE **Still Doing CSV? It's 2021! CSA – System Operation and Maintenance** *presented by :* COMPLIANCE GROUP • CSA — Impacted SOPs • CSA – Change Management • CSA — Continuous Monitoring, Periodic Review and Revalidation CSA concepts apply broadly to all validation for intended use of a computerized system. • What a Monitoring Program Looks Like • The value of tracking issues in Production • How to ensure Change Management reviews are practical and achievable • Ensuring success with good procedures • Executing Continuous Monitoring • What to review • The value of a great checklist for assessment • How to remediate deficiencies • Learn when revalidation might be required! *Khaled Moussally, Executive Vice President, Quality,* **Compliance Group** *Stephen J. Cook, Vice President, Quality and Compliance,* **Compliance Group** *Harsha Chulki, Head of Global IT Quality, Compliance and CSV,* **ICU Medical Inc.**
3:05-3:50 PM	LIVE **How Much Validation is Enough? CSA Case Studies** • Understand the importance of planning and critical thinking • Evaluate ways to assess risk and use the level of risk to inform the level of assurance required • Discuss case study examples to show how to balance speed and quality through: – Effective documentation – Agile scenarios – Change management (normal vs simplified/pre-approved changes) *Raechelle Raimondo, Former Executive Director, Global IT Systems Assurance and Compliance,* **Allergan** *Pritam Khade, Director, Global Quality Compliance,* **Allergan Inc** *Shana Kinney, Associate Director, Validation,* **REGENXBIO**
3:50 PM	**TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND DIVERSITY AND INCLUSION PODCASTS**

Day Three: Thursday, April 15, 2021

**Please note all times are listed in EST*

10:00-10:30 AM

RISE AND SHINE YOGA

Rise and shine this morning by participating in a wellness activity before kicking off the final day of the conference. Enjoy some stretching with yoga instructors to start the day off right.

10:30-10:45 AM

LIVE

Day Three Kick-Off

Senthil Gurumoorthi, Director, **Gilead Sciences**

10:50-11:35 AM

LIVE

Cloud Computing Validation – Lessons Learned from the Front-Lines

- Strategies for a successful cloud migration
- Ensuring compliance of data stored at the cloud provider
- New challenges and considerations regarding SaaS solutions
- Mitigating risk and ensuring data integrity through cloud computing security

Conversation Contributors: *Ferdi Steinmann, Senior Global Industry Strategist, Life Sciences,* **OpenText**
Joanne Goldberg, Senior Principal IT Business Systems Analyst, **Medtronic**
Ron Scharadong, Senior Director, Technology Quality – CSV, **Johnson & Johnson**
Scott Lundstrom, Sr. Industry Strategist, Healthcare, **OpenText**

11:35-11:45 AM

TAKE TIME TO STRETCH AND VIEW ON-DEMAND DIVERSITY AND INCLUSION PODCASTS

11:45 AM-12:30 PM

LIVE

Analyze and Diagnose Risks from SaaS Vendor Audit Findings and Insights

- Creating a vendor audit diagnosis map
- Analyze vendor answers to critical question 'a la minute'
- Obtaining objective evidence: effectiveness check of vendor deliverables
- Examining vendor deliverables against answers to diagnose compliance risks

Holly Baldwin, Manager, Quality Validation CSV, **Sanofi**

12:30-1:20 PM

TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND DIVERSITY AND INCLUSION PODCASTS

1:20-1:25 PM

Content Highlight *presented by :* Kneat

1:30-2:15 PM

LIVE

Evaluating the Intersection of QA and IT

Quality Assurance and Information Technology rely on good governance for successful execution. Come to this session to understand how you can bring the QA and IT policies and processes together to achieve and sustain reliable results.

- Align IT procedures based on a process model
- Add quality reviews to IT development and operations processes
- Implement quality cause investigation techniques in IT problem management process

Joanne Goldberg, Senior Principal IT Business Systems Analyst, **Medtronic**

2:15-2:25 PM	**NETWORKING AND HYDRATION BREAK**
2:25-3:10 PM	LIVE **Ensuring Data Integrity in Virtual Environments** • Explore new technologies in the life sciences industry • Discuss implementation of IT systems and potential control measures required • Analyze the reliability of tools in the virtual environment to ensure integrity of the data maintained by these systems • Evaluate techniques for optimizing CSV and data integrity *Chris Wubbolt, Principal,* **QACV Consulting**
3:15-3:20 PM	LIVE **Closing Remarks** *Elise Wyatt, Conference Producer,* **Informa Connect – IVT Network**

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IN-DEPTH, ON-DEMAND CONTENT — WHAT YOU WANT. WHEN YOU WANT IT.

There is much to experience and meet about at **Computer Systems Validation and Software Assurance Week.** On-Demand content is available anytime, to accommodate your needs and schedule.

Computer Systems Validation and Software Assurance 101

In this session, you will discover and discuss:

- How to perform software validation
- How to scale software validation
- How to implement and perform risk-based approach to software validation
- How to write validation plan/URS/FR/IOPQ/validation summary

Praveen Kalluri, Director, Quality Assurance – Computer System Validation, **PTC Therapeutics**

Navigating Excel Spreadsheet Validation

As part of Data Integrity assurance, regulators have focused on spreadsheets used to support quality regulated activity. This has resulted in observations, warnings and product recalls when the spreadsheets were not validated. This presentation focuses on the basics of spreadsheet validation and how to assure that your spreadsheet meets all data integrity requirements.

- What is validation?
- Why do we need to validate spreadsheets?
- Do we have to validate statistical software apps?
- When is validation required?
- How?
- Discuss the proper use of an unvalidated spreadsheet
- Review approaches to complying with 21 CFR 11

Clark Davies, Sr. Software Quality Engineer, **Abbott Nutrition**

Podcasts Exploring Industry Diversity, Inclusion and Equity

Discover IVT Network podcasts exploring diversity, inclusion and equity in the life sciences.

- Women in Science, Technology, Engineering and Mathematics – What's the real deal?
- Top 3 Trending Topics in Pharmaceuticals – Data Integrity, AI and Leadership
- Workplace Diversity and Gender Parity In Life Sciences

FDA Lifecycle Approach to Manufacturing Process Validation – Applications to CSV, Processes, Equipment and Quality Systems

- Review outline, definitions, and objectives
- Discuss the FDA lifecycle approach overview – Stages 1, 2, and 3
- Explore other processes, CSV, equipment, equipment systems, and quality systems
- Provide example applications
- Assess positives and negatives

Paul L. Pluta, Ph.D., Editor-in-Chief, ***Journal of Validation Technology*** *and* ***Journal of GXP Compliance,*** **Informa Connect**

Risk Management for Computerized System – From Vendor Selection to Retirement

- What is Risk Management?
  - In which parts of the lifecycle of a Computerized System does Risk Assessment play an important role?
  - What are the benefits of doing an efficient Risk Management for Computerized Systems?
  - How is Merck performing Risk Management for Computerized systems?
    * Risk-based Audit Planning for Computerized Systems
    * Risk Logs for Computerized Systems
    * Risk Based Computerized System Validation

Dr. Karoline Habermann, Quality Strategy Lead, Computerized Systems, **Merck KGaA, Darmstadt, Germany**

REGISTRATION

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Solution Providers/Consultants	$2199

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