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Norm Fjeldheim, Senior Vice President, Chief Information Officer and Global Head of Facilities, **Illumina**

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- Data Integrity and Compliance with Drug CGMP Final Guidance
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A LOOK AT THE **PAST 20+ YEARS**

of computer systems regulation and the milestones that came with it

1997
- **FDA** issues Title 21 CFR Final Part 11 regulations

2002
- **FDA** issues General Principles of Software Validation; Final Guidance for Industry and FDA Staff

2003
- **FDA** issues Guidance for Industry Part 11, Electronic Records: Electronic Signatures – Scope and Application

2007
- **FDA** issues the final version of Guidance for Industry Computerized Systems Used in Clinical Investigations

2011
- **EC** publishes last revision of EU Annex 11 to the GMPs on Computerised Systems

2016
- **World Health Organization** releases Final Guidance Document on Good Data and Record Management Practices

2018
- **FDA** releases Data Integrity and Compliance With Drug CGMP Questions and Answers Final Guidance for Industry
- **MHRA** releases Final 'GXP' Data Integrity Guidance and Definitions

2019
- **CDRH** slated to release Computer Software Assurance for Manufacturing, Operations and Quality Systems Software Draft Guidance
- **IVT** celebrates the **20TH ANNUAL CSV CONFERENCE**

Join Us for a Networking and Cocktail Reception at the Close of Day One to ***Celebrate 20 Years of CSV Excellence***

LEARN FROM THE INDUSTRY'S TOP EXPERTS


Jerry Anderson, Director, QA, **Ionis Pharmaceuticals**


Harsha Chulki, Head of Global IT Quality & CSV, **ICU Medical**


Paola DePaso, Director, Vault Quality, **Veeva Systems**


Denise Diehr-New, Validation Engineer III, **Hikma**


Norm Fjeldheim, SVP, CIO and Global Head of Facilities, **Illumina**


Michael Gameng, Associate Director, GxP Enterprise Applications, **MyoKardia**


Saurav Ghosh, Consulting Director, **NNIT**


Calvin Kim, GXP IT Compliance Manager, **Bayer**


David Liu, Associate Director, **Celgene**


Khaled Moussally, Head Quality Management Systems & Managing Partner, **Compliance Group**


Christine Foley Nash, Senior Manager, Validation, **Kedrion Biopharma Inc.**


Joe Pierce, Founder, CEO, **Endpoint Technologies**


Cynthia Pleach, Manager, Quality Assurance IT, **Sage Therapeutics**


Loan Quach, Senior Manager, Quality Management Services, **Box, Inc.**


Doug Shaw, CISA, Director of IT & CSV Consulting, **Azzur Group**


Ken Shitatmoto, MS, Senior Director, IT, **Gilead Sciences**


Lance Smith, IT Associate Director, **Celgene**


Raul Soto, Senior Principal Software Engineer, **Johnson & Johnson Vision Care**


Jason Spiegler, Senior Director, Industry Portfolio Development, **Siemens Product Lifecycle Management Software Inc.**


Chris Wubbolt, Principal, **QACV Consulting, LLC**


Jimmy Yeh, Validation Manager, Quality Management Services, **Box, Inc.**


Joseph Zec, Associate Director, CSV and Compliance, **Shire plc**

AGENDA AT A GLANCE

DAY ONE *Tuesday, April 23, 2019*

12:00	*Main Conference Registration*
1:00	*Chairperson's Welcome and Opening Remarks*
1:15	**CIO ADDRESS | Engaging Digital Transformation — Achieve Increased Collaboration through Innovations in Technology and Facility Design**
2:00	**NEWS FLASH** **Analyze FDA's Data Integrity and Compliance with Drug CGMP Final Guidance for Industry**
2:45	**CSV TRENDS ADDRESS** **Innovations in Technology, Regulatory Shifts and Navigating the Global Data Privacy Landscape**
3:30	*Networking and Refreshment Break*
4:00	**REGULATORY INSIGHT PANEL** **Game Changer! Update on FDA and Industry Collaboration on Computer Software Assurance**
4:45	**Validation for the Cloud — Using Agile and Automation to Meet Validation Requirements**
5:30	*Close of Day One and Networking Reception*

DAY TWO *Wednesday, April 24, 2019*

8:00	*Breakfast Buffet Opens*
8:30	**CHOOSE BETWEEN TWO EYE-OPENER BREAKFAST SESSIONS (A-B)**

A) Approach the Vendor Selection Process for Clinical Trials from a CSV Perspective — A Insights from a Virtual Pharma Company

B) Review 20 Years of e-Systems Compliance — Then and Now

9:30	**CHOOSE BETWEEN THREE EDUCATIONAL BREAKOUT SESSIONS (1-3)**

SESSION 1 — ADVANCED/LEADERSHIP

Building Collaborative Teams for Successful Validation

SESSION 2 — TECHNICAL PRACTICE

Computer System Validation Process Innovation in Molecular Diagnostics

SESSION 3 — IT/DATA MANAGEMENT

Utilize a Lifecycle and Risk-Based Approach to Streamline the CSV Process for Clinical Trial SaaS

10:30	*Networking and Refreshment Break*
11:00	**CHOOSE BETWEEN THREE EDUCATIONAL BREAKOUT SESSIONS (4-6)**

SESSION 4 — ADVANCED/LEADERSHIP

Master the Validation of Data Analytics Platforms, Programs and Data Infrastructure

SESSION 5 — TECHNICAL PRACTICE

Risk-Based Computer Systems Validation — A Holistic Model

SESSION 6 — IT/DATA MANAGEMENT

Bridging the Gaps in Data Integrity — Assess Risk to Streamline Audit Trail Review

12:30	*Networking Lunch*
1:30	**CHOOSE BETWEEN TWO INTERACTIVE WORKSHOPS (7-8)***

7) Cloud Computing and Cloud Validation Masterclass
*There will be a 30-minute refreshment break at 3:00

8) Managing Computer Systems Controls
*There will be a 30-minute refreshment break at 3:00

5:00	*Close of Day Two*

AGENDA AT A GLANCE

DAY THREE *Thursday, April 25, 2019*

8:30 *Breakfast Buffet Opens*

9:00 **CHOOSE BETWEEN THREE EDUCATIONAL BREAKOUT SESSIONS (9-11)**

SESSION 9 ADVANCED/LEADERSHIP

Advanced Collaborative Session — Strategies for Identifying and Procuring Resources to Meet CSV Business Needs

SESSION 10 TECHNICAL PRACTICE

Effective Risk Management in Validation

SESSION 11 IT/DATA MANAGEMENT

Implement or Migrate GXP Document and Quality Management Systems

10:30 *Networking and Refreshment Break*

11:00 **CHOOSE BETWEEN THREE EDUCATIONAL BREAKOUT SESSIONS (12-14)**

SESSION 12 ADVANCED/LEADERSHIP

SaaS Validation Roundtable — Navigating the Challenging Single and Multi-Tenant SaaS Landscape

SESSION 13 TECHNICAL PRACTICE

Prepare for FDA Audits and Inspections — The Ultimate CSV Handbook

SESSION 14 IT/DATA MANAGEMENT

Create Your Own Go-To Guide for GXP Systems Compliance — Documents, SOPs, Change Control and Audit Trails

12:30 *Networking Luncheon and Vendor Prize Drawing*

1:30 **TOWN HALL | Industry Benchmarking to Identify Gaps in Regulatory Guidance**

2:15 *Chairman's Closing Remarks*

2:30 *Close of Conference*

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DAY ONE TUESDAY, APRIL 23, 2019

12:00 *Main Conference Registration*

1:00 *Chairman's Welcome and Opening Remarks*
Harsha Chulki, Head of Global IT Quality & CSV, **ICU Medical**

1:15 **CIO ADDRESS | Engaging Digital Transformation — Achieve Increased Collaboration Through Innovations in Technology and Facility Design**

With a unique combination of responsibilities as Chief Information Officer and Global Head of Facilities, Norm Fjeldheim shares his experiences in IT infrastructure, facility design and project implementation. Discover how these advances streamline overall business efficiencies and specifically influence the responsibilities of validation, engineering, IT and quality teams.

- Digital transformation — Empowering customers, business and employees
- IT compliance challenges — Navigating risk-based validation, systems landscape and regulatory impact
- Validation maturity — Technology insights to enable validation scoping, tools to drive operational efficiencies and process maturity
- Case study — Paperless validation, value proposition, obvious efficiencies and hidden benefits
- Interactive audience Q&A

Norm Fjeldheim, Senior Vice President, Chief Information Officer and Global Head of Facilities, **Illumina**

2:00 **News Flash! Analyze FDA's Data Integrity and Compliance with Drug CGMP Final Guidance for Industry**

In December 2018, FDA released the long-anticipated final guidance – Data Integrity and Compliance with Drug CGMP: Questions and Answers. This session presents the main points that the guidance covers, and shares examples of how industry has implemented data integrity controls based on this guidance to date.

- Review FDA's Final GMP Data Integrity Guidance
- Identify differences between final and draft guidance documents
- Discuss new sections added to Final GMP Data Integrity Guidance
- Determine FDA's focus based on new guidance

Chris Wubbolt, Principal, **QACV Consulting, LLC**

2:45 **CSV TRENDS ADDRESS**
Innovations in Technology, Regulatory Shifts and Navigating the Global Data Privacy Landscape

Life sciences organizations have already embarked on their journey to go digital and embrace the cloud. There is also an increasing trend of mergers and acquisitions taking place within the industry. These industry shifts pose a unique situation for the CSV and data integrity functions as they manage rapid movement and transformation of GXP data and systems. How will you keep pace with the innovation and remain compliant?

- Review the current industry trends that are impacting computer systems validation
- Discover the potential of Robotic Process Automation (RPA) in transforming testing and qualification processes
- Learn how to migrate a GXP system in a compliant manner
- Identify ways to establish a CSV maturity model within your organization using KPIs and metrics

Saurav Ghosh, Consulting Director, **NNIT**

3:30 *Networking and Refreshment Break*

4:00 **REGULATORY INSIGHT PANEL**
Game Changer! Update on FDA and Industry Collaboration on Computer Software Assurance

As the CDRH announced in their FY 2019 Proposed Guidance Development list, a Computer Software Assurance for Manufacturing, Operations, and Quality System Software draft guidance is slated to be released. In this session, hear from members of the FDA/Industry collaborative team on the scope of what this guidance may entail.

- Discuss industry recommendations for anticipated FDA draft guidance
- Hear success stories of ERP and laboratory software remediation
- Analyze the challenges and solutions to automating non-product CSV

Khaled Moussally, Head Quality Management Systems & Managing Partner, **Compliance Group**
Jason Spiegler, Senior Director, Industry Portfolio Development, **Siemens Product Lifecycle Management Software Inc.**

4:45 **Validation for the Cloud — Using Agile and Automation to Meet Validation Requirements**

Cloud services and agile software development can provide many advantages to businesses but present new challenges to software validation and GxP compliance. As both a cloud service provider and a user of agile, Box developed a validation approach with embedded quality that helps overcome these challenges while increasing validation efficiency. This session highlights this validation approach, applying agile and automation to product artifacts meeting validation requirements and industry best practices.

- Agile methodology
- Box validation approach
- Considerations when evaluating a cloud product
- Answer top questions/concerns

Loan Quach, Senior Manager, Quality Management Services, **Box, Inc.**
Jimmy Yeh, Validation Manager, Quality Management Services, **Box, Inc.**

5:30 *Close of Day One*

Please Join Us for a **Networking, Wine and Cheese Reception**
Immediately Following the Close of Day One

DAY TWO WEDNESDAY, APRIL 24, 2019

8:00 *Breakfast Buffet Opens*

8:30 CHOOSE BETWEEN TWO EYE-OPENER BREAKFAST SESSIONS (A-B)

A Approach the Vendor Selection Process for Clinical Trials from a CSV Perspective — Insights from a Virtual Pharma Company

This presentation reviews the vendor selection process for clinical trials from a small- to medium-sized virtual pharma company perspective, specifically focusing on CSV and systems. In this fast-paced environment, timelines are pushed and accelerated if positive results are generated from clinical trials. This is a dynamic landscape and from a CSV perspective, it is important to understand how to remain agile and adapt.

- Learn how to make CSV for clinical systems a business priority
- Share top tips for navigating the vendor selection process — What to look for and what are the red flags
- Review the post-trial data exportation process and know what should be included (audit trail, metadata, etc.)

Michael Gameng, Associate Director, GxP Enterprise Applications, **MyoKardia**

B Review 20 Years of e-Systems Compliance — Then and Now

With the advent of new technologies and working models, such as the use of third-party "as-a-service" providers, the selection, validation, implementation and use of computerized systems has changed significantly over the years. However, the regulatory requirements for computerized systems and electronic records have remained the same.

In fact, due to their impact on data integrity, the focus on computerized systems and electronic records has increased.

- Compare how we used to implement, validate and use computerized systems to current practices today
- Highlight the benefits of the new processes and methodologies, but also the areas of increased risk
- Review regulatory findings related to computerized systems then and now

Chris Wubbolt, Principal, **QACV Consulting, LLC**

9:30 CHOOSE BETWEEN THREE EDUCATIONAL BREAKOUT SESSIONS (1-3)

1 Building Collaborative Teams for Successful Validation

ADVANCED/LEADERSHIP

This session focuses on defining how both the company and the software partner can work together to ensure a successful and efficient validation. Often the activities of validation are relegated completely internally or outsourced. The ultimate validation plan should be dynamic and flexible and designed to take advantage of the talent and resources of both companies.

- Common structure of validation projects
- Appropriate activities for the software vendor
- Assess options for separating roles and tasks within a validation project
- How business expertise and software expertise impact validation activities
- Long-term planning to maintain a validated system

Joe Pierce, Founder, CEO, **Endpoint Technologies**

2 Computer System Validation Process Innovation in Molecular Diagnostics

TECHNICAL PRACTICE

This case study provides insight on how to respond to the increasing regulatory oversight by implementing a new and innovative computer system validation and change management program.

- Perform a 360-degree review of all GXP testing processes, with the goal to make them best in class
- Re-engineer the CSV process and transition to a fully streamlined, compliant, end-to-end electronic system
- Improve ability to manage validation activities, address compliance responsibilities, cut cycle times and increase productivity
- Discuss the journey and the rewarding outcomes for implementing a paperless validation solution for CSV
- Achieve a lean and repeatable process that delivers productivity, cycle time, compliance and data integrity benefits

Lou Killian, Director, Customer Success, **Kneat Solutions**
Shane Pew, Director of Quality Assurance, **Myriad Genetics**

3 Utilize a Lifecycle and Risk-Based Approach to Streamline the CSV Process for Clinical Trial SaaS

IT/DATA MANAGEMENT

This presentation brings attendees through the process of implementing a clinical system from vendor auditing to configuration, platform validation, study validation and maintenance phases, with a focus on achieving inspection-readiness using an efficient approach.

I. Maximize Benefits of a SaaS Solution

- Predict and remediate compliance gaps, too much testing and unexpected delays
- How to best leverage vendor software platforms when testing evidence
- Understand how data integrity controls are shared between the software vendor and the end user
- Work with vendor to apply best SDLC practices

II. Implement a Risk-Based Methodology for Validating a Clinical SaaS System

- Audit checklist and tips for crafting a quality agreement with your software vendor
- SOP considerations for onboarding and maintaining a clinical SaaS solution
- Explore common challenges and remediation planning

III. Guide Your Organization Through the Implementation Process While Assuring Regulations Are Met

- Clinical system inspection readiness steps
- Define and test intended use and appropriate data integrity controls during validation
- Leverage third-party configuration partner deliverables
- 'Connecting the dots' from vendor software testing to platform validation to study validation

Doug Shaw, CISA, Director of IT & CSV Consulting, **Azzur Group**
Shana Kinney, Senior Manager, Computer Systems Validation, **REGENXBIO Inc.**

10:30 *Networking and Refreshment Break*

11:00 CHOOSE BETWEEN THREE EDUCATIONAL BREAKOUT SESSIONS (4-6)

4 Master the Validation of Data Analytics Platforms, Programs and Data Infrastructure

ADVANCED/LEADERSHIP

In this session, participants learn how to use a Systems Development Lifecycle (SDLC) approach to successfully validate data analytics software platforms, programs, and their underlying infrastructure, for use in GXP regulated environments.

I. Setting the Stage
- Identify which validation documents you need
- Translate your intended use into use cases and user requirement specifications that are effective and testable

II. How to Test the Various Components of a Data Analytics Ecosystem
- Software platforms like SAS, Cognos, BusinessObjects and Tableau
- Reports and dashboards
- Extract, transform and load programs
- Trending and statistical analysis programs

III. Determine What Types of Assessments You Need
- Compliance, risk, data integrity, electronic records, signatures, etc.

IV. How to Maintain Your System's Validated State After Go-Live
- Change control process
- Periodic review
- Inventory of validated programs

Raul Soto, Senior Principal Software Engineer, **Johnson & Johnson Vision Care**

5 Risk-Based Computer Systems Validation — A Holistic Model

TECHNICAL PRACTICE

I. Background
- Brief overview of current state issues
- Brief normalization on risk models
- High-level overview of system-level risk, SQA and non-product CSV

II. System-Level Risk (SLR)
- Overview of the SLR model
- Engage in a detailed discussion with examples for each parameter of SLR, including, what it is and how to calculate it
  - * complexity score
  - * distribution score
  - * functionality score
  - * GXP record criticality
- How to calibrate SLR scores for your organization
- How to apply SLR to determine deliverables/activities based on SLR

III. Leveraging Software Quality Assurance (SQA)
- Overview of software quality assurance
- Discussion regarding the differences between and advantages of SQA over validation
- Process requirements for SQA (quality of deliverables, etc.)
- Model for leveraging SLR and SQA in validation
- Automation and SQA — The impact to validation

IV. Non-Product CSV
- Overview of non-product CSV model
- Understanding basic assurance, unscripted testing, limited scripted testing and robust scripted testing
- Introduction of functional assurance
- Walk-through of empirical data derived from the application of the model to multiple systems

V. Interactive Exercise
Using a real-life example, participants apply the non-product CSV model. Interactive discussion provides participants with the opportunity to fully understand the model.

BONUS MATERIAL
- Reference tables for calculating SLR
- Reference tables for non-product CSV

Ken Shitamoto, MS, Senior Director, IT, **Gilead Sciences**

6 Bridging the Gaps in Data Integrity — Assess Risk to Streamline Audit Trail Review

IT/DATA MANAGEMENT

I. Define Data Integrity and Audit Trail Review
- What is data integrity?
- What is audit trail review?
- Data integrity and audit trail review symbiosis
- What are the regulations?
- Utilize a two branch audit trail review strategy

II. Understand Industry Guidelines
- What systems do the regulations refer to?
- How often do audit trails need to be reviewed?
- What do we look at?
- Who should do the review?
- When should audit trail reviews be performed?

III. Develop a Risk-Based Approach (RBA) — Know Your System and How Data Integrity Relates to It
- Understand why a RBA should be developed
- What are the risk considerations?
- Evaluate risk for high-risk systems
- Evaluate risk for low-risk systems

IV. Interactive Exercise
As a group, participants assess the risk for common GxP systems (LIMS, Documentum, change control, MES, LMS).

V. Effectively Implement an Audit Trail Review Process
- Conduct a gap assessment
- Develop remediation activities (CAPA)
- Implement an audit trail review process — SOPs, application administration plans, training, etc.
- Challenges
- Frequently asked questions

Denise Diehr-New, Validation Engineer III, **Hikma**

12:30 *Networking Luncheon*

DAY TWO WEDNESDAY, APRIL 24, 2019

1:30 CHOOSE BETWEEN TWO INTERACTIVE WORKSHOPS (7-8)*

7 Cloud Computing and Cloud Validation Masterclass

Workshop Objective:
In this 101-level workshop, participants compare and contrast the different types of cloud environments used in biopharma and medical device manufacturing, and learn how to maintain quality and data integrity in the cloud.

I. Evaluate the Different Cloud Environments
- IaaS vs. PaaS vs. SaaS
- True Software as a Service (SaaS) environment and vendor assessment
- Hosted environment and cloud washing
- SaaS software integration considerations
- Staffing skill sets

II. Manage Quality and Data Integrity in the Cloud
- Data integrity and transfer issues
- Security department concerns
- Legal and privacy requirements
- Automated compliance documentation
- Collaboration with Quality and IT teams
- Working with vendors

III. Case Study
- Gain lessons learned from Celgene's migration to AWS Cloud and Medidata

IV. Interactive Audience Q&A
Participants partake in engaging discussion regarding their projects and concerns. Both technical and organizational topics will be covered and participants are encouraged to raise their systems for conversation.

Workshop Leaders
Lance Smith, IT Associate Director, **Celgene**
David Liu, Associate Director, **Celgene**
**There will be a 30-minute refreshment break at approximately 3:00*

8 Managing Computer Systems Controls

Workshop Objective:
Participants learn how to create appropriate processes and collaborate with vendors to ensure the overall quality of computer systems controls.

I. Identify Controls
- How do computer system controls differ from quality controls?
- Prepare SOPs and processes for managing controls

II. Create a Data Flow Diagram and Assess Risks
- Evaluate data flow patterns to develop a diagram that suits your organization's process
- Conduct a risk assessment based on the gap analysis

III. Reconcile the Computer Systems Lifecycle with the Data Lifecycle
- Develop SOPs to monitor the data lifecycle
- Identify gaps in data integrity throughout the computer system and create a remediation plan

IV. Collaborate with Vendors to Manage Controls
- Share proven strategies for vendor quality oversight processes
- Know where the responsibility of the manufacturer lies vs. where the responsibility of the vendor lies

V. Interactive Exercise
Participants separate into groups based on particular challenge areas and develop an action plan for systems control management.

Workshop Leaders
Calvin Kim, GXP IT Compliance Manager, **Bayer**
Chris Wubbolt, Principal, **QACV Consulting, LLC**
**There will be a 30-minute refreshment break at approximately 3:00*

5:00 *Close of Day Two*

DID YOU KNOW?

IVT Network also publishes two bi-monthly peer-reviewed journals and over 160 training products which can be found on www.ivtnetwork.com. All IVT Network conference attendees receive a **7-day free trial** and 10% off their membership fee! **Want to know more?** Contact Sean Parkman at **sean.parkman@ivtnetwork.com** or by phone **339-298-2143.**

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- Advanced/Leadership Track
- Technical Practice Track
- IT/Data Management Track

DAY THREE THURSDAY, APRIL 25, 2019

8:30 *Breakfast Buffet Opens*

9:00 CHOOSE BETWEEN THREE EDUCATIONAL BREAKOUT SESSIONS (9-11)

9 Advanced Collaborative Session — Strategies for Identifying and Procuring Resources to Meet CSV Business Needs

ADVANCED/LEADERSHIP

In this advanced collaborative, senior-level professionals engage in open discussions around managing CSV and IT teams, adapting to the changing regulatory environment and ensuring teams have the resources they need. Topics of discussion may include:

- How do you balance getting products to market as quickly as possible with maintaining excellent quality standards?
- Understand the resources your team needs to be successful
- Identify and overcome roadblocks to new technology implementation
- Embrace the key differentiators — Strong systems, collaboration and good people

Harsha Chulki, Head of Global IT Quality & CSV, **ICU Medical**

10 Effective Risk Management in Validation

TECHNICAL PRACTICE

Regulators have historically suggested that industry take a risk-based approach to compliance. Guidance indicated that the preferred approach was to base the rigor of validations and other regulatory compliance issues on a documented and justified risk assessment. So, what does this mean in practice? This session presents a practical approach to incorporating risk management activities into the validation lifecycle. Topics of discussion may include:

- Performing risk assessments at the start of the validation process
- Performing risk assessments and risk control during the validation process
- Suggestions for tailoring the validation process based on risk
- Performing risk review after the validation process
- The role of risk management during change control

Joseph Zec, Associate Director, CSV and Compliance, **Shire plc**

11 Implement or Migrate GXP Document and Quality Management Systems

IT/DATA MANAGEMENT

Whether you're going from pure paper to your first electronic system or upgrading/migrating to a new electronic system, there are many important decisions to make and considerations to plan for.

I. The Basics

- General requirements for a controlled document management system
- General requirements for a quality management system
- Mistakes that can lead to observations from FDA
- Collaborative authoring/review vs. approvals
- Challenges with a paper-based system

II. How to Pick an Application

- Start with determining requirements and process reengineering
- Can we use SharePoint?
- Off-the-shelf vs. configured applications
- Document change control and document approvals
- Read and understand training capability
- Best of breed or multi-application platform?

III. Implementation Considerations

- Project planning and resourcing
- Vetting by business stakeholders
- Validation, vendor qualification and 21 CFR Part 11
- Data importing/data migration — What's important?
- Administration, continuity and availability

IV. Case study

- Moving from separate premise-based EDMS and QMS systems to an integrated platform in "the cloud"

BONUS MATERIAL

- Audit checklists for software vendors and application service providers

Jerry Anderson, Director, Quality Assurance, **Ionis Pharmaceuticals**
Paola DePaso, Director, Vault Quality, **Veeva Systems**

10:30 *Networking and Refreshment Break*

11:00 CHOOSE BETWEEN THREE EDUCATIONAL BREAKOUT SESSIONS (12-14)

12 SaaS Validation Roundtable — Navigating the Challenging Single and Multi-Tenant SaaS Landscape

ADVANCED/LEADERSHIP

What exactly is SaaS? What is the risk of changing to a SaaS model? How does it impact the validation process? If you are thinking about changing to SaaS or struggling with implementing SaaS, join this roundtable to share experiences and hear from others.

I. Software as a Service

- Definition
- Delivery options
  - on premise
  - single tenant
  - multi-tenant
  - third-party implementation
- Risks

II. Impact to Validation and Supporting Processes

- Validation process — Who does what?
- Validation documentation — Who writes? Who approves? Where is it kept?
- Backup/recovery — Ensure their process meets your needs
- Change control — Who owns it? When do you get pre-approval?
- Vendor management
- Periodic review
- Service contracts
- Documentation control

III. What to Do? What Not to Do?

Participants exchange lessons learned and discuss best practices for moving to a SaaS model.

Cynthia Pleach, Manager, Quality Assurance IT, **Sage Therapeutics**

DAY THREE THURSDAY, APRIL 25, 2019

13 Prepare for FDA Audits and Inspections — The Ultimate CSV Handbook

TECHNICAL PRACTICE

I. Understand the Key Topics in CSV

- Discuss the regulatory focus on CSV and data integrity
- Conduct a validation applicability assessment for systems
- Facilitate a 21 CFR Part 11 regulatory requirement assessment — Security, data integrity, audit trail and e-signature
- Data integrity assessment including data flow and data lifecycle
- Critical thinking...A lost art in risk-based approach to CSV and system lifecycle?
- Periodic review of risk management
- Emphasis on risk management strategy — Is testing overrated?

II. A Practical Implementation of Risk-Based Computerized System Validation

- Common CSV/IT supplier audit scope and findings
- Assess and mitigate supplier risks in quality clauses in contractual clauses
- Risk mitigation strategy — Technical and procedural controls
- Review an example of a typical risk assessment practice
- Case studies — CSV pitfalls (validation don'ts and more don'ts)

III. Interactive Exercise — Knowledge Exchange

This session engages participants with real-life examples of relevant inspection/audit findings in computerized system development (IT supplier) and validation (vendor) practices, to drive emphasis on critical thinking aspects of risk management in computerized system validation. Through facilitated interactive discussions, attendees take part in a round-the-room survey of challenges and strategies for risk-based approach to validation activities.

Calvin Kim, GXP IT Compliance Manager, **Bayer**

14 Create Your Own Go-To Guide for GXP Systems Compliance — Documents, SOPs, Change Control and Audit Trails

IT/DATA MANAGEMENT

I. Overview

- What is needed?
- Why is this needed?
- Benefits of performing GXP system compliance

II. Document Lifecycle

- Flow of required documents
- Description of each type of document
  - how the document is used
  - timing of document in lifecycle
  - who prepares the document
  - who approves the document

III. Interactive Exercise — A Day in the Life

Participants work together to outline required documentation for a real-life systems compliance project.

Bonus Material

- A list of FDA guidance documents with location
- A checklist guide for GXP Systems compliance lifecycle

Christine Foley Nash, Senior Manager, Validation, **Kedrion Biopharma Inc.**

12:30 *Networking Luncheon and Vendor Prize Drawing*

TOWN HALL

1:30 **Industry Benchmarking to Identify Gaps in Regulatory Guidance**

As technology continues to advance rapidly, the industry needs guidance from regulators in order to appropriately validate computer systems and remain compliant. In this exclusive live benchmarking session, participants have the opportunity to detemine where the gaps in guidance exist and discuss recommendations for FDA and other regulators to focus attention on in 2019.

Joseph Zec, Associate Director, CSV and Compliance, **Shire plc**

2:15 *Chairman's* Closing Remarks
Harsha Chulki, Head of Global IT Quality & CSV, **ICU Medical**

2:30 *Close of Conference*

REGISTRATION

PI19045

REGISTRATION FEE:

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PLEASE NOTE:
All advertised discounts are taken from the final, Standard Rate.

CHOOSE BREAKOUT SESSIONS:

WEDNESDAY, APRIL 24, 2019

8:30–9:30	A	B	
9:30–10:30	1	2	3
11:00–12:30	4	5	6
1:00–5:00	7	8	

THURSDAY, APRIL 25, 2019

9:00–10:30	9	10	11
11:00–12:30	12	13	14

VENUE

Hyatt Regency La Jolla at Aventine
3777 La Jolla Village Drive
San Diego, California 92122
Reservations: (800) 323-7249
Hotel Phone: (858) 552-1234

SUBSTITUTION & CANCELLATION

Your registration may be transferred to a member of your organization up to 24 hours in advance of the conference. All cancellations received in writing on or before 14 days prior to the start date of the event will be refunded, less a $499 administrative charge. No refunds will be made after this date; however, the registration fee less the $499 administrative charge can be credited to another CBI conference if you register within 30 days from the date of this conference to an alternative CBI conference scheduled within the next six months. In case of conference cancellation, CBI's liability is limited to refund of the conference registration fee only. Cancellation of a conference due to events beyond our control* are subject to a $499 administrative charge should you or a colleague be unable to attend the rescheduled date. CBI reserves the right to alter this program without prior notice. Please Note: Speakers and agenda are subject to change. In the event of a speaker cancellation, every effort to find a suitable replacement will be made. The opinions of the conference faculty do not necessarily reflect those of the companies they represent or CBI.

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ACCOMMODATIONS

To receive IVT's special discounted hotel rate: Online: **cbinet.com/csv**
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Book Now! The **Hyatt Regency La Jolla at Aventine** is accepting reservations on a space and rate availability basis. Rooms are limited so please book early. All travel arrangements subject to availability.

PLEASE NOTE: All hotel reservations for this conference should be booked directly with the hotel. IVT does not use Housing Bureaus and none are authorized to call on our behalf.

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Looking to bring your team?
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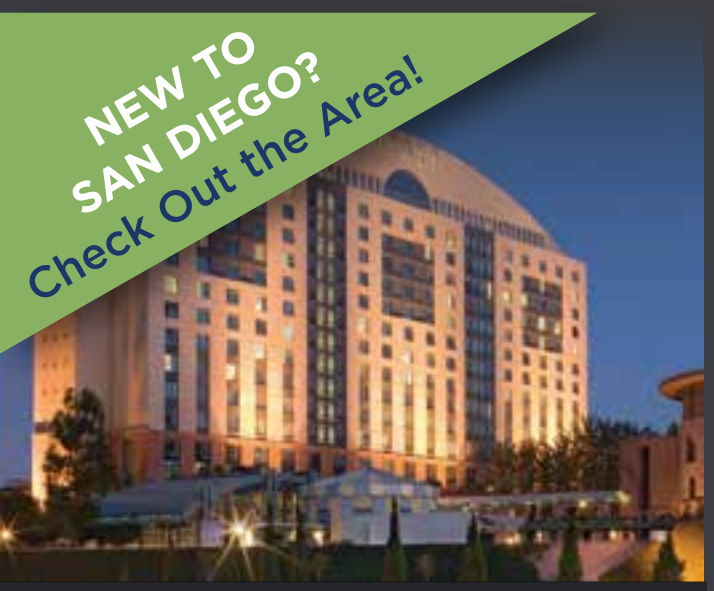

Located just 15 minutes from downtown San Diego, Hyatt Regency La Jolla at Aventine is a haven for activities along the coast.

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