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IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
UBM IVT, a division of UBM Life Sciences

Computer and Software Validation

Risk-based CSV • Mobile Devices and Apps • Cloud Qualification • Data Integrity

1-3 DECEMBER 2015 • DOUBLETREE BY HILTON AMSTERDAM CENTRAAL STATION • AMSTERDAM, THE NETHERLANDS

ELITE INDUSTRY PERSPECTIVES FROM:

- Jerry Anderson, Director, Quality Assurance & Compliance, **Isis Pharmaceuticals**
- Joe Fraser, Director of IS Internal Control and Compliance North and South America, **Sanofi**
- Shelley Gutt, BSc, Senior Manager, IT Quality, **Covance Inc.**
- Ludwig Huber, Ph.D., Director, **Labcompliance**
- Abhinaya R, Head – Validation Services, **Zifo Compliance Services**
- Ivan Soto, Director QA Validation, **Alexion Pharmaceuticals**
- Raul Soto, MSc, BsME, CQE, Principal Engineer, **Johnson & Johnson Vision Care**
- Siegfried Schmitt, Ph.D., Principal Consultant, **PAREXEL International**
- Debbie Turner, Associate Director, Validation, **Alkermes**
- Andy Tyrrell, BSc, ACA, CISA, CISSP, Senior IT Manager, Global Information Security & Risk Management, **Covance Inc.**
- Chris Wubbolt, BS, MS, Principal Consultant, **QACV Consulting**

CHOOSE FROM **25 WORKSHOPS, PLENARY AND EXPANDED SESSIONS** INCLUDING:

- Data Integrity Governance
- Identify Network Security Gaps
- Guidance for IT Outsourced Cloud Computing
- Conduct an Audit of Your CSV Program
- Develop a Validation Maturity Model (VMM) for Your Organisation
- A Risk-based Approach to Audit Trails
- Change Control and Configuration Management
- Keep CSV Costs Down While Increasing Quality Care
- The Quality Risk Management Continuum for Automated Systems
- A Risk-based Lifecycle Approach to Software Development, Testing and Validation

...AND MUCH MORE!

PLUS! CHOOSE BETWEEN THREE IN-CONFERENCE WORKSHOPS

Risk-based Computer System Validation

Spreadsheet Validation 101

Network Infrastructure Qualification

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DAY ONE TUESDAY, 1 DECEMBER 2015

12:00 *Conference Registration*

13:15 *Chairman's Welcome & Opening Remarks*

Joe Fraser, Director of IS Internal Control and Compliance North and South America, **Sanofi**

13:30 FDA, EU and Global Guidance for CSV, Data Integrity, Cloud Computing and Mobile Applications

- Industry expectations vs. the regulatory view for cloud computing
- FDA guidance for mobile applications
- Recent guidances and inspection issues addressing data integrity
- Remaining issues with the PIC/S-EU GMP Annex 11 implementation
- Increasing importance of product and service providers for compliance

Bonus Material

- SOP: Using Cloud Computing in Regulated Environments
- SOP: Integrity and Security of Electronic Records

Ludwig Huber, Ph.D., Director, **Labcompliance**

14:15 Data Integrity Governance — How to Get Your Company to Embrace Data Integrity

- Governance — Determining and understanding the term and terminology — We need to speak the same language across all levels in the organisation
- Data Integrity governance — The regulators' expectations — What is it that they want to see; what's new?
- Making DI governance happen — Based on real examples, what works and what doesn't?
- Measuring success — How to make sure your DI governance is working — Don't leave it to the inspectors to tell you!

Bonus Material

- Extracts from key documents on the subject of DI governance

Siegfried Schmitt, Ph.D., Principal Consultant, **PAREXEL International**

15:00 *Networking & Refreshment Break*

15:30 Identify Network Security Gaps — Why and How?

- Understand the threat landscape
- Learn about key network security controls
- Evaluate approaches to uncovering gaps in security
- Learn the importance of continuous monitoring

Bonus Material

- Glossary of terms
- Sample network security audit program

Andy Tyrrell, BSc, ACA, CISA, CISSP, Senior IT Manager, Global Information Security & Risk Management, **Covance Inc.**

16:15 Avoid CSV Pitfalls by Knowing Warnings from the FDA — Overcome CSV's Top Challenges

- Review of excerpts from recent warning letters
- Discuss the available validation/ compliance guidance
- Develop an attack plan for quickly identifying your biggest compliance gaps

Jerry Anderson, Director, Quality Assurance & Compliance, **Isis Pharmaceuticals**

17:00 *Close of Day One*

Networking, Wine and Cheese Reception

immediately following the final session on day one

DAY TWO WEDNESDAY, 2 DECEMBER 2015

7:30 CONTINENTAL BREAKFAST

7:30 **CHOOSE BETWEEN TWO EYE-OPENER BREAKFAST DISCUSSIONS**

1. **Understand CSV User Requirements**
   Andy Tyrrell, BSc, ACA, CISA, CISSP, Senior IT Manager, Global Information Security & Risk Management, **Covance Inc.**

2. **The Quality Risk Management (QRM) Continuum for Automated Systems**
   Siegfried Schmitt, Ph.D., Principal Consultant, **PAREXEL International**

8:30 CHOOSE FROM THREE INTERACTIVE WORKSHOPS (A-C)

WORKSHOP A Develop, Implement and Maintain a Risk-Based CSV Program

I. Document Your CSV Quality System

- Ensure alignment with your Corp Quality System(s) (Directives, Standards, etc.)
- Define the scope
- Detail the responsibilities
- Define the organisational details
- Document the CSV quality system requirements
- Detail the documentation roadmap
- Define how the program is maintained

II. Defining the Lifecycle Approach

- Performing a system criticality assessment
- Determine scope based on functional risk and system criticality
- Determining the lifecycle documents required
- Determining the level of detail for each lifecycle document
- Understanding the relationship between lifecycle documents
- Establish the lifecycle management (during design, build, validation and post go-live)

III. Interactive Exercise

- Define the level of control required dependent upon the system criticality and risk

Using two system criticality scenarios (GxP Critical and Non-GxP Systems) define the System Lifecycle approach to follow in order to implement and maintain the systems efficiently and in a compliant manner.

Joe Fraser, Director of IS Internal Control and Compliance North and South America, **Sanofi**

WORKSHOP B Spreadsheet Validation 101 — Create and Validate FDA-Compliant Excel Spreadsheets

I. **Regulatory Agency Expectations**
- ISPE's GAMP™ software categorisation
- Infrastructure qualification
- Spreadsheet utilisation to determine GxP risk
- Regulatory and inspection risk

II. **Single-Use Spreadsheets**
- Verification of data and calculations

III. **Multiple-Use Spreadsheet Templates**
- Steps to validate multi-use spreadsheets
- Controls for storage and use
- Controls for changing validated spreadsheets over time

IV. **Data Storage Spreadsheets**
- Spreadsheets that simply track data, e.g., issuance of unique numbers
- Spreadsheets that derive and store data over time

Jerry Anderson, Director, Quality Assurance & Compliance, **Isis Pharmaceuticals**

WORKSHOP C Effective Strategies to Validate Mobile Devices and Software Applications

I. **Introduction**
- ALCOA +
- Major regulatory guidelines
  * USA * Global

II. **Types of Mobile Apps**
- Informational apps
- Apps that support GxP operations or quality systems
- Apps that are considered medical devices
- Data integrity challenges for mobile apps and devices

III. **Informational Apps**
- Examples
- Applicable regulations

IV. **Apps that Support GxP Operations and Quality Systems**
- Examples
- Applicable regulations
- Mobility-specific issues for validation
- Thin vs. thick clients

V. **Apps That Are Considered Medical Devices**
- Examples
- Is your mobile app or device a "medical device"?
- Applicable regulations
- Design control and design review
- Remote access

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

There will be a 30-minute networking and refreshment break at 10:00am

12:00 NETWORKING LUNCHEON

13:30 CHOOSE BETWEEN THREE 90-MINUTE SESSIONS (1-3)

SESSION 1 Senior-level Think Tank — Strategies for the Advanced Computer and Software Validation (CSV) Professional

In this closed-door summit, senior level computer validation and quality managers from pharmaceutical, biotech and medical device companies engage in open discussions with their colleagues about strategies for managing their most pressing challenges. The content for the summit is driven by the participants, who are surveyed ahead of time about the topics they wish to discuss.

This session is open to the first twenty senior-level professionals who pre-register for the interactive discussion group. In order to pre-register, you must have over 5-years of experience in CSV execution and currently work for a pharmaceutical, medical device or biotech company.

IVT reserves the right to qualify participants for the workshop.

Debbie Turner, Associate Director, Validation, **Alkermes**

SESSION 2 Guidance for IT Outsourced Cloud Computing and Data Integrity

I. **Understand Data Integrity Requirements and Expectations**
- Review applicable regulatory requirements
- Review record integrity controls
- Provide an overview of how record integrity risks should be managed to comply with regulations

II. **Discuss Challenges When Outsourcing to the Cloud**
- Cloud record integrity challenges
- Record availability
- Record retention

III. **Demonstrate Compliance in a Cloud Environment**
- Continuous monitoring for compliance
- Provide evidence of compliance

Bonus Material
- Considerations for outsourced cloud computing

Chris Wubbolt, BS, MS, Principal Consultant, **QACV Consulting**

SESSION 3 Conduct an Audit of Your CSV Program — A Global Policies and Standards Approach

I. **Strategies Needed for Performing an Audit of Your CSV Global Program**
- Learn what are the applicable global requirements
- Understand applicable requirements and how they impact your global CSV program
- Learn the tools needed to perform an audit of your CSV global program

II. **Perform an Audit of Your Global CSV Program**
- Create a gap assessment tool to perform the audit
- Use the gap assessment tool to perform the audit
- Learn the outputs from performing an audit of your global CSV program

III. **Use the Outputs from the Audit to Improve Your Global CSV Program**
- Formally document and track all gaps in a quality system
- Create a remediation plan
- Close all the gaps in your global CSV policies and standards

Ivan Soto, Director QA Validation, **Alexion Pharmaceuticals**

15:00 NETWORKING AND REFRESHMENT BREAK

15:30 CHOOSE BETWEEN THREE 90-MINUTE SESSIONS (4-6)

SESSION 4 A Risk-based Lifecycle Approach to Software Development, Testing and Validation

I. **The Software Development Lifecycle**
- Lifecycle phases
- Development models, controls and testing

II. **System Validation Overview**
- The goals of validation
- The "validated state"
- Validation models
- Validation throughout the lifecycle

III. **Taking the Risk-based Road**
- Weighing risk
- Levels of risk
- System vs. requirement risk
- What about COTS
- Right-sizing validation

IV. **Interactive Exercise**

Participants evaluate different system development efforts and learn to create appropriate validation strategies.

Bonus Material
- Validation deliverables for each development phase

Shelley Gutt, BSc, Senior Manager, IT Quality, **Covance Inc.**

SESSION 5 Perform Data Integrity Assessments — A Practical Approach

I. **Prepare for DI Assessments — How to Get Started**
- Assessment standards
- Assessment teams
- Scoping

II. **Executing the DI Assessments — Let's Get Going**
- On-site assessments
- Remote assessments
- Piloting
- Maintenance phase assessments
- Follow-up assessments

III. **Documenting DI Assessments — How to Document, What to Document, Who to Report to and What to Do with the Data**
- Recording observations
- Repositories
- Diagnostic tools
- Project files
- Trending
- Reporting

Siegfried Schmitt, Ph.D., Principal Consultant, **PAREXEL International**

SESSION 6 Network Infrastructure Qualification

I. **A Brief History and What Regulatory Agencies Expect**
- When warning letters are issued, the industry reacts
- A repeat of the "what do we do?" cycle for computer compliance changes
- Stated expectations of regulatory agencies — FDA, EMA, Japan's PMDA, Health Canada
- Network infrastructure's role continues to grow
- Today's GxP risk and inspection risk

II. **Why Infrastructure Qualification Is Important — And Not Just to Regulators**
- The limitations of application validation
- You, your data, your network and the second law of thermodynamics
- Bad stuff happens… and so do bad guys
- The costs and benefits of qualification

III. **What Should Be Qualified?**
- A risk-based look at IT infrastructure's impact on GxP applications
- Understanding the risk associated with various network services
- What shouldn't be qualified?

IV. **Approaches to Infrastructure Qualification**
- How "computery" is your company, how much do you leverage infrastructure and what are your resources?
- GAMP's guidance
- A quality management system for IT
- Involvement of the quality unit
- Targeted full qualification

V. **Interactive Exercise — Approach for Your Company**

Attendees should bring a list of the IT network infrastructure items their company uses for GxP purposes. The group works together on developing a risk- and resource-based approach for increasing confidence in their infrastructure and reducing compliance risk.

Jerry Anderson, Director, Quality Assurance & Compliance, **Isis Pharmaceuticals**

17:00 CLOSE OF DAY TWO

DAY THREE THURSDAY, 3 DECEMBER 2015

7:30 CONTINENTAL BREAKFAST

7:30 **EYE-OPENER BREAKFAST DISCUSSION**

Develop, Implement and Maintain a CSV Program Globally — A Case Study
Abhinaya R, Head – Validation Services, **Zifo Compliance Services**

8:00 CHOOSE BETWEEN THREE 90-MINUTE SESSIONS (7-9)

SESSION 7 A Risk-based Approach to Audit Trails

I. **Auditable Records Review**
- What is an auditable electronic record?
- The fundamental purpose of an audit trail
- Requirements of an audit trail
- Data integrity and audit trails
- Common sense and storage capacity

II. **Risk-based vs. "Risky"**
- What is a risk-based approach?
- What does the FDA say about risk?
- Weighing the risks
- Roles and responsibilities for risk assessment

III. **Analysis and documentation**
- The power of simple
- Categories of risk
- Risk analysis tools
- Strike a balance
- High impact vs. low impact records
- Risk analysis justification and acceptance

IV. **Interactive Exercise**
Participants analyse a case study and learn how to structure a risk assessment and establish appropriate documentation.

Bonus Material
- An example risk assessment worksheet

Shelley Gutt, BSc, Senior Manager, IT Quality, **Covance Inc.**

SESSION 8 QA and IT — A Partnership for Compliance

I. **QA/IT Partnerships — An Overview**
- QA and IT functions within a typical organisation
- Identify organisational structures to maximise efficiencies
- Collaborate on strategic planning
- Ensure both operational and compliance needs are met

II. **Control Points for Compliance and Record Integrity**
- Collaborate on IT and electronic record integrity strategies
- Develop policies on validation, electronic recordkeeping controls and security
- Create effective and efficient procedures to assure compliance
- Implement control points to monitor compliance

III. **QA and IT Roles and Responsibilities**
- Establish clearly defined roles and responsibilities
- Implement an organisational structure to support efficiencies while maintaining separation of regulatory responsibilities
- Maintain a constructive dialogue for continuous improvement in technologies, processes and procedures

IV. **Interactive Exercise**
Participants discuss their own organisational structures and what works and what does not work.

Bonus Material
- Pros and cons of various organisational structure

Chris Wubbolt, BS, MS, Principal Consultant, **QACV Consulting**

SESSION 9 Change Control and Configuration Management of Computer Systems

I. **Understand Regulatory Requirements and Industry Practices**
- Regulations and guidances from the U.S. FDA and EU
- Current inspection and enforcement practices
- Recommendations from industry committees — ISPE's GAMP™, PDA and IEEE
- Develop related SOPs for planned and unplanned changes
- Handle changes throughout the entire system lifecycle

II. **Putting Critical Changes into Practice**
- Handle changes during the specifications and development phase
- Risk assessment for changes of computer systems and networks
- What to revalidate and test after the changes
- How to deal with changes made by vendors and service providers
- How to deal with unplanned changes, e.g., security patches

III. **Interactive Exercise**
Using prepared case studies, attendees discuss and make recommendations on how to handle planned and unplanned changes.

Bonus Material
- SOP for version control of software
- SOP for change control of computer systems
- Six case studies for planned and unplanned changes

Ludwig Huber, Ph.D., Director, **Labcompliance**

10:00 NETWORKING AND REFRESHMENT BREAK

10:30 CHOOSE BETWEEN THREE 90-MINUTE SESSIONS (10-12)

SESSION 10 Develop a Curriculum for Computerised/Automation Systems — GxP Quality Professionals

I. Quality Organisations and the Value of Formal Training Plans
- Quality assurance and CSV quality roles — A partnership
- Quality partners in your organisation
- The importance of context, roles and responsibilities in training

II. Skills and Knowledge Areas for the Successful Curriculum
- Regulatory requirements
- Company culture and quality training strategy
- Integrating company policies with training modules
- Working in the "gray area"

III. Building the Training Plan
- Targeted training, learning styles and timing and identifying areas of focus
- Training types — On-boarding, refining, ongoing and external
- Training records

IV. Interactive Exercise
Participants are guided through a discussion on implementation of an effective training program — A phased approach.

Shelley Gutt, BSc, Senior Manager, IT Quality, **Covance Inc.**

SESSION 11 Implement a Validation Plan for Legacy Systems

I. Applicable Validation Requirements for Legacy Systems
- Identify the requirements applicable to legacy systems
- Perform a gap assessment of the legacy systems
- Manage gaps in your quality system

II. Validation Strategy for Legacy Systems
- Define the validation strategy for legacy systems
- Learn the assessments needed for legacy systems
- Learn whether one or more validation plans are needed for legacy systems
- Create the validation plan

III. Legacy System Lifecycle Documentation
- Create system specification documents for legacy systems
- Validate Part 11 requirements
- Take a risk-based approach to the validation of legacy systems

IV. Summarising the Validation Planning for Legacy Systems
- Summarise the execution of the validation plan for legacy systems
- Learn the content needed in the summary report

Ivan Soto, Director QA Validation, **Alexion Pharmaceuticals**

SESSION 12 Perform a Gap Analysis of Your CSV Processes

I. Review Your CSV Programs
- Understand regulatory requirements which pertain to your CSV processes
- Evaluate policies and procedures which govern CSV
- Identify systems which must be included in your CSV program

II. Establish Processes to Perform a Gap Analysis
- Create a gap analysis plan, including governance, prioritisation, tracking and management reporting
- Develop a team to conduct the gap analysis
- Develop standard forms and checklists to perform the gap analysis

III. Remediation Activities
- Establish a process to remediate any gaps identified through the gap analysis process
- Prioritise remediation activities
- Identify metrics and key performance indicators for monitoring and future continuous improvement activities

Bonus Material
- Gap analysis plan template

Chris Wubbolt, BS, MS, Principal Consultant, **QACV Consulting**

12:00 NETWORKING LUNCHEON

13:00 CHOOSE BETWEEN TWO 90-MINUTE SESSIONS (13-14)

SESSION 13 Data Migration and Verification — Validation Strategies when Transferring Data from Legacy Systems

I. Verification
- How much is enough?

II. Automated Verification tools
- When to use them
- How to document their use

III. System Specific Issues
- Data format changes between systems
- Migrate partial data sets
- Migrate one data set to multiple locations
- Migrate data from a local system into the cloud
- E-signatures

IV. What Can Go wrong?
- Incomplete migrations
- Data corruption
- Date formats and time zones
- When to roll back

Deborah S. Turner, Associate Director Validation, **Alkermes plc**

SESSION 14 Keep CSV Costs Down while Increasing Quality Care

I. Challenges with Traditional CSV
- Challenges related to a paper based system
- Challenges related to qualification of different SMEs
- Learn the areas that impact cost and efficiency
- What is validation cost and how it can be estimated

II. Effective Strategies to Streamline CSV
- Where to start to streamline validation
- Redesign the validation with the goal to streamline practices
- Create risk-based procedures and practices

III. Cost Effective Streamlined CSV Strategies
- Learn real-life examples that can be easily implemented at your facility
- Paperless validation vs. electronic document management systems
- Pre-approved test scripts
- Integration of software and equipment validation
- Risk assessments

Ivan Soto, Director QA Validation, **Alexion Pharmaceuticals**

14:30 NETWORKING AND REFRESHMENT BREAK

14:45 CHOOSE BETWEEN TWO 90-MINUTE SESSIONS (15-16)

SESSION 15 Validation of Manufacturing Execution Systems (MES)

I. System Development Lifecycle Approach
- Benefits of MES
- ANSI/ISA-95 control hierarchy levels
- Define the scope
- Risk and compliance assessments
- GAMP — COTS vs. customisation vs. configuration
- Installation and decommissioning

II. Validation and Project Deliverables
- Software validation deliverables
- Hardware and infrastructure validation deliverables
- Interfaces
- Electronic records and signatures
- Configuration management
- Impact to other systems

III. Going Live
- System governance
- Hypercare
- Change control

Raul Soto, MSc, BsME, CQE, Principal Engineer, **Johnson & Johnson Vision Care**

SESSION 16 Manage Changes Made to Cloud Infrastructures, Platforms and Applications

I. Vendor Controls
- Quality agreement
- Audits
- Contract
- Notifications
- Vendor relationship

II. Response Window
- Timing
- Review
- The core team

III. Testing
- Sandbox
- Regression scripts
- Tests targeted to the change
- Production environment

IV. Risk Mitigation
- Manage data integrity during changes in a multi-tenant environment
- Changes that fail

Deborah S. Turner, Associate Director Validation, **Alkermes plc**

16:15 CLOSE OF CONFERENCE

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CHOOSE BREAKOUT SESSIONS BELOW

WEDNESDAY, 2 DECEMBER 2015

8:30 - 12:00	A	B	C
13:00 - 14:30	1	2	3
15:00 - 16:30	4	5	6

THURSDAY, 3 DECEMBER 2015

8:30 - 10:00	7	8	9
10:30 - 12:00	10	11	12
13:00 - 14:30	13	14	
14:45 - 15:15	15	16	

VENUE:

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