

A Comprehensive Look into the World of Electronic Data, Records and Signatures

# Electronic Records Management

March 14 – 17, 2006 • the Netherlands, Amsterdam • NH Grand Hotel Krasnapolsky

## A Must Attend Event Dealing with the Following Critical Issues:

- Managing e-Records & Signatures for Global Compliance
  - Data Migration
  - Liability & Document Management
  - E-Signatures
  - Pitfalls to Avoid When Implementing an EDRMS
  - Securing E-Records in Transit
  - Using the SAFE Standard
  - Implementing Risk-Based Approaches
  - Best Practices in E-Document & Records Storage
  - Records Integrity
  - ERM Systems Security
  - Designing Electronic Records
  - Long Term Archiving
- And Much More!**

## WHO SHOULD ATTEND?

- Records Managers/ Directors
- Compliance Managers
- Document Specialist-Storage & Retrieval Units
- IT Department
- Document and Data Management
- Systems Specialists
- Project Managers
- Document Management Systems Units
- Systems Specialists
- Corporate Records Managers/Units
- Digital/Imaging/Electronic Specialists

### SPECIAL REGULATORY FOCUS ON:

- **COMPLIANCE: GAMP/FDA/SOX/Part 11**
- **EDRMS**
- **Data Migration**
- **E-Signatures**
- **ERM Systems Security**
- **Archiving**

### Hear from the following Industry Experts, Including Ex-FDA, Pharmaceutical/Biotechnology/High-Tech Organizations:

- Agilent Technologies
- American Red Cross
- AstraZeneca Sweden
- Berlex Biosciences
- Boehringer Ingelheim Pharmaceuticals, Inc.
- CimQuest, Inc.
- Clarkston Consulting
- CSSC Inc.
- EduQuest Inc.
- GE Healthcare Global IT
- IBM, PriceWaterhouse Coopers
- Medarex, Inc.
- MedImmune
- Mi Services Group
- PharmE
- Sanofi-Aventis
- Shook, Hardy & Bacon, LLP
- Vertex Pharmaceuticals
- Waters Corporation



# 37

**HANDS-ON  
INTERACTIVE  
SESSIONS AND  
PRACTICAL  
IMPLEMENTATION  
WORKSHOPS**

### SUPPORTING PUBLICATIONS

**BioPharm**  
INTERNATIONAL  
The Science & Business of BioPharmaceuticals

**LC|GC**  
INTERNATIONAL  
THE JOURNAL OF SEPARATION SCIENCE

**Pharmaceutical  
Executive**

**Pharmaceutical  
Technology**  
EUROPE

*Journal of*  
**VALIDATION  
TECHNOLOGY**

*Journal of*  
**GXP**  
Compliance



## Electronic Records Management

March 14 – 17, 2006 • the Netherlands, Amsterdam

Receive Valuable  
Bonus Information for  
Your Own Future Use

# Electronic Records Management Event • Tuesday, March 14, 2006

## Pre-Conference Half-Day Workshops

### 7:30 AM – Continental Breakfast and Registration

#### **Interactive Workshop A** 8:30 AM - 12:00 PM **Determining What Is or Isn't an Electronic Record**

Robert Becker, Senior Manager, Software Validation, Medarex

##### **I. Deciding Which Records to Identify**

- Identifying the kinds of "regulatory" records
- Defining the term predicate rule
- Suggestions on finding all the records at your organization

##### **II. What is an Electronic Record?**

- Reviewing examples that may or may not be
- Defining official copy

##### **III. Assessing Criticality**

- Identifying different levels of control for different types of records
- Evaluating risk-based tools criticality
- Discussing suggestions for assuring record accuracy

##### **IV. Interactive Session**

Examples of records, their source and purpose will be provided. Participants will form small groups and working together will recommend record criticality ranking, archive suggestion and level of control. Each team will report to all attendees their conclusion.

Participants will take home the following Bonus Information:

- Record collection form
- Risk analysis matrix

#### **Interactive Workshop B** 8:30 AM – 12:00 PM **Identifying What Files are Relevant for Backups and Archives**

Debbie Sydlo, Sr. Manager, Global QA Systems Validation and Compliance, Sanofi-Aventis

##### **I. Backups and Archives**

- Distinguishing between backups and archives
- Allowing for record retention and legal requirements
- Understanding the idea of 'chain of evidence'
- Determining what to "back up", and what to "archive"

##### **II. The "Ever-Popular Part-11" Discussion**

- What has "Part 11" really done for us?
- Understanding why Part 11 is an issue for backups and archives
- Living with the rules of Part 11?

##### **III. Interactive Exercise**

Attendees will have a practice session defining elements of an e-record strategy (i.e. - back-up, archive, controls, etc.) as a group.

Participants will take home the following Bonus Information:

- A checklist identifying 'key' files required for backup and archives

#### *Special Thanks to ERM Program Technical Advisors:*



**Ludwig Huber, Ph.D.**, is worldwide Compliance Program Manager at Agilent Technologies and editor of [www.labcompliance.com](http://www.labcompliance.com). He was a team review member of PDA's task forces "21 CFR Part 11" and "Validation of Laboratory Data Acquisition Systems", of the GAMP special interest group on Laboratory Equipment and of IVT's task force on Network Infrastructure Qualification.



**Akos Bartha, Ph.D.**, Quality Manager at AstraZeneca Sweden Operations, with responsibilities for training, advisory and QA support on Part 11, records management and quality system issues for computerized systems.



**Dr. Siegfried Schmitt**, Quality Director at GE Healthcare Global IT, is an expert in the field of computerized systems validation and regulatory compliance and acts as technical advisor to this conference.

#### **Interactive Workshop C** 8:30 AM – 12:00 PM **Principles of Defining and Managing Records: Electronic versus Paper**

Akos Bartha, Ph.D., Technical & Quality Adviser, AstraZeneca Sweden Operations

##### **I. Defining Records and their Components**

- Understanding the definition of records and metadata
- Learning about the requirements for data elements (ALCOA)
- Standards and guidelines defining the attributes of trustworthy records

##### **II. Requirements for Record Keeping**

- GXP Predicate Rules and other records requirements
- Current FDA guidance and regulatory expectations
- Utilizing standards and guidelines for record management
- Establishing a company archiving policy

##### **III. Managing Electronic Records**

- Controls for electronic and paper records
- The consequences of record and system lifecycle

## Tuesday, March 14, 2006 Pre-Conference Half-Day Workshops

- Challenges of long term record retention and disposal
- Risk management principles for record archiving

### IV. Interactive Exercise

Attendees will learn about defining record retention requirements and setting up an archiving policy.

#### *Participants will take home the following Bonus Information:*

- A procedure with step-by-step instructions and templates for documenting retention requirements for electronic and paper records

### **Interactive Workshop** **D** 8:30 AM – 12:00 PM **Strategies, Procedures & Tools for Long Term Archiving and Retrieval**

*Victoria Lander, Corporate Compliance Manager, Waters Corporation*

#### I. Data/Electronic Record Storage Considerations

- Media issues - including media refresh considerations
- Understanding technology considerations
- Storage conditions
- Maintaining a validation state for an e-record storage system

#### II. Data/E-Record Longevity

- Looking at the withdrawn FDA Guidance Document on e-Record maintenance
- Helpful tips from the guidance that still make sense

#### III. Compliance Issues for Long-term Archiving

- Considering system changes
- Addressing cyber security issues
- Maintaining 21 CFR Part 11 compliance

#### IV. Data/e-Record Retrieval Concerns

- Protecting record integrity
- Disaster recovery strategies
- Data integrity verification procedures

#### V. Interactive Exercise

Participants will be involved in an interactive discussion of general considerations for long-term archiving of key/regulated electronic records.

## Tuesday, March 14, 2006 Main Conference 90 Minute Sessions

### 12:00 PM – Registration

### 1:30 PM – Chairperson's Welcome and Opening Remarks

### 1:45 PM

#### **Managing Electronic Records and Signatures for Global Compliance**

*Ludwig Huber, Ph.D., Compliance Program Manager, Agilent Technologies*

Ensuring authenticity, integrity and reliability of electronic records is a concern for all national healthcare agencies. They all have specific requirements, many are common, but there are also some differences. This presentation will highlight most obvious differences and suggest an e-records/signature management model that meets all requirements of national and international regulations and guidelines.

- Overview on national and international e-records/signature regulations and guidelines US FDA, Europe, Japan, Australia
- Europe: Annex 11 to EU GMP directive, PIC/S Guide, EU Digital Signature directive
- Japan: New regulation on records and signatures
- Strategies for implementation of worldwide requirements into your e-records/signature program

### 2:30 PM

#### **Risk Based Approach to Electronic Records**

*Robert Becker, Senior Manager, Software Validation, Medarex*

- History of Part 11 and where are we today
- Establishing a records inventory and software applications inventory
- Using the risk priority method for ranking criticality
- Establishing levels of validation and control based on risk
- Reviewing GAMP Good Practices Guide, practicality and limitations

#### *Participants will take home the following bonus information:*

- Risk priority matrix
- Electronic document checklist

### 3:15 PM – Refreshment Break

**Tuesday, March 14, 2006**  
**Main Conference 90 Minute Sessions**

**3:30 PM**  
**Document Management Systems for the 21st Century**

*Martin Browning, President, EduQuest, Inc.*

This presentation will focus on the changing paradigm for document management that will impact industry for the remainder of the 21st Century.

- Understanding the need for cost reduction
- Demands for and on data
- Regulatory requirements
- Recognizing the criticality of the infrastructure
- Learning to maintain compliance with requirements
- Assessing management oversight

**Participants will take home the following Bonus Information:**

- Several sets of questions and challenges (in checklist format) based upon the concept of Ten Simple Questions®- designed to aid in determining and challenging requirements

**4:15 PM**  
**Long Term Storage Options:  
Considering the Key Issues**

*Dr Siegfried Schmitt, Quality Director, GE Healthcare Global IT*

This session is a real and up-to-date example of an implementation, complemented by as yet unpublished information from the GAMP Monograph, currently under review by ISPE.

- Understanding the scope of compliance- more than just FDA and EU regulations
- Applying the rules for indexing and retrieval
- Setting of expiry dates and the records formats

**5:00 PM- Close of Day One  
Networking Cocktail  
Reception**



**Wednesday, March 15, 2006**  
**Main Conference Half-Day Workshops**

**7:30 AM – Continental Breakfast**

**Interactive Workshop** **E** **8:30 AM – 12:00 PM**  
**Avoiding the Pitfalls: Selecting, Implementing and  
Managing Electronic Document and Records  
Management Systems**

*Martin Browning, President, EduQuest, Inc.*

How do we select electronic document and records management systems? After the selection, the real work begins: implementing and validating the chosen system(s). What must we do? Now that we have moved from paper-based document and record management, what must we do to maintain the system?

**I. Choose an Effective Evaluation and Selection Process**

- Assessing requirements and risks
- Reviewing history
- Performing audits

**II. Identify the Implementation and Validation Processes**

- Outsourcing concerns
- System Integrators
- Figuring out validation

**III. Manage and Maintain**

- Establishing processes and procedures
- Monitoring and maintaining
- Evolving and improving

**IV. Interactive**

Each module will be followed by an exercise designed to reinforce the key points of the module. These interactive sessions will utilize a Quality audit approach to challenge the materials covered during the preceding presentation.

**Participants will take home the following Bonus Information:**

- Several sets of questions and challenges (in checklist format) based upon the concept of Ten Simple Questions® – designed to aid in determining and challenging requirements for choosing, implementing, and maintaining electronic document and records management systems

**Interactive Workshop** **F** 8:30 AM – 12:00 PM

### Implementing Risk-Based Approaches for Electronic Records and Signatures

Ludwig Huber, Ph.D., Compliance Program Manager, Agilent Technologies

#### I. Regulatory Requirements and Industry Standards for Risk Management

- FDA requirements and expectations
- EU and international requirements: EU, ICH, PIC/S, GHT
- Industry standards for risk management: GAMP Guides, ISO 14971
- Risk management models and tools

#### II. Risk Management Process

- Developing a risk management master plan
- Best practices to identifying the real hazards and harms
- Assessing impact on electronic records and signatures and define risk levels
- Risk mitigation and on-going controls
- Documentation for the FDA

#### III. Implementing Risk Based Controls for Computer Systems

- Impact on validation
- Electronic audit trail
- Record maintenance and archiving
- Security and change control
- Controls of new vs. existing systems

#### IV. Interactive Exercise

Participants will analyze real-life situations and identify processes and records with high, medium, and low risks. Once risk levels of records are identified, validation and other tasks for each category will be defined. Participants will receive prepared templates and examples that can be used for easy implementation.

**Participants will take home the following Bonus Information:**

- For an easy start participants will receive two SOPs: Risk Based Validation of Software and Computer Systems" and "Risk Assessment for GxP Systems" with templates.
- To get the most out of this workshop, download workshop and reference material: [www.labcompliance.com/ivt](http://www.labcompliance.com/ivt)

**Interactive Workshop** **G** 8:30 AM – 12:00 PM

### Case Study: From Relational Databases to Dependable E-Records

David Stokes, Principal Validation Consultant, Mi-Services Group

#### I. Regulatory Expectations for E-Records

- Establishing the need for reliable audit trails
- Securely and irrevocably signing E-Records
- Producing human readable copies of records for regulatory review
- Copying electronic records for off-site review

#### II. The Relational Database Problem

- Finding out why applications based on relational databases are different
- Identifying why such applications cause problems during regulatory inspections
- Figuring out the approach that needs to be taken to overcome these shortcomings

#### III. Developing the Oracle E-Records Solution

- Understanding the regulatory requirements
- Soliciting the needs of the user community via the Customer Advisory Board
- Designing the technical solution to be as broadly applicable as possible
- Reviewing the solution design against US and EU predicate rules

#### IV. Interactive Session: The Theory - Using a Compliant E-Records Solution

This interactive session is aimed at helping attendees understand the approach that needs to be taken in order to leverage a compliant E-Records solution

#### V. The Practice – A User's Story

In this session attendees will hear from a real user of the Oracle E-Records Framework in the pharmaceutical sector. This will include the advantages of such a relational database solution as well as the problems and pitfalls of implementation.

#### VI. Buyer Beware

- Defining requirements for E-Records compliance
- Determining the questions to ask when reviewing the E-Record solutions of vendors

**Participants will take home the following Bonus Information:**

- Applicable sections from User Requirements template
- Business process and E-Signature workflow mapping documents and E-Record scope mapping documents
- Screen shots from compliant applications using the techniques and solutions discussed in the workshop

**Interactive Workshop** **H** 8:30 AM – 12:00 PM  
**Best Practices in Electronic Document and Records Storage**

*Dr Siegfried Schmitt, Quality Director, GE Healthcare Global IT*

**I. Documents and Records**

- Learning to speak one language: the basics about records and documents
- Why store information electronically?
- Some references on records and document management

**II. Defining Business Needs**

- Obtaining the information from the business on their needs
- Documenting the requirements in a suitable format for many R&D, Manufacture, IT, etc.
- Moving from URS to request for bid

**III. Technical Solutions**

- Deciding how and what to select
- Making it future-proof?
- Capturing qualification results - eliminating paper prints from screen shots

**IV. Compliance**

- Addressing compliance requirements- is compliance a show-stopper?
- Making information available to an inspector - simple?

**V. Interactive Exercise: Complete a Use Case and a User Requirements Specification**

Many users think of requirements from a system perspective, i.e. what is it that my existing system can do? However, this is an unsuitable approach for the selection of a new system where the question must be: what is the document that I create and how do I need to create it? The generic templates that will be provided to the attendees will be a great help in understanding how this is best accomplished.

**VI. Validating the System**

- Deciding if it is a local or a global system
- Using GAMP? What about 21 CFR 11?
- Who is responsible, the business or IT?

**Participants will take home the following Bonus Information:**

- Use Case / URS template in electronic format

**12:00 PM – Lunch**

**Optional Roundtable Lunch:**

**Issues, Challenges, and Common Ground for Records Managers**

**1:30 PM Chairperson's Opening Remarks**

**1:45 PM**

**Attaining a Balance in Records Management**

*Akos Bartha, Ph.D., Technical & Quality Adviser, AstraZeneca Sweden Operations*

This session will focus on strategies to meet the challenge of managing regulated records in a cost effective way.

- The impact of FDA's current interpretation for electronic records and signatures
- When to use electronic (Part 11) records - a business choice and its consequences
- Policies, standards and training for a common interpretation across departments / sites
- Strategies to deal with hybrid systems - paper versus e-records

**2:30 PM**

**21CFR Part 11 – Should I Care Anymore?**

*David Stokes, Principal Validation Consultant, Mi-Services Group*

It's been a challenging few years. The FDA withdraws existing guidance on Part 11 and GAMP writes a white paper. The FDA then issues a new guidance document, followed weeks later by guidance from PIC/S. The world waits for guidance from Japan and meanwhile the FDA considers the feedback from their public consultation on Part 11. What is happening in the world of ERES?

- What lies behind the FDA's current position on Part 11
- Why you should still care (but not worry) about Part 11
- Leveraging GAMP's recent "A Risk-Based Approach to Compliant Electronic Records and Signatures" good practice guide
- Changes that will be necessary to many company's Part 11 Policy documents

**Participants will take home the following Bonus Information:**

- Example copies of bonus material that have been successfully used on projects to support compliance with the FDA's current position on Part 11 that meets the expectations of current FDA and GAMP Guidance
- Examples of annotated predicate rules, URS and E-Record verification prerequisites

**Wednesday, March 15, 2006  
Main Conference General Sessions**

**3:15 PM – Refreshment Break**

**3:30 PM**

**Keeping E-Records Safe in Transit and at Rest**

*Paul Drapeau, Lead Network Engineer, Security, Vertex Pharmaceuticals Inc.*

Participants will get an IT security practitioner's viewpoint on options for securing e-records in transit and in storage. Many security "best practices" go a long way to fulfilling regulatory requirements.

- IT security tools from the viewpoint of e-records transmission and storage
- Mapping current capabilities to regulatory and best practice requirements
- How much encryption/authentication/integrity is enough?
- Ideas for safely getting e-records through the firewall

**Participants will take home the following Bonus Information:**

- Encryption, data transmission, and partner VPN policy templates that can be put in place to help secure e-records in transit and in storage

**4:15 PM**

**OPEN FORUM Q & A**

*Akos Bartha, Ph.D., Technical & Quality Adviser, AstraZeneca Sweden Operations*

*David Stokes, Principal Validation Consultant, Mi-Services Group*

*Paul Drapeau, Lead Network Engineer, Security, Vertex Pharmaceuticals Inc.*

**4:45 PM – Close of Day Two**

**HOTEL INFORMATION**

**NH Grand Hotel Krasnapolsky**

Dam 9, 1012 JS Amsterdam, the Netherlands

Tel: +31-20-554-9111

Fax: +31-20-622-8607

[www.nh-hotels.com](http://www.nh-hotels.com)

A special room rate has been prearranged for conference participants. Call the hotel directly at the above number and mention IVT to receive the reduced room rate.



**Thursday, March 16, 2006  
Main Conference Half-Day Workshops**

**7:30 AM Continental Breakfast**

**Interactive Workshop I 8:30 AM – 12:00 PM**

**The 10 Best Pieces of Advice on Electronic Records Management – How Does Your Company Measure Up?**

*Wylene Lengel, Manager, Clarkston Consulting*

Participants will participate in 3 benchmarking sessions with their colleagues on the topics below (or other topics of their choosing), develop their 10 best pieces of advice from the topic of interest, and present their list to the rest of the groups.

**I. Interactive Session 1**

- Identifying files that are relevant for backups and archives
- Figuring out who is responsible in your organization for managing ERM and why
- What are words to the wise on Part 11 and ERM?

**II. Interactive Session 2**

- Explaining best practices for handling e-submissions
- What are your lessons learned on e-data migration?
- Staying ahead of the changing technology challenges in ER management

**III. Interactive Session 3**

- Handling retention times and the methods for filing and disposal of electronic records
- Best practices for long-term storage and maintenance of electronic records
- Key points to consider for long-term storage of ER

**Participants will take home the following Bonus Information:**

- Deliverables from the workshop
- Reading list of related publications

**Interactive Workshop J 8:30 AM – 12:00 PM**

**URS Development - Key Deliverable for Success of your EDMS Implementation Project**

*Gail Butler, Senior Manager, Corporate Computer Validation, MedImmune*

**I. Conformance to User's Requirements**

- Overview of where the User's Specification fits in the process of validation
- Figuring out how URS meshes with other validation documentation, i.e. Computer Validation Plan and the Risk Assessment

**II. A Risk-Based Approach**

- Limiting validation testing of your automated Global

EDMS solution and applying the principles of the risk-based validation test planning

- Determining the role of the URS in this area

### III. Is There an FRS Yet?

- Understanding the V-Model and how it fits in validation planning
- How does your Global EDMS URS line up with the succeeding deliverables, particularly the FRS?
- Using your URS to select a vendor

### IV. Interactive Exercise: Are the Requirements Functional?

How are requirements written from what the System Owning group does in their day-to-day work? This exercise will give you the tools to understand how to help the System Owners and users develop testable or verifiable requirements statements. This is an art and you will understand the basic methodology that, with practice, will support better validation projects in general but is required for complex implementations such as global EDMS projects.

### V. Non-functional Requirements

- Discussing "mini" validation activities within your larger validation project
- The devil is in the details! What about validation of those reports? What about all that legacy data?

### VI. Not Once Did I Mention Software!

- Understanding that this process requires no background in IT systems or software programming
- Recognizing that the URS is system independent and so should your System Owners and user's approaches be to development of their requirements

#### *Participants will take home the following Bonus Information:*

- URS Template for a global, enterprise-wide EDMS system to use in developing your own EDMS project

### **Interactive** Workshop **K** 8:30 AM – 12:00 PM "Risk E-Business" -- Regulatory and Litigation Implications of Electronic Document Management

Gordon B. Richman, Vice President, Strategic Compliance Consulting and General Counsel EduQuest, Inc,  
Madeleine M. McDonough, Esq., Partner, Shook, Hardy & Bacon, LLP

#### I. FDA Enforcement and the Consequences of Non-Compliance

- The inspection and enforcement process (a.k.a. the "road to enforcement")
- Assessing how the environment has changed

#### II. FDA 483 and Warning Letter Citations on Electronic Systems

- Real-life examples of compliance and enforcement problems
- Developing trends in the U.S. and elsewhere
- Recommendations for success

#### III. Recent Litigation Developments in E-Discovery

- Status of pending proposed revisions to federal rules of civil procedure
- Understanding recent legal developments in electronic discovery
- Imposing sanctions against companies for E-discovery violations- recent cases

#### IV. Recommendations for Implementing Best Practices and Effective Procedures with Electronic Documents

- Internal records management
- Preparing witnesses
- Building a defensible and winning approach for electronic discovery

#### V. Interactive Session:

Speak your mind and have your most pressing questions answered during an open Q&A session. Pick the brains of two experienced professionals who have been involved in the full range of electronic systems issues, including software development, validation, FDA enforcement, product liability and commercial litigation, complex discovery matters, and the development of electronic databases for defending pharmaceutical and medical device companies in court.

#### *Participants will take home the following Bonus Information*

- EduQuest's reference CD entitled "Computerized System Validation References for FDA and the Industry."

### **Interactive** Workshop **L** 8:30 AM – 12:00 PM Best Practices for Complying with Regulatory Requirements for Retaining Electronic Records

Charlie Sodano, Manager, Information Systems, Berlex Inc.

#### I. Current Regulatory and Legal Requirements for Electronic Records

- Code of Federal Regulations (CFR) requirements
- FDA guidance

#### II. FDA Schedules

- Defining retention schedules for laboratory data
- Knowing guidelines on best practices
- Complying with practical strategies and procedures
- Identifying other relevant federal legislation and international initiatives

### III. Interactive Exercise: Practical Strategies and Technology Forecasts

Attendees will participate in a discussion of hardware and software technologies in the workplace. Recommendations will be made for short and long term archiving.

**Participants will take home the following Bonus Information:**

- A document containing the best practices for handling and storing electronic media

### **Interactive** Workshop **M** 8:30 AM – 12:00 PM Validating an Electronic Record Management System

Lyn Roman, Project Manager, PharmaE

#### I. Why an Electronic Record Management System?

- Pros and cons of an ERM
- Defining project scope
- Determining system requirements
- Incorporating 21 CFR Part 11

#### II. Implementation Deliverables

- Securing validation, system and procedural documents
- Establishing training requirements

#### III. It's Implemented - Now What?

- Controlling system access
- Performing security audits
- Multi-site considerations
- Running periodic reviews

#### IV. Interactive Exercise

Attendees will use the regulations to build some high-level requirements to provide a base for any ERMS implementation.

**Participants will take home the following Bonus Information**

- A list of key project considerations, documentation deliverables and general project order for an implementation

### 12:00 PM – Lunch

*Optional Roundtable Lunch:*

### Records Management: Present and Future Concerns

### **Interactive** Session **1** 1:30 PM – 3:00 PM Managing Open Systems for Compliance

Ludwig Huber, Ph.D., Compliance Program Manager, Agilent Technologies

#### I. Issues and Technical Solutions for Open Systems

- FDA's approach for e-mail and other Internet use
- Recognizing the difference between open vs. closed systems using case studies
- Difficulties with out-of-the box software
- Developing a culture for security and compliance

#### II. Tools and Procedures for Compliance

- Encryption and digital signatures
- Virtual private networks for remote access
- Digitally signed e-mails with certificates for authentication
- Validating web applications and e-mail transfer
- Documentation for the FDA

#### III. Interactive Exercise

Participants will analyze real life situations and define an action plan on how to use e-mails for regulated activities. Attendees will receive prepared templates and examples that can be used for easy implementation.

**Participants will take home the following Bonus Information:**

- For an easy start participants will receive two SOPs: "Using the Internet in Regulated Environments" and "Validating Web Applications" with templates.
- To get the most out of this workshop, download workshop and reference materials: [www.labcompliance.com/ivt](http://www.labcompliance.com/ivt)

### **Interactive** Session **2** 1:30 PM – 3:00 PM My Reprocessing Software has Become Obsolete – Plan of Action

Akos Bartha, Ph.D., Technical & Quality Adviser, AstraZeneca Sweden Operations

#### I. Requirements and Principles for Record Retention

- Regulatory requirements for records and system documentation
- Challenges to ensure long-term retention of electronic records
- Understand the impact of FDA's narrow scope guidance for Part 11

#### II. Decommissioning Plan and Securing Records

- Goals and drivers for decommissioning
- Planning for decommissioning computer systems / software

## Thursday, March 16, 2006 Post Conference 90-Minute Sessions

- Current industry practices and guidance (GAMP) for record retention

### III. Case: Chromatography Data System Software

- Mapping business use, documentation, records and signatures
- The important role of your software vendor
- Practical examples of record retention strategies for CDS

### IV. Interactive Exercise

Attendees will participate in an interactive session to discuss strategies for securing electronic records.

#### *Participants will take home the following Bonus Information:*

- A template for planning system decommissioning and record retention

### **Interactive Session 3** 1:30 PM – 3:00 PM Using the SAFE Standard for Digital Signatures, Electronic Transactions and Submissions and the Accreditation Process

Mollie Shields-Uehling, CEO, SAFE BioPharma Association  
George G. Kuniholm, Regional Manager, CSSC Inc.

#### I. Healthcare Industry Trends

- Shifting from paper to Electronic Records in Healthcare Industry
- Creating trust in the patient / doctor relationship
- Legal Enforceability and Regulatory Compliance concerns

#### II. Identity Assurance and The SAFE Standard

- Policies, procedures and guideline requirements for SAFE
- Technical specifications for SAFE
- Legal and liability risk management under SAFE

#### III. Current SAFE Implementations and Organization

- The SAFE organization
- Current implementations
- CSSC the accreditation auditor

#### IV. Accreditation Process

- The SAFE audit process
- What an accreditor looks for during the process
- The accreditation timeline

#### V. Interactive Exercise

Attendees will be asked to create a Project Plan for becoming SAFE accredited with Project proposal and justification.

### **Interactive Session 4** 1:30 PM – 3:00 PM Archiving Scientific Data and Part 11 Controls

Ron Armstrong, Manager, Computer Systems Compliance, R&D Quality Assurance, Boehringer Ingelheim Pharmaceuticals, Inc.

#### I. Figuring Out How Part 11 eRecords Requirements Affect my Archive Requirements?

- Establishing data integrity requirements
- Identifying retrievability requirements
- Reviewing usability requirements

#### II. Translating Requirements Into Real Solutions

- Assessing the jumble of technologies that must be considered
- Learning about on-line or near on-line archival
- What about migrating the data?

#### III. Interactive Session

Participants will survey current trends.

### 3:00 PM – Refreshment Break

### **Interactive Session 5** 3:30 PM – 5:00 PM Learning How to Identify, Control and Preserve Your Data: Defining Primary Data, Raw Data and Meta Data

Debbie Sydlo, Sr. Manager, Global QA Systems Validation and Compliance, Sanofi-Aventis

#### I. Data Defined and Tools for Analysis

- Case tool vendor evaluation, based on system type
- Case tool vs. manual methods for data analysis
- Example of a Decomposition Model

#### II. Interactive Exercise

The exercise for this session will be based on a simple company manufacturing process model. The group(s) will approach this interactive workshop by building a model of the process and systems (manual and/or computer), determining what records (documents and/or supportive data) are required to be available. The desired result will be an identification of the typical "files" to be retained and controlled.

#### III. Laboratory Process Analysis

- Building a basic decomposition model
- Applying workshop logic to your own company's files and records
- Monitor, audit and continuous improvement TIPS for on-going management and control of data

**Participants will take home the following Bonus Information:**

- A Case Study Additional Example – Decomposition modeling of a Laboratory Process
- Checklist with key questions to identify and categorize, data

**Interactive Session 6 3:30 PM – 5:00 PM**  
**E-Record Integrity – How Certain is “Sure Enough”**

*David Stokes, Principal Validation Consultant, Mi Services Group*  
*Deb Milligan, CQA(ASQ), CSQE(ASQ), Manager Regulatory Compliance, American Red Cross*

**I. USA versus the World**

- Understanding the scope and implications of the US FDA's relaxation of E-Record compliance expectations
- Aligning with the expectations of other international regulatory agencies
- Navigating the issue of 21 CFR Part 11 compliance

**II. Risk Based Electronic Records**

- Reviewing digital e-signature requirements
- Using digitized (not digital) signatures to assure the integrity of electronic records
- Using paper based audit trails to assure the integrity of electronic records

**III. Interactive Session: Verification Strategies to Assure E-Record Integrity**

Participants will work together in groups to work on improving the following processes:

- Documenting the scope of their E-Records
- Defining and documenting the source of their master data
- Assessing risk associated with the through-life management of their E-Records

**Participants will take home the following Bonus Information:**

- Examples of E-Record validation and verification pre-requisites
- Examples to be applied to digitally signed E-Records, electronically signed E-Records, 'wet-ink' signatures applied to copies of E-Records, digitized signatures applied to E-Records and the use of third party PKI solutions

**Interactive Session 7 3:30 PM – 5:00 PM**  
**Understanding System Related Logs & Record Related Audit Trails**

*Paul Drapeau, Lead Network Engineer, Security, Vertex Pharmaceuticals Inc.*

**I. Audit Trail Requirements**

- Deciding what information makes up a complete log
- Infrastructure requirements for good audit trails and logs

**II. Network and Operating Systems Logs in the Application's Context**

- Operating System Logs: the good and the bad
- Network logs: firewalls, VPNs, IDS/IPS, sniffers

**III. Server Daemon Logs**

- Web server logs and database logging

**IV. Putting it all Together**

- Correlating logs
- Suggested tools for log analysis and parsing

**V. Interactive Exercise:**

Participants will use actual log data to forensically reconstruct application events that have effects on e-records.

**Participants will take home the following Bonus Information:**

- A checklist for preparing and locating log information throughout the information systems environment that can supplement application audit trails

**Interactive Session 8 3:30 PM – 5:00 PM**  
**Electronic Records Management – Good Practices and Regulatory Expectations**

*Kevin C. Martin, Vice President, Business Development, CimQuest, Inc.*

**I. Electronic Records Management from a Business Perspective**

- Addressing multiple regulatory authorities, including FDA, SEC, SOX, FDIC, and HIPPA
- Understanding good electronic records management concepts
- Applying a risk management approach to records

**II. Interactive Exercise**

Through this interactive exercise attendees will discuss data integrity controls which points to a COBIT frame work. This exercise will show how one would go about harmonizing governances (e.g.: SOX and PDMA). This is the same approach that points to a single control that would cover any governance that is affected by data integrity.

**Participants will take home the following Bonus Information:**

- Bonus material outlining the process mapping framework, in tree form, that can be used as a tool to help attendees get started with the process in their own companies

**5:00 PM – Close of Day Three**

Friday, March 17, 2006  
Post Conference 90-Minute Sessions

7:30 AM Continental Breakfast

**Interactive Session 9** 8:30 AM – 10:00 AM  
**Migrating from Paper to Electronic – It CAN be Done Successfully**

Lyn Roman, Project Manager, PharmaE

**I. Defining the Current Situation**

- What types of records do you have?
- Figuring out if there is one software solution - KEGI
- Initial steps to choosing solutions

**II. Key Considerations for the Migration**

- Assessing document history
- Identifying transfer methods
- Determining audit consequences

**III. Defining Next Steps**

- Creating a Project Plan
- Identifying what documents are required
- Deciding who should be involved

**IV. Interactive Exercise**

Attendees will discuss their migration concerns and how to approach solving issues.

**Participants will take home the following Bonus Information:**

- Examples of different data migration techniques and suggestions for choosing methods based on the data type

**Interactive Session 10** 8:30 AM – 10:00 AM  
**Applying Six Sigma to Records Management**

Pranay Butala, MS, MBA, Business Consulting Life Sciences  
Practice Engagement Manager, IBM, PriceWaterhouse Coopers

**I. Basic Principles of Six Sigma**

- Benefits of Six Sigma
- Considerations to keep in mind before implementing
- Drawbacks

**II. Terminology, Process, Method**

- SIPOC, QFD, Lean Sigma
- Other key processes

**III. Applying Six Sigma**

- Understanding what needs to be in place to start
- What roles are recommended?
- Choosing processes

**IV. Six Sigma for Records Management**

- Using a practical approach for your company
- Trying to minimize time, cost, resources
- Making the process more efficient

**V. Interactive Exercise**

Participants will work in groups to use a six sigma principle or method towards records management in their organization. Then describe how it currently is done, and then recommend a new approach. Keep in mind resources, costs, and intermediate phases or 'baby steps' towards the goal.

**Interactive Session 11** 8:30 AM – 10:00 AM  
**ISO 15489 & ERM: What is it all about?**

Wylene Lengel, Manager, Clarkston Consulting

**I. History and Scope of ISO 15489**

- Standardizing international best practices
- Who/what technical committee wrote this standard?
- Identifying what stage is the standard in now

**II. Part 1 - The Elements of a Record Management Program**

- Managing records
- Supporting a quality process framework
- Designing and implementing a records system

**III. Part 2 – One Methodology for Implementation**

- Record management: policies and responsibilities
- Strategies, design, and implementation
- Monitoring and auditing

**IV. Interactive Session**

Participants will discuss:

- Prior knowledge of and use of ISO 15489
- What key standards they are using as the basis for record management
- How they could apply ISO 15489

**Participants will take home the following Bonus Information:**

- Current articles on ISO 15489 and/or ERM
- List/s of applicable standards on records and information management

**Interactive Session 12** 10:30 AM – 12:00 PM  
**Creating and Keeping Electronic Signatures Together with Electronic Records: A Real Life Example**

Ron Armstrong, Manager, Computer Systems Compliance, R&D  
Quality Assurance, Boehringer Ingelheim Pharmaceuticals, Inc.

**I. How do Part 11 Requirements for eSigs Translate into Real Signatures I Can Work With?**

- Some practical reasons behind Part 11 requirements
- How the requirements help you define the system
- Looking at a vendor's solution and evaluating

## II. How do I Keep my Signatures with my Records?

- Based on knowing what an eSig should be, real example of a solution
- Theoretical example using a different mechanism to preserve signature

## III. Do I Need eSigs?: Determining Benefits, Implications: Real Life Examples

- Open discussion of benefits of automating documents
- What eSigs will, and will NOT do for your organization
- Explaining the benefits to users/management

### 10:00 AM – Refreshment Break

## **Interactive** Session **13** 10:30 AM – 12:00 PM Case Study: Incorporating Part11 into New Systems Development Project

Pranay Butala, MS, MBA, Business Consulting Life Sciences Practice Engagement Manager, IBM, PriceWaterhouse Coopers

### I. The Traditional SDLC and its Validation Stream

- Examination of validation points within the SDLC
- Documentation needed for the validation points

### II. CFR Part11 Requirements

- Interpreting the requirements as per the type of system
- Where in the SDLC to incorporate the requirements

### III. Case Study

A brief case study to help participants evaluate how to manage Part11 into a new systems project

#### Participants will take home the following Bonus Information:

- Checklist or template to aid in the evaluation of the case study of a new systems project

## **Interactive** Session **14** 10:30 AM – 12:00 PM Best Practices and Solutions for Long Term Archiving of Electronic Records and Signatures

George Kuniholm, Regional Manager, CSSC Inc.

### I. Archiving Approaches and Technologies

- Preservation of functionality using flexible formats such as XML
- Archiving to non-proprietary and portable format
- Forget archiving: migrating to the next technology
- Cost verses benefit considerations

## II. Case Studies

- Clinical DMS
- Inventory Tracking System
- Digitized Case Report Forms (CRFs)
- E-authorizations to ship investigational materials including E- signatures

## III. Interactive Exercise

Participants will be presented with case studies involving systems that process GCP data, GLP data and GMP data and asked to make archiving decisions based on regulatory risk, best practice, and practical considerations.

#### Participants will take home the following Bonus Information:

- A checklist of things to consider when archiving electronic records

## **Interactive** Session **15** 10:30 AM – 12:00 PM CASE STUDY: Identity Management Services for Enhanced Compliance

Paul Drapeau, Lead Network Engineer, Security, Vertex Pharmaceuticals Inc.

### I. Identity Management

- Applying the principals and business value of identity management
- Implemented identity management at Vertex Pharmaceuticals, through business systems- such as directory services, email, application environments, and databases

### II. Centralizing Authentication and Authorization

- Identifying the problems with having too many user-names and passwords
- Securing global account uniqueness and its value
- Centralizing authentication and authorization services at Vertex Pharmaceuticals in an open systems environment

### III. Dynamic Data-Driven Groups

- Thinking beyond manually maintained lists of people
- Enforcing data-driven groups to help enforce proper access controls
- Automating group membership management at Vertex Pharmaceuticals

### IV. Interactive: Questions and Discussion

Active participation will be encouraged throughout this session.

## Close of Conference

# Electronic Records Management Event

## Event-At-A-Glance: March 14-17, 2006

**TUESDAY, MARCH 14, 2006**

**7:30 AM – Continental Breakfast and Registration**

**Pre-Conference Half-Day Interactive Workshops A – D  
8:30 AM - 12:00 PM**

**WORKSHOP A**  
Determining What Is or Isn't an Electronic Record

**WORKSHOP B**  
Identifying What Files are Relevant for Backups and Archives

**WORKSHOP C**  
Principles of Defining and Managing Records: Electronic versus Paper

**WORKSHOP D**  
Strategies, Procedures and Tools for Long Term Archiving and Retrieval

**12:00 PM – Lunch for attendees of Workshops A, B, C, D**

**12:00 PM - Main Conference Registration**

**Main Conference General Sessions**

**1:30 PM- Chairperson's Welcome and Opening Remarks**

**1:45 PM**  
Managing Electronic Records and Signatures for Global Compliance

**2:30 PM**  
Risk Based Approach to Electronic Records

**3:15 PM**  
Refreshment Break

**3:30 PM**  
Document Management Systems for the 21st Century

**4:15 PM**  
Long Term Storage Options: Considering the Key Issues

**5:00 PM – Close of Day One Networking Cocktail Reception**



**WEDNESDAY, MARCH 15, 2006**

**7:30 AM – Continental Breakfast**

**Main Conference Workshops E-H  
8:30 AM - 12:00 PM**

**WORKSHOP E**  
Avoiding the Pitfalls: EDRMS

**WORKSHOP F**  
Implementing Risk Based Approaches for Electronic Records and Signatures

**WORKSHOP G**  
Case Study: From Relational Databases to Dependable E-Records

**WORKSHOP H**  
Best Practices in Electronic Document and Records Storage

**Main Conference General Sessions**

**12:00 PM – Lunch**

**Optional Roundtable Lunch**  
Issues, Challenges and Common Ground for Records Managers

**1:30 PM**  
Chairperson's Welcome and Opening Remarks

**1:45 PM**  
Attaining a Balance in Records Management

**2:30 PM**  
21CFR Part 11 – Should I Care Anymore?

**3:15 PM- Refreshment Break**

**3:30 PM**  
Keeping E-Records Safe in Transit and at Rest

**4:15 PM**  
OPEN FORUM Q & A

**4:45 PM – Close of Day Two**

**THURSDAY, MARCH 16, 2006**

**7:30 AM – Continental Breakfast**

**Workshops I-M  
Main Conference  
8:30 AM - 12:00 PM**

**WORKSHOP I**

The 10 Best Pieces of Advice on ERM

**WORKSHOP J**

URS Development - Key Deliverable for Success of your EDMS Project

**WORKSHOP K**

"Risk E-Business": Regulatory and Litigation Implications of EDM

**WORKSHOP L**

Best Practices for Compliance with Retaining Electronic Records

**WORKSHOP M**

Validating an Electronic Record Management System

**12:00 PM – Lunch**

**Optional Roundtable Lunch**  
Records Management: Present and Future Concerns

**Post Conference 90-Minute Sessions 1-4  
1:30 PM – 3:00 PM**

**SESSION 1**

Managing Open Systems for Compliance

**SESSION 2**

My Reprocessing Software

**SESSION 3**

Using the SAFE Standard

**SESSION 4**

Archiving Scientific Data and Part 11 Controls

**3:00 PM – Refreshment Break**

**Post Conference 90-Minute Sessions 5-8  
3:30 PM – 5:00 PM**

**SESSION 5**

Learning How to Identify, Control and Preserve Your Data

**SESSION 6**

E-Record Integrity – How Certain is "Sure Enough"

**SESSION 7**

Understanding System Related Logs and Record Related Audit Trails

**SESSION 8**

Electronic Records Management – Good Practices and Regulatory Expectations

**5:00 PM – Close of Day Three**

**FRIDAY, MARCH 17, 2006**

**7:30AM – Continental Breakfast**

**Post Conference 90-Minute Sessions 9- 11  
8:30 AM – 10:00 AM**

**SESSION 9**

Migrating from Paper to Electronic – It CAN be Done Successfully

**SESSION 10**

Applying Six Sigma to Records Management

**SESSION 11**

ISO 15489 and ERM: What is it all about?

**SESSION 12**

Creating and Keeping eSigs with eRecords: A Real Life Example

**10:00 AM – Refreshment Break**

**Post Conference 90-Minute Sessions 12- 15  
10:30 AM – 12:00 PM**

**SESSION 13**

Case Study: Incorporating Part 11 into New Systems Development Project

**SESSION 14**

Best Practices and Solutions for Long Term Archiving of Electronic Records and Signatures

**SESSION 15**

CASE STUDY: Identity Management Services for Enhanced Compliance

**12:00 PM – Close of Conference**

# Electronic Records Management • March 14 – 17, 2006 • the Netherlands Amsterdam

Complete this registration form, include payment in U.S. funds, and send to:

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For hotel information see page 7.

## Tuesday, March 14, 2006

### Pre-Conference Half-Day Workshops

8:30 AM – 12:00 PM ..... \$795 USD

A  B  C  D  (Choose one)

### Tuesday - Thursday, March 14-16, 2006

**MAIN CONFERENCE: General Sessions, Interactive Sessions and Workshops including:** Managing e-Records & Signatures for Global Compliance • Risk Based Approach to e-Records • Document Management Systems for the 21st Century • Long Term Storage Options • Keeping e-Records Safe in Transit and at Rest • Managing Open Systems for Compliance – And More! .....\$1995 USD

**Please choose one breakout session in each timeframe.**

### Wednesday Interactive Workshops:

8:30 AM – 12:00 PM

E  F  G  H  (Choose one)

**Wednesday Round Table Lunch** (Please check here to attend)

### Thursday Interactive Workshops:

8:30 AM – 12:00 PM

I  J  K  L  M  (Choose one)

**Thursday Round Table Lunch** (Please check here to attend)

## Thursday, March 16, 2006

### Post-Conference 90-Minute Sessions

1:30 PM – 3:00 PM .....\$395 USD

1  2  3  4  (Choose one)

3:30 PM – 5:00 PM .....\$395 USD

5  6  7  8  (Choose one)

## Friday, March 17, 2006

### Post-Conference 90-Minute Sessions

8:30 AM – 10:00 AM .....\$395 USD

9  10  11  12  (Choose one)

10:30 AM – 12:00 PM .....\$395 USD

13  14  15  (Choose one)

### **The Ultimate Passport \$2595 USD**

Attend the entire event at this best value price.

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### COST TOTALS: ELECTRONIC RECORDS MANAGEMENT

#### Tuesday, March 14, 2006

Pre-Conference Workshops A – D \$795 USD \$ \_\_\_\_\_

#### Tuesday – Thursday, March 14-16, 2006

Main Conference including Workshops E – M \$1995 USD \$ \_\_\_\_\_

#### Wednesday, March 15, 2006

Optional Round Table Lunch \$50 USD \$ \_\_\_\_\_

#### Thursday, March 16, 2006

Optional Round Table Lunch \$50 USD \$ \_\_\_\_\_

#### Thursday, March 16, 2006

Post-Conference 90-Minute Sessions 1 – 8 \_\_\_\_\_ X \$395 USD \$ \_\_\_\_\_

#### Friday, March 17, 2006

Post-Conference 90-Minute Sessions 9 – 15 \_\_\_\_\_ X \$395 USD \$ \_\_\_\_\_

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**The Ultimate Passport** \$2595 USD \$ \_\_\_\_\_

**SUB TOTAL** \$ \_\_\_\_\_

\* **Early Bird Discount -10%** \$ \_\_\_\_\_

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# Electronic Records Management

March 14 – 17, 2006 • the Netherlands, Amsterdam • NH Grand Hotel Krasnapolsky

## SPECIAL REGULATORY FOCUS ON:

- **Managing e-Records & Signatures for Global Compliance**
- **Implementing Risk-Based Approaches**
- **EDRMS**
- **Data Migration**
- **E-Signatures**
- **ERM Systems Security**
- **Archiving**

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- CimQuest, Inc.
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- CSSC Inc.
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- GE Healthcare Global IT
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- Medarex, Inc.
- MedImmune
- Mi Services Group
- PharmE
- Sanofi-Aventis
- Shook, Hardy & Bacon, LLP
- Vertex Pharmaceuticals
- Waters Corporation

## WHO SHOULD ATTEND?

- Records Managers/ Directors
- Compliance Managers
- Document Specialist-Storage & Retrieval Units
- IT Department
- Document and Data Management
- Systems Specialists
- Project Managers
- Document Management Systems Units
- Systems Specialists
- Corporate Records Managers/Units
- Digital/Imaging/Electronic Specialists

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INTERACTIVE SESSIONS AND PRACTICAL IMPLEMENTATION WORKSHOPS



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