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3rd Annual ADVANCED COMPUTER SYSTEM VALIDATION

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Practical Approaches to Utilize Risk Management, COTS, GAMP and Other Tools and Techniques for More Effective and Efficient CSV

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Risk-based Validation Strategies for Enterprise Resource Management Systems

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INCLUDED WORKSHOP

Reducing Validation Costs Leveraging GAMP, Risk and COTS

7 CASE STUDIES FROM EXPERTS

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Current Perspectives on an Old Friend.... 21 CFR Part 11

HOW TO APPLY RISK MGMT TO CSV

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DAY ONE
THURSDAY, MAY 17, 2007

7:45 REGISTRATION AND BREAKFAST

8:45 CHAIRPERSON'S WELCOME AND OPENING REMARKS

CASE STUDY

IN-DEPTH INTERACTIVE WORKSHOP

9:00 REDUCING VALIDATION COSTS LEVERAGING GAMP, RISK AND COTS

Chris Potter, Vice President
HPFM, INC.

The increasing use of GAMP methodology and Commercial, Configurable/ Canned off the Shelf (COTS) packages creates opportunities for streamlining the validation effort. This presentation will discuss how the GAMP validation approach can leverage vendor work and how to make use of current guidelines related to risk management. This session will describe the approach to validation of a COTS system and should answer:

- What are the validation requirements for the different GAMP categories?
- How can you leverage vendor work on a COTS system?
- How can risk management help?
- What is configuration and what is custom?
- How can change management reduce revalidation?
- How do you allow for "local modification" to facilitate change?

About the workshop leader: Chris Potter from HPFM Inc. has 20 years of industry experience in Pharmaceutical manufacturing and QA/QC. He has spent the last 12 years consulting in computer systems validation in Pharmaceutical, BioTech and Vaccine corporations. He has led and participated in many successful large software implementations and validation projects including LIMS, ERP, BMS, SCADA, and analytical Laboratory systems.

12:00 LUNCHEON

NEW PART 11 UPDATE

1:00 CURRENT PERSPECTIVES ON AN OLD FRIEND….21 CFR PART 11

Victoria V. Lander, Corporate Compliance Manager
WATERS CORPORATION

As the highly anticipated update version of 21 CFR Part 11 is imminent, it is an opportunity to see what is coming, wait it will mean to you organization, and how to comply with the updated rule. This presentation will discuss the following areas:

■ What's Changed So Far?
- Review of the regulation
- Explanation of the final guidance
- What a 'risk-based' approach really means

■ What Changes Can We Expect?
- Why is the Part 11 rewrite taking so long?
- What's out, what's in?
- What to expect next

■ Program Administration
- Decisions do you need to make immediately
- Which documents and tools should you have in place already?
- Which documents and tools should you add/change?

■ Practical Application
- SOPs and forms for computer system assessment
- Risk-based validation deliverables and Part 11 controls
- Template-driven Part 11 functional specifications
- Making a case for your "legacy systems"

CASE STUDY

2:00 BENEFITS AND EXPERIENCES FROM AUTOMATED TESTING IN THE FDA REGULATED INDUSTRY

Eric Toburen, Director - Life Science Practice
GENILOGIX LLC

Wouldn't you like to reduce costs associated with FDA imposed computer systems validation (CSV) guidelines, and improve test coverage at the same time? Drawing from his experience in the use of automated testing tools in FDA regulated environments, Eric Toburen will discuss the challenges of complying with FDA validation guidelines. Life Sciences companies are already seeing the benefit deploying these tools making their validation projects more efficient while reducing compliance risk. Find out how automated testing and test management practices can shorten the CSV lifecycle and improve test coverage.

As part of the discussion a case study paper will be presented that was developed by the GAMP Special Interest Group on Test Automation entitled: Test Automation in a Pharmaceutical Environment

3:00 BREAK AND REFRESHMENTS

CASE STUDY

3:15 ACCELERATING VALIDATION AND COMPLIANCE EFFICIENCIES THROUGH BPM
Subbu Vis, Director
VALIMATION

This topic outlines the steps for utilizing BPM (Business Process Management) solutions to automate complex business process workflow and repetitive tasks from the Compliance/ Validation realms. The idea is to utilize latest BPM technology to automate and control compliance processes while reducing risk and cost. The presentation will be filled with case studies of various real-life compliance/validation scenarios in order to impress upon the efficiencies that can be gained using BPM/ automation. Case Studies will include:

- Managing Excel spreadsheets using server based services
- Project Lifecycle Management
- Document Management
- Paperless Forms Management
- e-Executions

Benefits with the approach are:

- Gain practical knowledge in utilizing latest BPM tools and technologies to automate compliance and validation
- Realize the value of paperless automation
- Envision the future of compliance and validation

CASE STUDY

4:15 DOCUMENTING THE SYSTEM INSTALLATION PROCESS – HOW TO GET THE MOST OUT OF AN IT DEPARTMENT
Mats Bergkvist
SDLS CORPORATION

The session will describe the first set of validation "tests" performed for a new system during its lifecycle – Installation Qualification (IQ). There are many different schools of what should be included and to what level. The presentation will also discuss how an IQ provided by a vendor can be incorporated for maximum benefit. Other items that will discussed are:

- Key success factors in communication with IT Department
- Structure of an effective system documentation
- Differences between Qualification vs. Validation testing and the documentation requirements
- Who does what – roles and responsibilities
- Training
- How to manage multiple vendors during an system installation and configuration

5:15 INTERACTIVE PANEL DISCUSSION

INCLUDING ALL DAY ONE SPEAKERS

- Observations and direction
- Trends in new technologies and their application for validated systems
- Questions and answers

5:45 END OF DAY ONE

DAY TWO
FRIDAY, MAY 18, 2007

7:30 BREAKFAST

8:25 CHAIRPERSON'S OPENING REMARKS

EXTENDED SESSIONS ON APPLYING RISK MANAGEMENT TO CSV

8:30 HOW TO USE RISK MANAGEMENT TO DETERMINE THE NATURE AND EXTENT OF REGULATORY COMPLIANCE INCLUDING MANAGING SOFTWARE VALIDATION EFFORTS
Victoria V. Lander, Corporate Compliance Manager
WATERS CORPORATION

Commercial Off-the-Shelf Software (COTS) forms the basis of many regulated computer system projects. Whether you use networked laboratory data systems, spreadsheets or electronic batch records systems, these commercial software products need to be validated at the user's site. The creation and implementation of a good Risk Management protocol to determine the extent and the specifics of validation for computerized systems can save the user time and resources, and lead to a more efficient validation process. Risk Management can be applied to a firm's overall compliance initiatives, as well as, the installation, testing and on-going performance control of COTS in a regulated environment in order to determine the extent of regulatory efforts.

This presentation will cover:

- Validation as a part of an overall quality program
- The role of Risk Management to deal with software complexity and level of customization for validation
- Risk Analysis to improve quality and productivity to the validation process
- Interpreting and adopting the ICH Q9 Risk Management guidance for software validation
- Achieving and maintaining state of validation compliance
- Benefits of applying Risk Management methodologies to your firm's overall compliance effort

10:15 MID-MORNING BREAK

CASE STUDY

10:30 RISK-BASED VALIDATION STRATEGIES FOR ENTERPRISE RESOURCE MANAGEMENT SYSTEMS

Gregg Bell, Manager
PDL BIOLOGICS

Validation strategies for Enterprise Resource Management (ERM) systems must address: multi-site / multi-phase implementations, complex network infrastructures, interfaces with other business systems, disaster recovery systems, and compliance to GxP and Sarbanes-Oxley regulations based on intended use. This session will explore the risk-based validation strategies of a multi-phase SAP R/3 implementation. Topics to be addressed are:

- ERM infrastructure and business process risk assessment
- Efficient change management for GxP and non-GxP business processes and system components
- Unit, integration and regression testing strategies
- Maintaining the validated state

12:00 LUNCHEON

CASE STUDY

1:00 SINGLE SOLUTION FOR FDA, SEC AND OTHER IT/COMPUTER SYSTEM COMPLIANCE

James Robertson, IT & Computer System Compliance Consultant
VALIDATION EXPERTS LLC

This session will present an approach to achieve compliance of computerized systems and information systems in the IT infrastructure using the same procedures, controls and practices that IT already uses to meet regulatory as well as business requirements for information security. Indications are that this type of approach will be embraced by the revised 21 CFR Part 11 rule.

A system of IT controls has evolved over the last 40 years into ISO 17799 and a set of controls standardized by the Information System and Audit Control Association (ISACA) as well as a similar set of controls from NIST. Examples are COBIT that is widely used for Sarbanes Oxley compliance and NIST SB800-53 for compliance with the Federal Information Security Management Act of 2002 (FISMA).

Many pharmaceutical companies have dual processes for computerized systems compliance and for IT compliance. I will show that the two system really overlap and that a common system which serves both purposes may result in economies to the companies as well as achieve a more consistent level of ongoing compliance. The attendees will learn:

- Understand the history and parallels: Computer/software validation for quality and IT Controls for IT Governance.
- See how to combine these two compliance (and control) processes.
- See a mapping of COBIT controls to Part 11 controls with the consideration of the organizational issues

CASE STUDY

AN AUDITORS PERSPECTIVE IN QUALITY SYSTEMS

2:00 VALIDATED VERSUS NON-VALIDATED QUALITY SYSTEMS – AN AUDITORS PERSPECTIVE

Ralph L Dillon, Director Compliance
SURETY ASSOCIATES

What a cGMP auditor looks for on Computer Validation and the relationship with Predicate Rules for records and signatures. This presentation draws upon experiences from FDA enspections andpharmaceutical company audits of contract manufacturers.

Computers are used throughout business organizations driving sales projections in the board room, material sourcing and cost-accounting (ERP systems) in operations, manufacturing process control on the floor, analytical data acquisition and integration in the lab all the way through to distribution and logistics. All these systems are subject to being construed as an area to audit for computer validation and, where applicable, Part 11 rules for Electronic Records and Signatures. Where do you draw the inspection line? How do you distinguish between or among systems? And, really, how do you keep the auditor out of places he or she doesn't belong?

Topics include:

- Business vs cGMP computer systems
- Dealing with un-validatable systems (i.e., How do you validate data?)
- Preparing for an audit
- Supporting your practices in an auditatable systems (i.e., How do you validate data?)
- Preparing for an audit
- Supporting your practices in an audit

3:30 CLOSE OF CONFERENCE

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