Industry's Laboratory Compliance Event

Laboratory Controls & Compliance

August 18-21, 2003 ■ Short Hills, NJ
Hilton Short Hills

Hear from 32 Industry Experts, Including 15 Major Pharmaceutical/Biotechnology Manufacturers and Contract Laboratories…

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Baxter BioScience
Solvay Pharmaceuticals
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Gilead Sciences
Berlex BioSciences
Cardinal Health
Covance Laboratories
Sanofi – Synthelabo Pharmaceuticals
Cambrex Corporation
DioSynth
DPT Laboratories

…Plus Two Former FDA Officials

37 INTERACTIVE SESSIONS AND PRACTICAL IMPLEMENTATION WORKSHOPS

Extended Workshops and Sessions

FDA Risk-Based System Inspection Approach

IVT® INSTITUTE OF VALIDATION TECHNOLOGY

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Pre-Conference Half Day Interactive Workshops
Monday, August 18, 2003

7:30 AM – Registration and Continental Breakfast

Workshop A • 8:30 AM – 12:00 PM

Current Good Manufacturing Practice (cGMP) Testing Requirements in a Pharmaceutical Laboratory

Karen S. Ginsbury, President, PCI Pharmaceutical Consulting Israel Ltd.

I. Overview of cGMP Requirements for Testing in a Pharmaceutical Quality Control Laboratory
- Review European and U.S. FDA regulatory requirements
- Training and qualification of technicians and supervisors
- Facility requirements
- Equipment qualification, calibration, cleaning, and maintenance
- Reagent, culture controls, including types of water used
- Test methods and specifications
- Documentation and reporting requirements
- Retained samples and stability programs
- Methods validation, Statistical Process Control (SPC) and Out-of-Specification (OOS) results

II. Controls, Standards, and Out-of-Specification (OOS) Results
- Purchasing procedures for laboratory reagents
- Water quality for testing
- Learn positive and negative controls, duplicates, and replicates
- Developing a procedure for sampling, handling, and retesting of samples

Workshop B • 8:30 AM – 12:00 PM

Qualification for Laboratory Instrumentation and Computer Systems

Steve P. Calabro, Manager; Validation and Laboratory Controls, AAI International, KC

Gary E. Clapp, Ph.D., Vice President of Operations, AAI International, KC

A successful DQ, IQ, OQ, and PQ is the key to validating a variety of High Performance Liquid Chromatography (HPLC), Gas Chromatography (GC), and other types of laboratory equipment.Where and how to start the process of validation must be well planned out. Adopting a practical and universal approach to DQ/IQ/OQ/PQ leads to a streamlining of activities, time savings, effort, and cost.

I. Validation Protocols
- Examples of effective documents
- Review Master Validation Plan (MVP)
- Learn where to start, and who performs what and at what intervals

II. Critical Content of Your Documents and the Vendor's or Third Party's Validation Packages
- Understanding the holistic or modular approach to validation
- Revalidation and Performance Validation (PV)
- Instrument relocation

III. Legacy Instrument Validation and System Tracking
- Do you validate part or whole?
- Opening and closing the equipment information loop, who needs to know what, when, and how?
- Tracking and documenting the lifecycle of an instrument

Workshop C • 8:30 AM – 12:00 PM

Implementing 21 CFR Part 11 in Laboratories

Ludwig Huber, Ph.D., Worldwide Product Marketing Manager, Agilent Technologies

Going from paper to electronic records can significantly increase a laboratory's efficiency. FDA's regulation on electronic records/signatures enables laboratories to fully implement electronic records systems. Unfortunately, there are still many discussions on if and how requirements should be implemented in laboratory computer systems. Using practical examples, this workshop will enable attendees to understand laboratory specific requirements and to implement them in a most cost effective manner.

I. Introduction to Part 11 and Impact on Laboratories
- Learn about Part 11 requirements
- FDA expectations as of August, 2003
- Understand FDA's new Part 11 guidance on scope and application
- Understand the benefits of electronic versus paper records
- The reaction industry organizations: Part 11 industry coalition, PhRMA, ISPE

II. Implementing Critical Requirements
- Understand the importance and critical points of audit trails
- Learn about strategies for archiving and retrieval of data: short versus long-term
- How to bind handwritten and e-signatures with e-records
- How to make MS Excel compliant with Part 11

III. Part 11 and Validation
- Learn which computer systems should be validated
- Discuss critical requirements
- Learn what and how laboratory computers should be tested
- What to document and test after system upgrades
- How to validate MS office programs like Access and Excel

Pre-Conference Half Day Interactive Workshops
Monday, August 18, 2003

IV. Interactive Exercise: GAP Analysis
INTERACTIVE
Using two different case studies from a laboratory, two teams will write Part 11 specific elements of a user requirement specification. As a team, the requirements will be prioritized using the new Part 11 guidance as a model.

Download workshop and reference material from the Internet at: www.labcompliance.com/ivt to obtain the most benefit out of this workshop.

Workshop D • 8:30 AM – 12:00 PM

Laboratory Information Management Systems (LIMS) Selection, Validation, and CFR Part 11 – a Practical Approach to GMP Compliance
INTERACTIVE

Victor Rivera, Computer Validation Manager, Amgen
Sam Yazdani, Quality Control Information Systems Administrator, Gilead Sciences

I. Successful LIMS Selection:
- Develop a Validation Master Plan (VMP)
- Understanding a User Requirement Specification (URS)
- Vendor interviews, presentations, and audits
- Final recommendation to management and/or selection

II. LIMS Validation
- System development lifecycle
- Validation planning – the recipe for success
- Validation and the on-going change control relationship
- Regulatory expectations on computer-related systems validation
- The validation project team – members and responsibilities
- The art of testing
- Testing the system, or the process?
- How to write test cases, and assure coverage
- Testing the infrastructure
- Failure resolution, and regression testing – how to define what to retest

III. Interactive Exercise: Sample Logging
- Discover basic requirements for a generic sample logging functions
- Required design or configurations components
- Generate a test case for the function

IV. Interactive Exercise: GMP Impact
- Identifying the GMP components affected by LIMS
- Impact of LIMS to GMP components
- What to include in your URS
- LIMS final functionality
- Specific GMP, GCP, GLP (GXP) requirements related to LIMS

INTERACTIVE

V. Understanding 21 CFR Part 11 and LIMS
- Recognize the intent of the regulation
- Review the scope of 21 CFR Part 11
- Part 11 Assessment

12:00 PM – Luncheon for Pre-Conference Attendees

12:00 PM – Conference Registration

1:15 PM – Interpreting FDA Guidelines and Regulations for the Laboratory

Sandy Weinberg, Ph.D., Linnaeus Chair of Biomedical Entrepreneurship, Muhlenberg College and Laboratory Investigation Training Consultant to the FDA

This presentation provides an up-to-the minute summary of new FDA concerns in the laboratory, including:
- Guidelines, rules, interpretation, and regulations
- Understand 21 CFR Part 11 and the latest guidance
- General requirements of a risk assessment
- Other regulatory agencies

2:15 PM – FDA Enforcement Strategies for the Laboratory

John Markus, Sr. Regulatory Consultant, AAC Consulting Group, Former Chief Chemist and Investigator, FDA

This session provides an agency perspective on laboratory investigations. By reviewing FD-483s and Warning Letters, you will be able to understand and anticipate FDA's enforcement strategy related to laboratories. Attendees will discuss:
- Quality in the Laboratory
- The ever present aura of 'documentation'
- Integrity and reliability of results
- The investigative process
- Success in the regulatory laboratory

3:00 PM – Refreshment Break

3:30 PM – GMPs for the New Millennium: A Risk-Based Approach for the Laboratory

Albert A. Coreira, Vice President, Velquest

Most companies estimate that 70% of laboratory resources are dedicated to compliance activities. Current trends utilize a risk-based approach to identify the critical instruments, systems, and processes currently in use. This presentation provides an overview of the best practices and lessons learned in the identification of critical areas based on their risk to product quality. Review the key elements of today's compliance management systems, and what tools are required to determine the risk they pose to product. The presentation will also provide recommendations to assist in the migration from paper to electronic records in compliance with current regulations, such as 21 CFR Part 11.
- Discover technology and non-technology components of electronic record programs
- Implementing error prevention programs to increase correct-first-time results

4:15 PM – Conducting Laboratory Audits

Tom Paino, Quality Assurance Manager for Tyco Healthcare/Mallinckrodt

Follow the path of a product as it enters the analytical laboratory, as it is tested, and is either released or rejected by the quality unit.This presentation includes the sample receipt and storage areas, various instruments commonly found in the laboratory, and the analytical chemist's office area. Attendees will learn:
- Obtain a brief checklist of what to inspect during an audit
- Review examples of how logbooks consisting of bound, preprinted forms, facilitate consistency, quality, and compliance
- Observe photos of a showcase GMP-compliant analytical laboratory

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

7:15 AM – Roundtable Breakfast: Preparing for FDA Inspections for the Laboratory

7:30 AM – Continental Breakfast

WORKSHOP E • 8:30 AM – 12:00 PM

The Self Audit: Assessing Laboratory Compliance

Jerry Lanese, President, The Lanese Group, Inc.

Compliance in the laboratory is a major issue for all pharmaceutical firms, and the laboratory should have an on-going program of self-assessment.This session will provide the background and tools for self-assessment.

I. Interactive Discussion: Establishing the Laboratory Assessment/Audit Program
- Regulations, including 21 CFR 211
- Standards including ISO 17025
- Guidance, including ICH Q7A, GMP Preamble, Guide to Inspection of Quality Control Laboratories
- Internal procedures
- Scheduling of the audits

II. Performing a Laboratory Assessment
- Planning auditors activities; questions to ask
- Laboratory procedures that should be in place
- Elements that should be contained within procedures
- Records that are required by the procedures
- What laboratory individuals should be reviewed?
- How does the audit team verify that the laboratory is following proper procedures?

III. Follow-up of the Assessment
- Develop a Corrective and Preventative Action (CAPA)
- Laboratory plan of action
- Management responsibility to support the assessment program

WORKSHOP F • 8:30 AM – 12:00 PM

Analytical Test Method Validation and Verification: Implementation and Management

Paul Newton, Ph.D., Technical Project Manager, GlaxoSmithKline

I. Understanding Method Validation Terms and Current FDA Requirements and Other Regulatory Agencies
- Definitions for each method validation parameter
- Current International Conference on Harmonization (ICH) expectations

II. Designing the Process to be Meaningful and Valuable: Specific Experiments and Acceptance Criteria
- Detailed specific experimental approaches to method validation
- Specific quantitative acceptance criteria for each validation parameter

III. Managing the Method Validation Process to Increase Future Value, and Acting on Experimental Findings Post-Method Development
- Establish standardized and optimized processes
- Performing effective method validation exercises and testing with properly validated test methods

IV. Documenting the Method Validation Exercise to Realize Maximum Value
- Performing appropriate method validation exercises is necessary, but not sufficient
- The method validation report indicates to others the quality of the validation exercise
- Examples will be shared on how to give the most favorable impressions from this very important tool

V. Interactive Exercise:Understanding What Method Verification Means and How to Achieve It

Learn what is meant by, and is currently expected, regarding method verification. Attendees will discuss how method verification is appropriate, versus performing full method validation. Method verification documentation options will be discussed, and what to do with this documentation once it is completed.The issue of what specific extra activities can be of potential benefit, and what activities add no practical value will also be covered.

HALF-DAY INTERACTIVE WORKSHOPS
TUESDAY, AUGUST 19, 2003

WORKSHOP G • 8:30 AM – 12:00 PM

Conducting an Effective Laboratory Failure Investigation: Writing an Investigation Report

Ann Marie Gartska, Quality Assurance Specialist, Amgen, Inc.

A majority of FD-483 observations have been cited for poor laboratory investigations. Writing an effective investigation is more than just pen to paper; it must be a succinct, accurate description of an investigation. A well-written laboratory investigation takes into account root cause analysis, CAPA, and trending. In this presentation, attendees will examine how to conduct an effective laboratory failure investigation, and provide sound guidelines on how to write an investigation report.

I. Evaluating Laboratory Data
- Review and discussion of the Barr Decision
- Defining the difference between Out-of-Trend (OOT), OOS and outliers
- Scrutinizing the data. Asking the right questions

II. Root Cause Analysis (RCA)
- Critical thinking and investigational skills; basic RCA mechanics
- Identifying key contributing factors associated with test methods, specifications, and laboratory equipment
- Recognize Root Causes (RCs) to respond to non-compliance, failures, deviations, and complaints
- Using innovative techniques for determining RC

III. CAPA – Solution Strategies
- The difference between corrective action and preventive action
- Determining the right CAPA, and how to best use this system
- Choosing and implementing the corrective action

IV. Trend Analysis
- Identifying what to trend – quality markers
- Effective use of trend analysis to identify problems

V. The Laboratory Investigation
- Developing a checklist as a tool for failures
- Enhanced documentation practices to prevent 'reinventing' the wheel syndrome
- Lab investigations that should prompt manufacturing investigations

VI. Interactive Exercise: Complaint Investigations

Attendees will review examples of complaint investigations and CAPA-related documentation. Attendees will critique examples of forms and documents as related to writing styles and techniques.

WORKSHOP H • 8:30 AM – 12:00 PM

Best Long-Term Archiving Practices to Assure Data and Record Integrity and Authenticity: Meeting Regulatory and Legal Requirements

Charlie Sodano, Ph.D., Manager Information Services, Berlex Biosciences

Almost all research data, documents, and records today are being authored or generated electronically. However, the archive media of choice is still paper with a disaster recovery copy as microfilm for most operations. Laboratory and research records need to be retained somewhere between a few years to greater than 40 years, depending on the importance of the information to a company's business. As we move closer to routine electronic drug applications, patent submissions, and e-business transactions, there will be an increased emphasis on long-term storage of electronic records.

I. Current Regulatory and Legal Requirements for Electronic Records
- E-Sign, Environmental Particulate Aggregates (EPAs) Cromerr, HIPPA, and Sarbane-Oxley
- Obtain up-to-date information about existing legislation
- Learn what is required to comply

II. International Models and Standards
- Long-term electronic record archiving
- How the Australian government is going electronic by 2005
- The U.S. National Archives and Records Administration and electronic records
- Operational and Administrative System for Import Support (OAIS) and InterPARES

III. Interactive Exercise: Practical Strategies and Technology Forecasts

A multiple-choice quiz will be given on technology choices for electronic archives. After the results are tabulated and discussed, the speaker's recommendations will be presented.
- Review of hardware and software technologies
- Recommendations for short term (two-seven years) archiving
- Recommendations for long term archiving (eight-40 years)

12:00 PM – Luncheon

Main Conference General Sessions
Tuesday, August 19, 2003

1:15 PM – The New Part 11 Guidance and Its Effect on the Laboratory

Ludwig Huber, Ph.D., Worldwide Product Marketing Manager, Agilent Technologies

In February, 2003 the FDA released a new draft guidance on applications and scope.The new approach is in line with FDA's 21st Century drug cGMP initiative.The final guidance is expected to be released in July/August. With new guidances, the FDA narrows the scope of Part 11 and requires to implement Part 11 specific requirements, based on justified and documented risk assessment. In this presentation, attendees will learn:
- FDA's new drug GMP initiative and the impact on Part 11
- Key differences between the old and new guidance
- Which laboratories and applications are affected
- How to deal with most critical requirements; record retention, e-audit trail, and binding signatures with e-records
- Identify high-risk computer systems and records
- A practical and cost-effective approach to implement the new guidance

2:00 PM – Understanding FDA Guidelines on Handling Out-of-Trend Results

Dr. Mohammad Kazemi, Ph.D., Quality Control Manager, Baxter BioScience

Proper identification and addressing the root cause for any Out-Of-Trend (OOT) result is crucial for continuous improvement of the assay and/or manufacturing processes. True root causes can only be identified through in-depth laboratory and/or manufacturing investigation. Clear classification of the OOT results is essential for choosing the correct approach for handling the necessary investigation, retesting, and reporting of the final results. Documentation, investigation, and handling of OOT results according to the FDA draft guideline on OOS will be discussed. Attendees will learn:
- Distinguishing between different types of OOT results
- What to consider in investigating OOT results
- How to handle OOT and/or retest results
- Benefit from OOT results investigation

2:45 PM – Refreshment Break

3:15 PM – The Laboratory: Cornerstone of Quality Systems

Barbara Zinck, Senior Director, Corporate Compliance, Cambrex Corporation

Assuring laboratory quality at the forefront can prevent later problems, save resources, and pave the way for success. Participants will understand the importance of the laboratory, quality systems, and the interdependence of the laboratory with other departments within a GMP-regulated manufacturing company.Quality areas that will be discussed include:
- Evaluation and recommendations
- Documentation and change control
- Technology transfer
- Internal audit systems
- Discrepancy and deviation reporting
- Supplier/vendor/contractor quality program

4:00 PM – Reducing Out-of-Specification (OOS) Investigation Backlogs: Causes and Effective Strategies to Prevent OOS Results Due To Analytical Error

Paul Newton, Ph.D., Technical Project Manager, GlaxoSmithKline

This presentation will address the cost of laboratory investigations due to analytical error. Prevention of OOS results due to avoidable analytical test method error will also be discussed in detail, with practical recommendations for their elimination.Tips will be provided on how to overcome invalid OOS results once they have been generated.
- Learn common causes of OOS results due to analytical error
- How laboratory analysts can contribute to erroneous test results
- What support analysts should be provided in order to help them avoid generation of invalid OOS results of 21 CFR Part 11 Electronic Records and Electronic Signatures regulation
- How test methods can introduce error

4:45 PM – A Mechanistic Approach to Aberrant Data Investigations for Analytical Laboratory Results

Phil Meeks, Director, Pharmaceutical Analysis, Cardinal Health

Aberrant data investigations can lead to retesting in order to properly resolve an issue. One must balance the need for such activities without inadvertently spiraling into a campaign of "testing into compliance."This presentation will provide guidance for utilization of a mechanistic approach to laboratory investigations. A system will be overviewed that allows for scientific, laboratory management, and quality assurance staff to make rational decisions based on scientifically sound data.A step-wise approach will be detailed.
- Distinguish between assignable, suspected, and unassignable cause
- Decide between a resampling versus retesting approach
- Determining when not to retest
- Practical tips for designing retest plans
- Tracking and trending of data

5:30 PM – Close of Day Two
Networking Cocktail Reception

7:30 AM – Continental Breakfast

WORKSHOP I • 8:30 AM – 12:00 PM

Ensuring Access Databases and Excel Spreadsheets are Part 11 Compliant

Ty Mew, President, Ofni Systems Inc.

Mary Chris Easterly, Technical Manager, QA Validation, Diosynth

Derek Wimmer, President, Wimmer Systems, LLC.

This seminar presents how to design, build, and validate Access® databases and Excel® spreadsheets in accordance with current practices, including 21 CFR Part 11.

I. Ensuring Access Databases are Part 11 Compliant
- Overview of databases for Part 11 compliance
- Technical controls and functionality
- Securing the Access environment
- Procedural controls required to be implemented
- Validation of Access programs
- Demonstrations and case studies

II. Making Excel Spreadsheets Part 11 Compliant
- Regulatory basis for compliance
- Organizational management of spreadsheets
- Implementation of compliance controls

III. Interactive Exercise

An open question and answer forum for discussing issues related to making Access databases and Excel spreadsheets compliant.

WORKSHOP J • 8:30 AM – 12:00 PM

How to Design a Risk-Based Approach to Validation

Ron E. Barnett, Validation Manager, Thermo Electron Corporation, Informatics

I. How to Identify Risks to Data Integrity
- Software and hardware requirements
- Complexity of your computerized system
- Policies and procedures
- Business rules
- Part 11 and the predicate rules
- Cost of the system as a factor

II. Interactive Exercise: Risk Factors
Attendees will put together risk factors that can be used to quantify risk.

III. Quantifying the Risk: A Spreadsheet Approach
- The quantifiable importance of a given risk factor
- Predicates, and levels of risk for a given factor
- The role of system complexity
- Role of the vendor

IV. Interactive Exercise: Assessing Risk
Attendees will quantify and create a spreadsheet that can be used to assess risk.

V. Interpreting the Risk
- Creating a risk index
- Creating a two dimensional risk plane
- Do you need to validate?
- Do you need to reassess your requirements
- Risk mitigation activities

WORKSHOP K • 8:30 AM – 12:00 PM

Compliance Issues for the Use of Electronic Laboratory Notebooks (ELN) in the Pharmaceutical Industry

Dick Doesberg, Global Functional Information Manager R&D, Solvay Pharmaceuticals BV

Victoria V. Lander, Market Development Manager, NuGenesis Technologies

I. Compliance Issues for the Use of Electronic Laboratory Notebooks (ELN) in the Pharmaceutical Industry
- FDA's 21 CFR Part 11
- What is an electronic notebook, and how can you use one in a regulated lab?
- Identifying how compliance issues affect the use of ELNs

II. Case Study for the Use of ELN in the Pharmaceutical Development Process
- Why – business case for an ELN in a chemical process development environment
- How– implementation considerations and details; Information Technology (IT) architecture
- Next – conclusion and future developments

III. Interactive Round Table Discussion

Attendees will review the challenges and issues related to implementing and utilizing an ELN in the regulated and pharmaceutical laboratory. Case studies and approaches to overcoming the obstacles involved in setting-up an electronic system will be reviewed.

Half-Day Interactive Workshops
Wednesday, August 20, 2003

Workshop L • 8:30 AM – 12:00 PM

GMP Requirements for Training Programs of Laboratory Personnel

Jerry Lanese, President, The Lanese Group, Inc.

GMPs require the training of all personnel engaged in the manufacture, and control of Active Pharmaceutical Ingredients (APIs) and drug products. This includes laboratory personnel.This presentation will begin with a discussion of the requirements for training, and how this applies to the laboratory environment. Attendees will discuss and define:

I. Training Program
- Where is it described?
- Program content
- Responsibility for managing the program
- Responsibility for maintaining the records maintains

II. Job Description
- Human relations department responsibilities
- Laboratory responsibilities
- Quality Assurance (QA) Responsibilities
- Content

III. Training Plan
- Review a format
- Content
- Timing
- Responsibilities

IV. Proficiency Testing
- Does proficiency testing apply to all positions, and all skills?
- How is proficiency testing performed?
- Source of samples
- Evaluation of results

V. Maintaining Demonstrated Proficiency
- How is proficiency maintained?
- Does maintaining proficiency apply to all tasks or skills?

12:00 PM – Luncheon

Post-Conference Expanded Sessions
Wednesday, August 20, 2003

Session 1 • 1:30 PM – 3:00 PM

Controlling and Characterizing Impurities: Developing a Strategy in Today's Rapid Product Development Environment

Bradford J. Mueller, Ph.D., Manager Analytical Development, AstraZeneca Pharmaceuticals LP

A major initiative in most pharmaceutical companies is to shorten the amount of time required to go from compound nomination to product launch.The compressed timelines create significant challenges for the analyst, especially in the area of controlling and characterizing impurities.

I. Overview of Regulatory Guidances
- ICH quality guidelines Q3A, Q3B and Q6A
- Expectations during Phase I/II/III

II. Development of Internal Procedures to Characterize and Control Impurities in Development
- Tracking and documenting of impurities
- Strategies for qualifying impurities
- Application of analytical screening procedures to identify new or unknown impurities

III. Setting and Defending Regulatory Specifications
- Justifying specifications based on limited stability/production data
- Understanding and controlling impurities

IV. Interactive Exercise: Impurities INTERACTIVE

Attendees will participate in devising a strategy for characterizing and controlling impurities during clinical stages of development.

Session 2 • 1:30 PM – 3:00 PM

Maximizing Efficiency and Ensuring Compliance through Effective Laboratory Design, Construction, and Qualification

Randall Pinchot, Chief Architect, Washington Group International

Rebecca Brewer, Director, Validation and GMP Compliance, Dober Group

I. Key Phases to Planning and Carrying out Laboratory Design Goals
- Assessment needs
- Facility programming
- Conceptual design and development
- Construction/construction phasing
- Qualification of the laboratory

II. Considering and Identifying the Needs of all Stakeholders

- Successful projects are the result of careful planning, considering the needs of all involved. Learn how to determine and identify the needs of:
  - Chemists
  - Microbiologists
  - Operations
  - Quality
  - Regulators

III. Understand and Learn to Manage the Complexities of a Wide Range of Projects

- New facilities
- Existing laboratories planned for retrofit
- Process and general facilities converted to laboratory space
- Ensure your designs are implemented without interruption to ongoing operations and testing
- Confirm that your planning includes qualification activities on your critical path to ensure a seamless transition and facility start-up

Session 3 • 1:30 PM – 3:00 PM

Developing a Maintenance and Calibration Program for HPLC Systems and Other Laboratory Equipment

Steve P. Calabro, Manager, Validation and Laboratory Controls, AAI International, KC

Gary E. Clapp, Ph.D., Vice President of Operations, AAI International, KC

This presentation will discuss the issues that need to be evaluated and addressed in our Preventative Maintenance (PM) and calibration Standard Operating Procedures (SOPs). Working SOPs will be presented throughout the presentation, and they will be made available to those in attendance. This presentation will primarily discuss HPLC system, PM, and calibration documents, but the concepts and even the SOPs themselves, can be utilized for any piece of equipment in the laboratory.

I. Interactive Exercise: Streamlining Your Efforts and Documents

INTERACTIVE

Attendees will discuss how several different styles in an document leads to a more effective SOP.

II. Deciding How to Calibrate Your Systems

- Holistic versus a modular approach
- Which tests are desired
- Preparing a maintenance and calibration system policy

III. Tracking and Documenting

- Preparing a maintenance and calibration instrument log book; an example will be provided for your own use
- Documents for a working HPLC pump and autosampler maintenance and calibration SOP
- Preparing an HPLC system troubleshooting procedure checklist
- Equipment investigation forms
- New equipment notification forms
- Equipment disposition (retirement) form

IV. HPLC PM and calibration schedule:The use of a Performance Verification (PV) protocol

- Preventative Maintenance (PM), calibration and revalidation

Session 4 • 1:30 PM – 3:00 PM

Working Towards the Electronic Notebook Using Stability Data

Kim Huynh-Ba, Manager, Vaccines QA Compliance, Wyeth

I. Documentation Systems to Record Analytical Data

- Designing the documentation system
- Regulatory compliance aspects
- Easy retrieval and data trending

II. Evolution from Paper to Electronic Notebook

- Recording of raw data
- Designing and utilizing a laboratory worksheet system
- Case study: laboratory worksheet system used in an analytical Research and Development (R&D) department
- Protecting data integrity
- Share data locally and globally
- Integrate the lab to a paperless LIMS
- How to prepare for FDA audits

INTERACTIVE

III. Interactive Exercise: Designing SOPs to Ensure Quality and Integrity

Attendees will discuss how to implement electronic worksheet principles in practice. An example electronic worksheet will be used to demonstrate the benefits of documenting in this system. As a group, attendees will be required to make a list of requirements for designing SOPs that will ensure the quality and integrity of the data documentation. Discussions will follow on how these SOPs can then be implemented into the quality system.

3:00 PM – Refreshment Break

90-Minute Post-Conference Expanded Sessions
Wednesday, August 20, 2003

Session 5 • 3:30 PM – 5:00 PM

Standard Operating Procedure (SOP) Management in the Life Sciences Enterprise

Andrew Grygiel, Life Sciences Industry Director, Documentum

I. Introduction to SOP Management
- Current state of SOP management
- Challenges of a paper-based SOP management system

II. Automating SOP Management
- Ensuring all regulated content is managed efficiently within regulatory guidelines
- Strategic advantages from providing knowledge chain linkages among product innovation, development, and manufacturing

III. Automating SOP Management with Enterprise Content Management (ECM) for Effective Compliance
- Learn how it can help a company's ability to be in compliance with regulatory bodies
- Create knowledge linkages to foster global and interdepartmental collaboration and communication
- Discuss best practice for automating SOP management

IV. Interactive Exercise INTERACTIVE
Examine the lifecycle of an SOP as it moves through an automated management process.

Session 6 • 3:30 PM – 5:00 PM

Understanding Regulatory Requirements for Reference Standards – the Foundation of Laboratory Testing

Jerry Lanese, President, The Lanese Group, Inc.

I.The Use of Reference Standards
- Analytical and physical testing
- Microbiological testing
- Calibration

II. Requirements for Reference Standards
- Current compliance expectations and good science
- Trace ability to recognized reference

III. Classification of Standards
- Reference standard
- Primary standard
- Consensus standard

V. Records Required by the Reference Standard Program
- Characterization of the standard
- Standard inventory and usage
- Comparison of house standard to compendial standard

Session 7 • 3:30 PM – 5:00 PM

Developing Justified and Documented Risk Assessment Procedures for Laboratories

Sandy Weinberg, Ph.D., Linnaeus Chair of Biomedical Entrepreneurship, Muhlenberg College and Laboratory Investigation Training Consultant to the FDA

I. Step-by-Step Procedures for Completing a Part 11-Required Risk Assessment for LIMS and Other Laboratory Systems
- Techniques for developing a multi-tier validation standard
- Evaluating a system's potential hazards
- Assigning probability and severity values to those hazards
- Determining the risk those adverse events represent

II. Using a Risk Grid to Determine Appropriate Validation Strategies
- Applying the final determination to the risk grid
- Cost-effective Part 11 compliance; lower compliance cost without sacrificing quality or regulatory acceptance
- Transfer Risk Assessment Skills to Other Regulatory Environments and Lab Systems

III. Interactive Exercise INTERACTIVE
Attendees will complete a risk assessment on their own LIMS environment.

Session 8 • 3:30 PM – 5:00 PM

Preparing for FDA Systems-Based Inspections

Ganapathy Mohan, Ph.D, Senior Director, Quality Assurance, Sanofi-Synthelabo Pharmaceuticals Research Division

I. Introduction to the QSIT Program
- Details of the different systems that will be inspected
- Industry perspectives
- Discover advantages and disadvantages

II. Developing a Comprehensive and Strategic Internal Auditing Program
- Observations from internal audits
- How to prepare for audits

III. Interactive Exercise INTERACTIVE
Attendees will have an opportunity to discuss FDA inspection experiences (without divulging any proprietary information) to others in the group and with the speaker.

90-Minute Post-Conference Expanded Sessions
Thursday, August 21, 2003

7:15 AM – Roundtable Breakfast: 21 CFR Part 11:The New Draft Guidance

7:30 AM – Continental Breakfast

Session 9 • 8:30 AM – 10:00 AM

Regulatory Agency Perspective: Auditing a Quality Control Laboratory in a Pharmaceutical Setting

Jay S. Allen, Senior Consultant, Stelex – The Validation Group, former FDA Investigator

I. Laboratory Compliance
- Equipped and staffed laboratory is essential for compliance with cGMPR
- Laboratory requirements of 21 CFR subpart I – Sections 211.160, 211.176

II. Conducting the Audit
- Receipt and documentation of samples received
- Necessary steps to determine if a laboratory is compliant
- Requirements to be in compliance

III. Interactive Exercise: FDA Observations
- Discuss common observations found during FDA inspections

Session 10 • 8:30 AM – 10:00 AM

Regulatory Requirements for Change Control in the Laboratory

Jerry Lanese, President, The Lanese Group

I. Regulatory Requirements for Change Control
- Review of FDA 21 CFR 211
- Proposed amendments
- International Conference on Harmonization (ICH) Q7A

II.The Change Control System
- Relation of laboratory to site change control system

III. Laboratory Specific Changes
- Changes to specifications, sampling plans, and test methods
- Site changes
- Change of instruments or instrument components

Session 11 • 8:30 AM – 10:00 AM

Conducting and Effectively Executing Stability Studies
Mike Klawikowski, Operations Supervisor, Covance Laboratories Analytical Services Group

I. Understanding FDA Regulations and Guidances
- Review of FDA 21 CFR 210 and 211
- International Conference on Harmonization (ICH) Review
- FDA's *Guidance for Industry: Stability Testing of Drug Substances and Drug Products*

II. A Contract Research Organization (CRO) as a Partner in Stability Studies
- Key elements needed for successful study execution
- Identifying the objective or statement of purpose
- Determining FDA regulatory requirements
- Assigning Quality Assurance (QA) (if applicable)/Quality Control (QC) responsibilities

III. Handling Out-of-Specification (OOS) Results in Stability Studies
- The investigation begins at the end, a two-step process
- Dealing with assignable cause
- What to do when no assignable cause is found
- Corrective action

IV. Interactive Exercise: Stability Study
This presentation will review the challenges to executing a stability study. Attendees will break into groups, and a case study will be discussed within each group.

Session 12 • 8:30 AM – 10:00 AM

Good Laboratory Practice (GLP) Compliance in a Development Laboratory

Lawrence Bush, Ph.D., Research Scientist IV, Amgen

Analytical laboratories supporting process development require high throughput capabilities, multiplicity of analytical methodologies to assess purity, potency, etc. of biopharmaceuticals. Analytical testing is required to be conducted under GLP compliance as per 21 CFR 58.A significant time savings, including resources may be achieved if both types of analytical testing could be conducted in the same laboratory. In this presentation, attendees will learn:
- Importance of generating a GLP compliance master plan
- Established documentation by the analytical laboratory
- Generation of Certificates of Analysis (CofA)
- GLP stability programs
- Qualifying an analytical method prior to routine use
- Establishing instrument qualification programs
- Developing training programs

10:00 AM – Refreshment Break

90-Minute Post-Conference Half Day Expanded Sessions
Thursday, August 21, 2003

Workshop 13 • 10:30 AM – 12:00 PM

Validation of HPLCs Used in Regulatory Applications

Jeff Schlichting, Manager of Quality Systems, DPT Laboratories

I. Validation as Part of a Documentation System
- Validation is a process and not an event
- Documenting the instrument lifecycle
- Documentation of validation activities

II.Writing the Validation Protocol
- Writing user specifications
- Elements of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) for High Performance Liquid Chromatography (HPLC)
- Change control and revalidation
- Expectations and pitfalls of vendor validation protocols

III. Classification Strategy for Laboratory Instruments
- How much documentation is needed?
- Supporting documentation
- Documentation practices for instrument failure

IV. Interactive Exercise: Instrument Systems INTERACTIVE

Attendees will classify an instrument system, propose OQ and PQ challenges, and develop on-going performance testing based on the provided user specifications. The group will then perform an assessment of a number of instrument failures and discuss documentation practices

Workshop 14 • 10:30 AM – 12:00 PM

How to Inspect a Contract Laboratory with the System-Based Approach

Kim Huynh-Ba, Manager, Marketed Product Support QA Compliance, Wyeth Vaccines

I. How System Observations Differ from the Old GMP-Type Observation
- Comprehensive operational SOPs
- Strategic auditing program
- Contract laboratory audits

II. Protocols and Strategies for Contract Laboratory Systems-Based Inspections
- Create a logistical plan with the contract lab
- Administer inspection protocol
- Establish GMP inspection training programs
- Prepare effective system documentation
- Best practices when working with a contract lab
- Change control and maintaining compliance

III. Interactive Exercise: Mock Study INTERACTIVE

The class will break up into three groups: one representing the company, one representing the contract lab, and the other representing a regulatory body. Using principles described in the presentation, and a suggested scenario, company officials will attempt to convince the inspector that a state of compliance has been achieved.

Workshop 15 • 10:30 AM – 12:00 PM

Handling OOS Chemical Testing Results when Evaluating Uniformity Characteristics of Batches

Paul Newton, Ph.D., Technical Project Manager, GlaxoSmithKline

I. Strategies to Prevent Out-of-Specification (OOS) Uniformity
- Prevent OOS uniformity results by optimizing the laboratory analytical process
- Investigation for uniformity OOS result needs to be designed differently from the “normal” OOS result laboratory investigation
- Develop laboratory investigation protocols

II.The Potential Gains and Risks
- Differences between uniformity and non-uniformity test results
- Batch uniformity testing
- Examples of laboratory investigation procedures
- Industry examples on uniformity samples

Workshop 16 • 10:30 AM – 12:00 PM

Documentation to Support GMP Compliance in the Laboratory

Anne Marie Garstka, Quality Assurance Specialist, Amgen, Inc.

I. Developing SOPs for the Lab Environment
- Key elements for laboratory SOP development
- How to use the SOP for training purposes
- Using SOPs to develop intro to lab training

II. Documentation Practices that Support Laboratory Investigational Findings
- Investigational checklists for lab investigations
- Data that supports drug applications
- Running an effective lab investigational program

III. Paperwork Trail:The Laboratory Notebook
- Good documentation practices for the lab notebook
- Reviewing the lab notebook

Laboratory Controls and Compliance

CONFERENCE-AT-A-GLANCE: August 18-21, 2003

SUNDAY, AUGUST 17, 2003 • 6:00 pm – 8:00 pm PRE-REGISTRATION

Monday
August 18, 2003
Pre-Conference • Day One

Half-Day Pre-Conference Workshops/General Sessions

7:30 AM – Registration and Continental Breakfast

8:30 AM – 12:00 PM
Pre-Conference Workshops

A. GMP Testing Requirements in a Pharmaceutical Laboratory

B. Qualification for Laboratory Instrumentation and Computer Systems

C. Web-Based Applications in the Regulated Laboratory

D. LIMS Selection, Validation, and Part 11

12:00 PM – Lunch for Pre-Conference Attendees

12:00 PM – Registration

Main Conference Begins
General Session
1:15 PM
FDA Guidelines and Regulations for the Laboratory

2:15 PM
FDA Enforcement Strategies

3:00 PM – 3:30 PM
Refreshment Break

3:30 PM
GMPs for the New Millennium: A Risk-Based Approach for the Laboratory

4:15 PM
Conducting Laboratory Audits

5:00 PM
Close of Day One and Networking Cocktail Reception

Tuesday
August 19, 2003
Conference • Day Two

Half-Day Interactive Workshops/General Sessions

7:15 AM
Roundtable Breakfast:
Preparing for FDA Inspections for the Laboratory

7:30 AM
Continental Breakfast

8:30 AM – 12:00 PM
Interactive Workshops

E. The Self Audit: Assessing Laboratory Compliance

F. Analytical Test Method Validation and Verification

G. Conducting an Effective Laboratory Failure Investigations

H. Best Long-Term Archiving Practices

12:00 PM – Luncheon

General Session
1:15 PM
New Part 11 Guidance and Its Effect on the Laboratory

2:00 PM
Understanding FDA Guidance on Handling OOT Results

2:45 PM
Refreshment Break

3:15 PM
The Laboratory: Cornerstone of Quality Systems

4:00 PM
Reducing OOS Investigation Backlogs

4:45 PM
A Mechanistic Approach to Aberrant Data Investigations for Analytical Results

5:30 PM
Close of Day Two and Networking Cocktail Reception

Wednesday
August 20, 2003
Conference Day Three

Half-Day Workshop/Post-Conference Expanded Sessions

7:30 AM
Continental Breakfast

8:30 AM – 12:00 PM
Interactive Workshops

I. Ensuring Access Databases and Excel Spreadsheets are Part 11 Compliant

J. How to Design a Risk Based Approach to Validation

K. Electronic Laboratory Notebooks

L. GMP Requirements for Training Programs of Laboratory Personnel

12:00 PM – Luncheon

90-Minute Post-Conference Expanded Sessions

1:30 PM – 3:00 PM

1. Controlling and Characterizing Impurities
2. Laboratory Design, Construction, and Qualification
3. Maintenance and Calibration Programs
4. Working Towards the Electronic Notebook

3:00 PM – 3:30 PM
Refreshment Break

3:30 PM – 5:00 PM

5. Standard Operating Procedure (SOP) Management
6. Regulatory Requirements for Reference Standards
7. Risk Assessment Procedures for Laboratories
8. Preparing for FDA Systems-Based Inspections

Thursday
August 21, 2003
Conference Day Four

Post-Conference Expanded Sessions

7:15 AM
Roundtable Breakfast:
21 CFR Part 11:The New Draft Guidance

7:30 AM
Continental Breakfast

90-Minute Post-Conference Expanded Sessions

8:30 AM – 10:00 AM

9. Auditing a Quality Control Laboratory in a Pharmaceutical Setting
10. Change Control in the Laboratory
11. Conducting and Effectively Executing Stability Studies
12. GLP Compliance in a Development Laboratory

10:00 – 10:30 AM
Refreshment Break

10:30 AM – 12:00 PM

13. Validation of HPLCs Used in Regulatory Applications
14. How to Inspect a Contract Laboratory
15. How to Handle OOS Chemical Testing Results
16. Documentation to Support GMP Compliance in the Laboratory

HOTEL INFORMATION

Hilton Short Hills
41 JFK Parkway
Short Hills, NJ 07078
Phone: 973-379-0100
Fax: 973-379-6870
www.hiltonshorthill.com

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ALL REGISTRATIONS MUST BE PRE-PAID

You MUST mark the workshops you will be attending… Fax, E-mail, Mail, or Call Us Today

Monday, August 18, 2003

Pre-Conference Workshops $795.00

8:30 am – 12:00 pm ☐ **A.** ☐ **B.** ☐ **C.** ☐ **D.**

Monday – Wednesday August 18-21, 2003

MAIN CONFERENCE:
☐ **General Sessions and Inclusive Workshops $1,895.00**

Main conference general session include:
- ***FDA Enforcement Strategies for the Laboratory***
- ***The Laboratory:The Cornerstone of Quality Systems***
- ***A Risk Based Approach for the Laboratory***
- ***Interpreting FDA Regulations for the Laboratory***
- ***Conducting Laboratory Audits***
- ***Data Investigations for Analytical Laboratory Results***
- ***Handling Out-of-Trend Results***
- ***Reducing OOS Investigation Backlogs***
- ***The New Part 11 Guidance and Its Effect on the Laboratory***

☐ ***7:15 am – Tuesday: Roundtable Breakfast $25.00***

Please choose one breakout workshop in each timeframe
Tuesday Interactive Workshops:
8:30 am – 12:00 pm ☐ **E.** ☐ **F.** ☐ **G.** ☐ **H.**

Wednesday Interactive Workshops:
8:30 am – 12:00 pm ☐ **I.** ☐ **J.** ☐ **K.** ☐ **L.**

Wednesday August 20, 2003

90-Minute Post-Conference Expanded Sessions

1:30 pm – 3:00 pm.....$395.00
❑ **Session 1** ❑ **Session 2** ❑ **Session 3** ❑ **Session 4**

3:30 pm – 5:00 pm.....$395.00
❑ **Session 5** ❑ **Session 6** ❑ **Session 7** ❑ **Session 8**

Thursday, August 21, 2003

❑ **7:15 am – Roundtable Breakfast $25.00**

90-Minute Post-Conference Expanded Sessions
8:30 am – 10:00 am.....$395.00
❑ **Session 9** ❑ **Session 10** ❑ **Session 11** ❑ **Session 12**

10:30 am – 12:00 pm.....$395.00
❑ **Session 13** ❑ **Session 14** ❑ **Session 15** ❑ **Session 16**

Monday, August 18, 2003 – Pre-Conference
Workshops A – D $795.00: $ _____
Monday – Wednesday, August 18 – 20, 2003 –
Main Conference $1,895.00: $ _____
Roundtable Breakfast ____ X $25.00: $ _____
Wednesday, August 20, 2003 – Post-Conference
Interactive Sessions 1 – 8 ____ X $395.00: $ _____
Thursday, August 21, 2003 – Post-Conference
Interactive Sessions 9 – 16 ____ X $395.00: $ _____
* Early Bird Discount -10%: $ _____

TOTAL ENCLOSED: $ _____

*** Early Bird Discount**

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- Full Conference Monday through Wednesday
- Four Post-Conference Expanded Sessions
- And all Networking and Social Activities
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