

Industry's Largest and Most Comprehensive Change Control Event!

Change Control

April 24-27, 2006 • San Diego, CA

Hear from the following Industry Experts:

- Acambis, Inc.
- Accupac, Inc.
- Braun Medical Device Companies
- Chrai Associates, Inc.
- Centocor, a JNJ Company
- DSM Pharmaceuticals
- Genentech, Inc.
- Kepner-Tregoe, Inc.
- Mannkind BioPharmaceuticals
- Sanofi Pasteur
- Schering Plough Corporation
- The Lanese Group, Inc.
- Waters Corporations

Featuring 10 Half-Day Workshops and 14 Expanded Sessions Including:

- Introduction to Change Control
- Change Control in the Laboratory
- Configuration Management and Change Control for Software and Computer Systems
- Change Management System using Six Sigma and Lean Thinking Tools
- Change Control Documentation
- Change Control SOP's
- Considerations for Contract Manufacturing/Packaging Facilities
- Training Personnel on CC
- Validation and Change Control



WHO SHOULD ATTEND?

MANAGERS & ASSOCIATES OF:

- Regulatory Affairs
- QA/QC
- CMC
- Engineering
- Documentation
- Packaging/Labeling

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INTERACTIVE
SESSIONS AND
PRACTICAL
WORKSHOPS

Change Control • April 24-27, 2006 • San Diego, CA



Change Control • Monday, April 24, 2006

Pre-Conference Half-Day Workshops

7:30 AM - Conference Registration and Continental Breakfast

Interactive Workshop A 8:30 AM - 12:00 PM
Introduction to Change Control

Elena L. Kalbach, M.Sc., CQA, Director of Quality Assurance and Regulatory Affairs, Accupac Inc.

I. Overview and Introduction

- What is change control?
- How do you determine what category of change is being implemented?
- Change control systems - simple or complex? electronic or paper-based?
- cGMP requirements for change control

II. The Change Control System

- Roles and responsibilities - change control initiators, implementers, systems, and operations managers
- Facets of change control - documentation, new products and facilities, "emergency" change controls, new methodologies, changes to processes
- Essentials of a change control program
- Components of change control system documentation – procedures and forms
- Regulatory requirements for drug products, biologics, and medical devices
- Maintenance of change control system - controlling open change control volume, assuring complete documentation for close out
- Meaningful change control metrics - ensuring proper visibility

III. Interactive Exercise and Case Studies

- Reviewing pitfalls from others' experience and lessons learned - review current FDA 483s related to change control
- Discussion of change control trends
- Case Study - method changes
- Case Study - managing change through new construction - project management and change control
- Case Study - proper reporting to regulatory authorities

IV. Interactive Exercise:

What is Missing from this System?

Gap analysis - A review of sample change control procedure forms; open change controls, sample completed change control, and determine what can improve the system. Would this sample system be inspection-ready?

Interactive Workshop B 8:30 AM – 12:00 PM
Change Control Requirements for Stages Prior to Validation

Suggy Chrai, Ph.D., MBA, President, Chrai Associates, Inc.

I. Definition of Stages Prior to Validation

- What defines a stage?
- What is the beginning of the stage?
- Where does the stage end?
- What are the different stages?
- Why change control for stages prior to validation?
- Linking of various stages

II. Definition of Requirements for Each Stage

- Developing requirements that are realistic
- Differentiating between various types of requirements
- Defining the proper level of detail

III. Formulation Development

- Identifying need for Change Control
- Differentiating between role and type of requirement
- Organizing validation needs into requirements

IV. Process Development and Scale -up

- Identifying need for Change Control
- Differentiating between role and type of requirement
- Organizing validation needs into requirements

V. Equipment Qualification

- Identifying need for Change Control for New and Legacy Equipment
- Differentiating between role and type of requirement
- Organizing qualification needs into requirements

VI. System Qualification

- Identifying need for Change Control for New and Legacy System
- Differentiating between role and type of requirement
- Organizing qualification needs into requirements

VII. Commissioning

- Identifying need for Change Control
- Differentiating between role and type of requirement
- Organizing specification needs into requirements.

Monday, April 24, 2006
Pre-Conference Half-Day Workshops

Interactive Workshop **C** **8:30 AM – 12:00 PM**
Improving Change Control with Lean Six Sigma Tools

Victor Awafo, Ph.D., Process Improvement Scientist, Six Sigma Black Belt, Sanofi Pasteur, Canada

I. Identifying and Targeting Gaps & Problems for Improvements in your Change Control Procedures using Lean Six Sigma Tools

- Problem statement
- Suppliers, Inputs, Process, Outputs & Customers (SIPOC)
- Thought Process Mapping (TMAP)
- Meeting your customer requirements, who are they and what do they want?

II. Improving your Change Control Process

- Historical data and baseline analysis
- Failure Modes and Effects Analysis (FMEA)
- Know which other Lean Six Sigma tools to use and how to use them
- Who is responsible?

III. Sustain and Control Gains After Improvements

- How to identify the critical metrics
- Control mechanisms
- Who is responsible?

IV. Managing Bottlenecks in your Change Control Process

- Know which Lean Six Sigma tools to use
- Who is responsible?

V. Interactive Exercise

- Design two high level Change control processes "as is"
- Walk through steps I-IV using Define, Measure, Analyze, Improve & Control (DMAIC) to improve these processes that the class has designed.

12:00 PM - Lunch for Pre-Conference Workshop Participants

*Special Thanks to the
Change Control Program Technical Advisor:*

ROBERT A. RHOADES, Vice President,
Compliance & Quality Management

Washington, DC • 202.833.8077 • 202.833.7057 (fax)
robert.rhoades@weinberggroup.com

Mr. Rhoades is Vice President, Compliance and Quality Management at THE WEINBERG GROUP. Within his twenty-seven year career, Mr. Rhoades has held a variety of leadership positions in Quality Management, counseling senior pharmaceutical and medical device executives regarding compliance and its impact on corporate performance and direction. His experience spans the Quality discipline from managing the Quality function at Baxter and Bausch & Lomb, to planning and implementing quality management and performance improvement systems for client companies. His most recent consulting experiences include guiding an Irish firm through the development and implementation of quality systems for its first FDA-regulated product, achieving a zero-deficiency pre-approval inspection. He has also led numerous compliance-related projects in the form of due diligence reviews for acquisition targets, the resolution of a production problem that threatened a serious business interruption, and the development of a complex corrective action plan which averted escalation of enforcement actions by the FDA. Mr. Rhoades has also worked in concert with client counsel on a wide variety of legal cases.

Mr. Rhoades' skills as a public speaker/instructor and project manager have often combined for successful outcomes. He has designed and delivered programs for two medical device manufacturers resulting in first-pass ISO9000 certifications. He also executed programs for client companies resulting in foreign facility registrations and product approvals by the FDA in England, Ireland, China, Germany and Indonesia. He is frequently an invited speaker at pharmaceutical and medical device conferences in both the US and Europe, and has authored several articles on quality-related topics. His first book, *Risky Business: Managing The Quality of America's Medicines*, was released in February 2004 by FDANews, and is now in its second printing. A second book, *Sustaining Compliance: Strategies for Maintaining Drug Quality*, was released in July 2005.

Mr. Rhoades holds a Bachelor of Science degree in Microbiology from Purdue University and a Master of Business Administration in Strategic Planning and Operations Management from Lake Forest (IL) Graduate School of Management. His professional affiliations include Senior Member, American Society for Quality; The Regulatory Affairs Professionals Society; The Food and Drug Law Institute; and The International Society for Pharmaceutical Engineers.



Monday, April 24, 2006

Main Conference General Sessions

12:00 PM- Main Conference Registration

1:00 PM – Chairperson’s Welcome and Opening Remarks

1:15 PM – Keynote Session

Change Control: A Foundation for Managing Compliance

Bob Rhoades, Vice President, Compliance and Quality Management, THE WEINBERG GROUP.

Change control is the underpinning of many major elements of the quality system in today’s FDA-regulated industry. It is not only a functional requirement of many regulations, but also represents a fundamental part of a company’s culture and philosophical approach to managing GMP compliance. This session will explore these thoughts, and provide real-life examples to help participants understand why change control is such a vital element of their quality system. The audience will:

- Understand the relationship of compliance to change control
- See how management responsibility affects change control
- Appreciate the impact change control has on many other systems
- Understand the potential impact of poor change control

2:00 PM

Change Control: FDA Inspectional Trends and Enforcement Actions

David R. Dills, Director of Publications, Regulatory & Compliance, Institute of Validation Technology

Change Control Trigger Points

- Determine what is required at a minimum for Change Control programs
- Identify the typical and recurring documentation red flags
- Understand why a well defined, deployed and maintained Change Control program is critical for managing any and all changes from design, development, production to post-market release

FDA Inspectional Trends and Enforcement Activities

- Learn what investigators are looking for with Change Control documentation and other supporting evidence
- Review recent 483s, Warning Letters and other stats and identify some of the recurring Change Control issues with recent inspections
- Understand why a robust Change Control program is the immune system for the manufacturer and why it can determine how the inspection will unfold

2:45 PM – Refreshment Break

3:00 PM

Considerations in Effective Change Control Management

Elena L. Kalbach, M.Sc., CQA, Director of Quality Assurance and Regulatory Affairs, Accupac Inc.

- Who are the main players in the change control process? Currently in your organization, is there too much or not enough involvement?
- What key components must be incorporated into your company’s change control system?
- Why preparation of the change control is the most important component of closing out a change control
- Effective communication in implementation and close-out of a change control
- Electronic versus paper-based change control systems – which system meets your company’s needs?
- Evaluating your company’s change control program and lessons learned as your change control program evolves

3:45 PM

Tracking and Documentation of Manufactured Production Lots When Under a Change Control

Amy Otto, Manager of QA Validation, Centocor, Malvern Operations

This session focuses on the role of the Quality Unit and Regulatory Affairs Department to ensure that release of product is tagged appropriately prior to being released into market for commercial sale and distribution.

- Identify process flow map to track batches based on change control
- Use batch records and track change control number through automated device
- Institute release document provided by Quality Change Control Department and Regulatory.
- Use change control system to identify lots impacted and to align with global logistics

4:15 PM

Manufacturing Process and Manufacturing Site Change Control

Joseph Tyler, CMC Consultant

Manufacturing process changes and manufacturing site transfers are common post approval occurrences. Before implementing these types of changes the regulatory requirements must be complied with. Comparability protocols can be used to make change easier.

**Monday, April 24, 2006
Main Conference General Sessions**

- FDA requirements
BACPAC
SUPAC
Analytical
- Classification of post approval changes
- Comparability protocols
- Site transfer case study

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



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**Tuesday, April 25, 2006
Main Conference Half-Day Workshops**

7:30 AM Continental Breakfast

**Interactive Workshop D 8:30 AM - 12:00 PM
Change Control and Laboratory Operations**

Jerry Lanese, Ph.D, President, The Lanese Group, Inc.

**I. Corporate and Site Management Changes that
Impact the Laboratory**

- Mergers and acquisitions
- New products and retired products
- Share impact of changes driven by corporate structure changes

**II. Site Change Control Systems and their
Relationship to the Laboratory**

- Requirements for change control
- Systems inspection program and change control
- Site programs - a general overview
- Relationship of site program to the laboratory

III. Specification Changes

- Specification change process and managing the specification
- Verification of the impact of the specification change

IV. Changes to Test Methods and Testing Site

- The method change process and managing the test method change
- Systems and records impacting the change
- Impact and risk of method changes
- Why test sites are changed

**V. Changes Involving Instruments and Instrument
Modules**

- Instrument systems and modules
- Change systems, records, and instrument changes
- Providing assurance that the system is performing as intended

VI. Changes in Standards, Reagents

- Systems and records supporting standards changes
- Monitoring the impact of standards changes
- Reagent changes - the routine
- Tracking reagent changes

VII. Changes in Personnel

- Personnel in the laboratory environment
- Ensuring that changing personnel has minimum impact
- Records of personnel changes

VIII. Sample Management

- Moving samples routinely
- Tracking samples and the risk of sample movement

Tuesday, April 25, 2006
Main Conference Half-Day Workshops

Interactive Workshop E 8:30 AM - 12:00 PM

The Successful Implementation of a Change Management System using Six Sigma and Lean Thinking Tools

Amy Otto, Manager of QA Validation, Centocor, Malvern Operations

I. Understanding Change Control at Your Site and the Industry Requirements

- FDA requirements - 21CFR Parts 210 and 211
- EU Guide - Annex 15
- ICH Guideline - Q7A
- Company policies or corporate guidance
- Site standard operating procedures
- 483 observations

II. Senior Site Management Involvement: What Do They Really Want to Know?

- Scope of the change control system
- Global vs. local
- Automated vs. manual system
- Aligned and harmonized with corporate requirements
- Impact from a logistical perspective
- Involvement of the site leadership team - change control boards

III. Clearly Defined Roles and Responsibilities- Define Your Role

- Owner of the change control system
- Customers of the change control system
- Required approvers on each change control
- Involvement of logistics - planning department
- Impact to safety
- Impact to filings - regulatory assessment

IV. Six Sigma and Lean Thinking for the Change Control System- Can it Work?

- Overview of DMAIC process
- Lean thinking tools
- Mapping the process for each procedure
- Mapping the process from your customer's perspective
- Mapping the process - essentials
- Defining process metrics to recognize goal achieved
- Defining cycle times - wants vs. needs

V. Redefining Your Change Control Process – What Works for You?

- Clearly defined roles and responsibilities
- Support from senior management
- Maintain control while supporting your customers
- Process flow and deployment charts as guides through the procedure
- Include only value-added steps in the process

- Hit your metrics and maintain them over the course of time

Interactive Workshop F 8:30 AM - 12:00 PM

Configuration Management and Change Control for Software and Computer Systems

Mark Kropp, MD, MannKind BioPharmaceuticals

I. Configuration Management for Computer Systems

- Phases of SDLC (Software Development Lifecycle Documentation) and requirements
- Parallel processing of activities
- Validation considerations throughout the lifecycle
- Customizing configuration for computer systems
- Scheduling configuration

II. Configuration Management for Software

- Developing configuration management for software
- Differentiating between various types of configurations
- Defining the proper level of detail for documentation

III. Change Control for Computer Systems

- Identifying computer systems
- Differentiating between configuration and change
- Organizing validation information into requirements

IV. Change Control for Software

- Defining different methods of change control
- Developing changes and documenting changes
- Implementing change control
- Implementing 21 CFR Part 11 information into requirements

V. Traceability Matrix

- Tracking changes
- Developing strict control
- Defining proper control
- Developing one source for tracking, design, development, and testing

VI. Interactive Exercise

Configuration Management and Change Control for Software and Computer Systems: In this interactive activity, the goal is to simulate a real project situation during a working session. The group will decide on the changes required and how to conduct control and management documentation. Participants will gather and write out the changes, develop the documentation, and begin a traceability matrix.

12:00 - Lunch for Main Conference Workshop Participants

Tuesday, April 25, 2006 Main Conference General Sessions

1:00 PM – Chairperson’s Opening Remarks

1:15 PM

Change Control in the 21st Century

Jerry Lanese, Ph.D, President, The Lanese Group, Inc.

- A review of the focus of change control between 1978 and 2000
- Evolution of regulatory requirements for change control
- Evolution - Quality Control to Quality Assurance
- Transition to quality systems
- FDA challenges
- Merging of standards and regulations

2:00 PM

Quality Agreements and Managing Change Control with Contract Manufacturers

Joseph Tyler, CMC Consultant

Managing change control at a contract manufacturing site is required by cGMP's. An effective way to define the responsibilities of the sponsor and service provider is to prepare a quality or technical agreement between the two parties. This presentation will discuss the roles of the sponsor and provider in contract manufacturing arrangement and will provide the necessary elements in a quality agreement.

- Responsibilities of the sponsor and provider
- Managing change control
- Drug master files
- Regulatory issues
- Quality agreement elements
- Quality agreement examples

2:45 PM

Tracking and Documentation of Manufactured Production Lots When Under a Change Control

Amy Otto, Manager of QA Validation, Centocor, Malvern Operations

This session focuses on the role of the Quality Unit and Regulatory Affairs Department to ensure that release of product is tagged appropriately prior to being released into market for commercial sale and distribution.

- Identify process flow map to track batches based on change control
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- Use change control system to identify lots impacted and to align with global logistics



TUESDAY, APRIL 25 • 3:45 PM

Complimentary Special Event:

Viejas Outlet Mall and Casino Trip

Bus leaves hotel at 4:00 pm and returns at 9:00 pm.
Attendees must check box on registration page!

Wednesday, April 26, 2006 Main Conference Half-Day Workshops

Interactive Workshop



8:30 AM - 12:00 PM

Implementing a Centralized Change Control Management System

Jackelyn Rodriguez, President, Monarch Quality Systems Solutions

Problems can be anticipated and their occurrence prevented using information from reviews of data and changes associated with operational and quality system processes, and by keeping abreast of changes in scientific and regulatory requirements. During this session participants will learn how to identify and use effective centralized change control approaches in order to develop and document effective processes to ensure that the need for change is evaluated relevant to the possible consequences.

I. Fundamentals of Change Control and Regulatory Requirements

- Definitions of change
- Analyze change control system as defined by FDA
- Types of change control systems
- Levels of change
- Change control and GMPs

II. Building a Formal Change Control

- Simplifying the System
- Best approaches to manage and track change control
- Where does change control apply?
- Identify the different types of changes
- Planning an effective Change control process

III. The Classification System: Evaluating and Monitoring Recommended Changes

- Scope of change control
- How to handle temporary changes, documentation and emergency changes
- How do you classify changes?
- Elements of a change control system
- Change control forms and implementation plans

IV. Interactive Exercise

Participants will given a case study for a "proposed change" and will be asked to determine if change should be approved for implementation.

Interactive Workshop H 8:30 AM - 12:00 PM **Change Control: Implementing a Global e-Solution**

Chet Bhatt, Manager - Tracking Information / Database Systems, Global Quality Information Systems, Schering-Plough Corporation

Change is faster and more complex today -- a fact hard to accept. Managing Change is as much a business need as it is a regulatory need for pharmaceutical companies. It is a process that can significantly impact the efficiency of an organization. The current business environment of centrally managed, and globally deployed computer systems demand an effective change control system to optimize the cycle time from "request to realize" without compromising quality. Simplification is the key to a successful change control system, and the goal is to meet business and compliance needs.

I. Interactive Exercise

- Definition
- Scope
- Critical elements governing the process of change

II. Computer Systems and Change Control - Presentation / Case Study

- Planning and implementing a global change control system

III. Tracking Change Requests - Discussion

- Simplification of change request form
- Impact assessment
People, Product, Processes
- Communicating status of change and closure

IV. Interactive Exercise

Participants will work on discussing and defining Change Management Process. Identifying and mapping of the "data elements" to the "process elements" for an electronic system.

Interactive Workshop I 8:30 AM – 12:00 PM **Post-Change Monitoring and Early Problem Identification**

Wade Speir, Senior Consultant, Life Sciences Practice, Kepner-Tregoe, Inc.

I. Describe Problem

- Problem statement
- Problem specifications

II. Identify Possible Causes

- Knowledge and experience
- Distinctions and changes

III. Evaluate Possible Causes

- Test against problem specification
- Determine most probable cause

IV. Confirm True Cause

- Verify assumptions, observe, experiment, fix, monitor

V. Interactive Exercise

Attendees will apply FDA cGMP CAPA compliant techniques for gathering, organizing, and analyzing change control-related manufacturing, lab, and quality data into timely, logical, comprehensive investigations suitable for internal use and FDA review.

Participants will take home the following Bonus Information:

- Kepner-Tregoe's book, "The New Rational Manager", covering root cause analysis
- Problem Analysis job aid card

12:00 PM – End of Main Conference

12:00 PM – Lunch

Interactive Session 1 1:30 PM – 3:00 PM
Validation and Change Control: The Validation Life Cycle

Gamal Amer, Ph.D., Senior Director, BE & K

This three-part session is aimed at introducing the concept of a validated state and managing change within the validation life cycle.

I. Validation and the Validated State

- Validation and its confirmatory nature.
- How validation is conducted
- The validated states and the importance of maintaining them
- The validation life cycle

II. The Importance of Change Control

- Types of change and their potential impact on the validated state
- Defining a change control system and its importance
- Outline of a change control system and possible procedure

III. Interactive Exercise

Participants should come prepared to discuss change control related issues they encounter at their work place. We will attempt to address these issues in the context of the change control system discussed earlier.

Interactive Session 2 1:30 PM – 3:00 PM
Considerations for Contract Manufacturing/Packaging Facilities

Elena L. Kalbach, MSc, CQA, Vice President, Quality Assurance & Regulatory Affairs, Accupac, Inc.

I. Roles and Responsibilities

- Contract Manufacturer/Customer
- Definition and assignments of responsibilities
- Elements of a contract manufacturing/packaging change control procedure
- Documentation expectations for contract facilities

II. Regulatory Considerations

- Customer and Contract sites
- Expectations for levels of approvals
- Managing customer-initiated changes

III. Interactive Exercise

Participants will review sample quality agreement excerpts for change control responsibilities and analyze the implications of the particular roles and responsibilities.

Additionally, participants will investigate a proposed change and discuss regulatory reporting considerations for both parties and formulate paths forward to approval/implementation.

Interactive Session 3 1:30 PM – 3:00 PM
Testing, the Missing Link: Effective Testing for IT Change Control

Holly A. Baldwin, IT Validation Analyst, B Braun Medical Inc.

I. What is Testing and Why is it Necessary?

- Define testing as it pertains to IT change control
- Testing rationale - regulations, guidelines, and good practices
- How does testing limit risk?
- Defining the scope of testing
- Types of testing and their purposes

II. Testing in the Realm of IT Change Control

- Exploring system environments and their links to testing
- Providing answers to burning testing questions
- Testing documentation - how do you know what to capture?
- Good testing practices

III. Interactive Exercise

Participants will analyze real life situations and define testing actions based on risk categories.

Interactive Session 4 1:30 PM – 3:00 PM
Consolidating Multiple Change Control Systems at Genentech

Peter Bland, Associate Director, Quality Operations Change Control, Genentech, Inc.

Genentech's change control systems developed organically over a number of years, meeting specific business needs as the company grew. This resulted in a host of change control subsystems that were fragmented and confusing for the users. The company has completed a Change Control Consolidation (C3) project to combine the change control subsystems into a single, flexible and easily understood process. This process manages changes for all validated cGMP systems and data.

I. Change Control Consolidation (C3) Project

- Assess the current state processes
- Design the desired future state process
- Document system requirements
- Perform platform selection
- System development and validation

Wednesday, April 26, 2006 Post-Conference 90-Minute Sessions

- Plan training and implementation
- Conduct lessons learned
- Put in place post-deployment monitoring and support
- Continue the vision and extends the platform

II. Interactive Exercise

Working session with the participants to identify critical functions needed in a change control process. The group will convert those functions into a high-level system requirement document.

3:00 PM – Refreshment Break

Interactive Session 5 3:30 PM – 5:00 PM **Designing, Developing, and Implementing a Simple, Robust and Effective Change Control Procedure**

Gamal Amer, Ph.D., Senior Director, BE & K

This two-part session will focus on developing and implementing a simple change control SOP that would address real life issues encountered by the attendees.

I. Change Control Procedure and its Importance

- The validated state: what does it mean?
- Types of changes you would encounter and their impact on the validated state.
- A change control system to ensure you remain in the validated state
- Developing a procedure and a change request form to manage change

II. Interactive Exercise: Designing an Effective Change Control Procedure

Participants will discuss real-life experience regarding change control. Attendees should come prepared with issues they have encountered recently.

Interactive Session 6 3:30 PM – 5:00 PM **Effective Change Control Risk Management**

Wade Speir, Senior Consultant, Life Sciences Practice, Kepner-Tregoe, Inc.

I. Identify Potential Problems

- State the action
- List potential problems
- Likely causes
- Consider causes of potential problems

II. Preventive Actions

- Take actions to address likely causes

III. Contingent Actions

- Prepare actions to reduce likely effects
- Set triggers for contingent actions

IV. Interactive Exercise

Participants will form teams to complete a change control and potential problems analysis.

Participants will take home the following Bonus Information:

- Kepner-Tregoe's book, "The New Rational Manager"; covering potential problem analysis
- Potential problem analysis job aid card

Interactive Session 7 3:30 PM – 5:00 PM **Using Risk Assessment and Change Control for 21 CFR Part 11 Compliance**

Virginia L. Corbin, Manager Corporate Compliance Marketing, Waters Corporation

I. Changes in the FDA Interpretation of 21 CFR Part 11 Compliance

- Discussion of the new FDA Draft Guidance Document for Part 11 interpretation
- What is a "risk-based" approach to Part 11?
- Current Part 11 status
- Fitting Part 11 compliance in with the new FDA "GMP for the 21st Century" initiative

II. Framework for Risk Management

- Why do a risk assessment?
- What are the commonly accepted industry approaches to risk management?
- How to apply FTA, HACCP, FMEA, and FMECA to risk assessment for Part 11

III. Change Control for 21 CFR Part 11 Compliance

- Moving forward with a Part 11 remediation plan
- Change control management for electronic records integrity
- Protecting electronic intellectual property

Participants will take home the following Bonus Information:

- White Paper: "Achieving Risk Management for FDA Compliance Using ISO 14971."
- Article from May 2004 Issue of Pharmaceutical Technology, "21 CFR Part 11 and Risk Assessment: Adapting Fundamental Methodologies to a Current Rule"

Wednesday, April 26, 2006
Post-Conference 90-Minute Sessions

Thursday, April 27, 2006
Post-Conference 90-Minute Sessions

Interactive Session 8 3:30 PM – 5:00 PM
Improving Change Agility and Compliance for Regulated Enterprise-Wide Systems

Joseph Schenk, President and CEO, QA Edge Inc.

I. Problems with Managing Change of Regulated Enterprise-Wide Systems (e.g. SAP)

- Confusion on FDA SOX requirements creates a slow bureaucratic process
- Too many 'chiefs' using a poorly defined process overwrite changes
- Mean Time To Repair (MTTR) too high because change history is inconsistent
- Emergency and unplanned changes are the norm causing instability with no audit trail
- Risk is not considered causing overwork and ineffective testing
- DEV-QA-PROD environments not controlled resulting in unexpected outcomes

II. Best Practices for Managing Enterprise-Wide System Change Control

- Questions to ask to assess the current situation
- Standardized processes for change management
- Applying risk assessment to determine scope and process (i.e. 'How much revalidation is really needed?')
- Using automation (e.g., process management, testing tools, etc.) to reduce cycle-time and produce consistent revalidation documentation
- Cultural considerations for implementation

III. Interactive Exercise

Participants will analyze models for managing change to SAP, prioritize best practices using lean thinking principles, and discuss techniques for evaluation of tools.

5:00 PM End of Day Three

7:30 AM Continental Breakfast

Interactive Session 9 8:30 AM – 10:00 AM
Training Personnel on Change Control Procedures

Felicia Ford-Rice, Director Quality Assurance, Acambis Inc.

I. Three Levels of Change Control Training

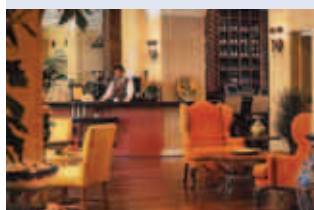
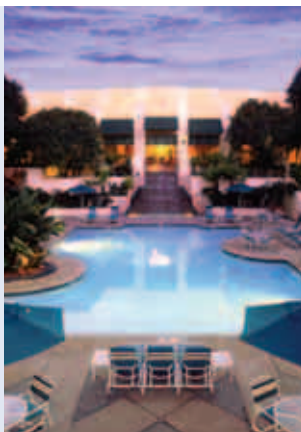
- Make Plain - Create awareness of change control requirements throughout the organization
- Explain - Discuss the role of the change control board, change initiator and affected departments and provide detailed information on change control processes
- Train - Identify who should receive training and the frequency of retraining personnel

II. Characteristics of Effective Change Control Training

- Define documentation requirements for training
- Create an effective presentation - a picture is worth a thousand words
- Provide clear, concise content
- Maximize retention of content (training effectiveness)

III. Interactive Exercise

Participants will receive a checklist to aid in performing a gap analysis of their current change control training programs. Participants will have the opportunity to identify improvements that could be implemented in change control training programs to increase training effectiveness and to discuss any specific issues.



Event Information

HOTEL INFORMATION

San Diego Marriott
Mission Valley
8757 Rio San Diego Drive
San Diego, California 92108
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A special room rate has been prearranged for conference participants.

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Interactive Session 10 8:30 AM – 10:00 AM
Creating Usable Validation Documentation for IT Change Control

Holly A. Baldwin, IT Validation Analyst, B Braun Medical Inc.

I. Validation Documentation - What Does that Mean?

- Defining the purpose for and types of documentation
- Potential pitfalls in creating documentation
- Documentation approval

II. Validation Documentation Guidelines

- Finding useful Templates
- How much is enough? Defining the required validation package
- Document approval doesn't mean the end of vigilance
- Good documentation practices

III. Interactive Exercise

Participants will have the opportunity to address their concerns on validation documentation as it pertains to their specific issues in the workplace.

Interactive Session 11 8:30 AM – 10:00 AM
Revalidation and the Impact on Change Control

David R. Dills, Director of Publications, Regulatory & Compliance, Institute of Validation Technology

I. Revalidation

- Learn why and when revalidation is necessary or required
- Understand the justification process and have a defensible position and rationale that supports this by integrating a risk-based approach
- The extent of revalidation will depend upon the nature of the changes and how they impact upon different aspects of production that had previously been validated.
- Learn that it may not be necessary to revalidate a process from scratch merely because a given circumstance has changed

II. Impact on Change Control

- Classifying changes: major, minor, or no impact as related to product, process or system – and customer/patient
- Learn why Change Control is the mechanism for facilitating the decision making process for all changes encountered
- Monitoring trends with validated processes.
- Monitoring data on quality characteristics
- Cause investigation
- Corrective action and revalidation

III. Interactive Exercise

Attendees will review recent FDA enforcement actions and are strongly encouraged to bring real-life examples for discussion of recent change control and revalidation issues and challenges. Group will also critique examples of Change Control documents as part of group discussion.

Interactive Session 12 8:30 AM – 10:00 AM
Understanding FDA and EU Regulations for Change Control

Virginia L. Corbin, Manager Corporate Compliance Marketing, Waters Corporation

I. Applicable Regulations

- US FDA GMP – 21 CFR 211 and 820
- US FDA GLP – 21 CFR 58
- ICH Q7A for APIs
- EU GMP Annex 11

II. Available Guidance

- OECD GLP Guidance
- Swiss AGIT Guidance
- FDA Guidance: "General Principles of Software Validation"
- FDA Guidance: "Cybersecurity for Networked Medical Devices"
- PIC/S Guidance for Computerized Systems

III. Putting It All Together

- Global Harmonization of Regulation and Guidance
- Case Studies and FDA Warning Letters - What to Avoid
- Tips and Tricks and Summary

10:00 – Refreshment Break

Interactive Session 13 10:30 AM – 12:00 PM
To Document or Not to Document: Providing Effective Supporting Documentation for Changes

Felicia Ford-Rice, Director, Quality Assurance, Acambis Inc.

I. Change Documentation Requirements

- Provide an accurate definition of the change
- Evaluate the impact of the change and define actions required to assess and minimize impact on product quality
- Determine regulatory authority notification requirements of change
- Assemble documentation required to demonstrate successful change implementation

II. Characteristics of Effective Supporting Documentation

- Organize your change documentation to ensure traceabil-

Thursday, April 27, 2006
Post-Conference 90-Minute Sessions

- ity, adequate revision history and record retention
- Distribution of documentation and notification to all affected departments
- Determining change classification, and producing clear, concise content with links to other quality systems
- Prioritizing changes to process documentation to ensure timely initiation, evaluation and closure manner

III. Interactive Exercise

Participants will practice creation of effective supporting documentation for a variety of process, equipment and facility changes.

Interactive Session 14 10:30 AM – 12:00 PM
Leadership Secrets for Computer Validation Professionals

Joseph Schenk, President and CEO, QA Edge Inc.

I. Computer Validation Professionals are Constantly Faced with Challenges

- Being required to get things done with no authority
- Constantly having to justify the value of validation
- Receiving the blame when project deliverables are delayed
- Convincing people to apply some intelligence and urgency to validation tasks

II. Understand How to Apply Leadership Principles to Deal with the Challenges

- Techniques for rapidly gaining respect, credibility, and loyal followers
- How to improve your personal effectiveness
- How to easily explain the Value-Add of computer validation to get buy-in

- How to spot leadership gap early warning signs
- How to neutralize negative people
- How to take credit and share credit when credit is due

III. Interactive Exercise

Participants will participate in a leadership exercise of a real life situation to practice implementing the “soft skills” discussed during the presentation.

Interactive Session 15 10:30 AM – 12:00 PM
Recent 483s and Warning Letter Observations: How Can You Avoid the Same Pitfalls?

Jackelyn Rodriguez, President, Monarch Quality Systems Solutions

Change control and periodic reviews are critical to ensuring deviations are minimized and that systems and processes are maintained in a “state of control”. Product quality and performance are ensured through the design of effective and efficient manufacturing processes, but what happens when something goes wrong?

I. FDA’s Latest Observations from Inadequate Change Control Programs

- Top warning letter observations
- What does FDA look for in Compliant Change Control Programs?

II. Pitfalls

- Common pitfalls
- Avoiding pitfalls
- Identifying tools for developing solutions

12:00 PM – Close of Conference

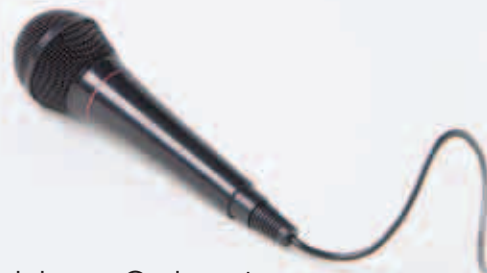
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Change Control

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MONDAY, APRIL 24, 2006	TUESDAY, APRIL 25, 2006	WEDNESDAY, APRIL 26, 2006	THURSDAY, APRIL 27, 2006
Pre-Conference Half-Day Workshops A - C 8:30 AM – 12:00 PM	Main Conference Half-Day Workshops D - F 8:30 AM – 12:00 PM	Main Conference Half-Day Workshops G - I 8:30 AM – 12:00 PM	Post Conference 90-Minute Sessions 8:30 AM – 10:00 AM
WORKSHOP A Intro to Change Control	WORKSHOP D Change Control and Laboratory Operations	WORKSHOP G Implementing a Centralized Change Control System	SESSION 9 Training Personnel on Change Control
WORKSHOP B Requirements Prior to Validation	WORKSHOP E Six Sigma and Lean Thinking Tools	WORKSHOP H Change Control: Implementing a Global e-Solution	SESSION 10 Validation Documentation for IT Change Control
WORKSHOP C Global Change Control Systems	WORKSHOP F Configuration Management for Software and Computer Systems	WORKSHOP I Post-Change Monitoring and Early Problem Identification	SESSION 11 Revalidation and the Impact on Change Control
12:00 – Lunch for Pre-Conference Workshop Participants	12:00 - Lunch	Close of Main Conference	SESSION 12 Understanding FDA and EU Regulations for Change Control
Main Conference General Sessions	1:00 PM – Chairperson’s Opening Remarks	12:00 PM - Lunch	10:00 – Refreshment Break
1:00 PM – Chairperson’s Welcome	1:15 PM Change Control in the 21st Century	Post Conference 90-Minute Sessions 1:30 PM – 3:00 PM	Post Conference 90-Minute Sessions 10:30 AM – 12:00 PM
1:15 PM Foundation for Managing Compliance	2:00 PM Quality Agreements and Monitoring Change Control	SESSION 1 The Validation Life Cycle	SESSION 13 To Document or Not to Document
2:00 PM FDA Inspectional Trends	2:45 PM Tracking and Documentation of Manufactured Production Lots	SESSION 2 Considerations for Contract Manufacturing/Packaging Facilities	SESSION 14 Leadership Secrets for Computer Validation
2:45 PM – Refreshment Break	3:45 PM SPECIAL EVENT: Viejas Outlet Mall & Casino Trip (Bus departs at 4:00 PM and returns at 9:00 PM)	SESSION 3 Effective Testing for IT Change Control	SESSION 15 Review of Recent Change Control 483s
3:00 PM Considerations in Effective Change Control		SESSION 4 Consolidating Multiple Programs	12:00 PM Close of Conference
3:45 PM Tracking and Documentation of Manufactured Production Lots		3:30 PM – 5:00 PM	
4:15 PM Manufacturing Process & Site Changes		SESSION 5 Simple, Robust and Effective Change Control SOP	
5:00 PM Close of Day One – Networking Cocktail Reception		SESSION 6 Effective Change Control Risk Management	
		SESSION 7 Risk Assessment and Change Control for 21 CFR Part 11	
		SESSION 8 Improving Change Agility and Compliance for Regulated Enterprise-Wide Systems	



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8:30 AM - 12:00 PM \$795 USD

A B C (Choose one)

Monday - Wednesday, April 24-26, 2006

MAIN CONFERENCE: General Sessions &

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Tuesday, April 25, 2006 • Interactive Sessions:

8:30 AM - 12:00 PM

D E F (Choose one)

General Sessions: 1:00 PM - 3:30 PM

SPECIAL EVENT: Viejas Outlet Mall & Casino

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Wednesday, April 26, 2006 • Interactive Workshops:

8:30 AM - 12:00 PM

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Wednesday, April 26, 2006 • Post-Conference Workshops:

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1 2 3 4 (Choose one)

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5 6 7 8 (Choose one)

Thursday, April 27, 2006 • Post-Conference 90-Minute Sessions

8:30 AM - 10:00 AM \$495 USD

9 10 11 12 (Choose one)

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