



Employee Training Under FDA Scrutiny: Creating and Maintaining Robust Training Programs

The Gaylord National Hotel
Washington, DC
March 23 -24, 2010

Tuesday, March 23rd

8:30 – 9:00

REGISTRATION AND CONTINENTAL BREAKFAST

9:00

Welcome

Casper Uldriks, Associate Director for Clinical Research & Government Affairs, FDA/CDRH

Thomas Maeder, Executive Director, MTLI, AdvaMed

Ellen Leinfuss, Chief Marketing Officer, Kaplan EduNeering

9:10 – 10:00

Regulatory Requirements

Casper Uldriks, Associate Director for Clinical Research & Government Affairs, FDA/CDRH

- 21 CFR 820.25 - what the Quality System Regulation requires on training of personnel
- Global training requirements under ISO, EMEA et al
- 30% of FDA QSR-related warning letters cite violations of training requirements:
 - Absent or inadequate SOPs
 - Poor training on procedures
 - Inadequate updating and auditing of training programs
 - Lack of training requirements
 - Performing needs analyses
- Why FDA is concerned and what the Agency is doing about it.
 - Failure of employees to appreciate the potential consequences of improper performance

10:00 – 10:45

Best Practices Components of an Effective QSR/GMP Training Program

Dave Peterson, Director, GMP & Quality Systems at Kaplan EduNeering

- Ownership of the training function

- The roles of senior management, line management, trainers
- High level process SOP
- Needs analysis model
- Curriculum driven qualification
- On-boarding new employees
- Train on Regulations, Job specific tasks
- Refresher vs Ongoing
- Documentation, monitoring, and reporting
- Change control of training resources
- Records retention
- Training responsibilities of suppliers or partners

10:45 – 11:00

BREAK

11:00 – 11:30

Inspecting on Training

Casper Uldriks, Associate Director for Clinical Research & Government Affairs, FDA/CDRH

- How field investigators inspect for training under QSIT
- Typical information requests during an audit
- How to effectively respond to information requests
- Trends that may cause concern

11:30 – 12:30

Developing Training Programs that Align with Employee Roles

*Dave Peterson, Director, GMP & Quality Systems at Kaplan EduNeering
Scott Barnard, VP, Business Solutions Group, Kaplan EduNeering*

- Defining the bodies of knowledge
- Written procedures / SOPs
- Establishing a controlled training and qualification process that is appropriate for the size, organization, and complexity of your company
- Selecting qualified trainers
- Maintaining an ongoing process
- On-the-job training
- Monitoring training effectiveness

12:30 – 1:30

LUNCH

1:30 – 3:30

Case Studies in Training – Presentations and Panel Discussion

Don Middlebrook, VP of Regulatory Affairs & Quality Assurance, Thoratec

*Laurence Kopyta, Quality System Compliance Group Partner, Medrad
Priscilla Hall, Compliance Education Manager, Ethicon Endo-Surgery
Francine Lasky, Vice President, Quality Assurance Manager, Scientific Device Laboratory*

- Methods of structuring training programs
- Risk-based approach to training
- Large vs small company training programs
- Multi-site, multi-national, multi-lingual training

- Training and changes in corporate culture during acquisitions
- Attaining management buy-in
- Positioning training as a strategic advantage and key business process

3:30 – 3:45

BREAK

3:45 – 4:45

Steps to Creating a Role-Based Qualification Curriculum

Dave Peterson, Director, GMP & Quality Systems at Kaplan EduNeering

Facilitated workshop activity

- Identifying the target audiences – work flow / job roles
- Identifying critical tasks or functions for each role
- Writing learning objectives
- Defining the learning progression
- Gathering available training materials
- Identifying and filling gaps in available training materials
- Finalizing curriculum architecture
- Assuring learning assessment
- Tracking and reporting progress

Exercise

4:45 – 5:00

Questions and Answers

ADJOURNMENT

5:00 – 6:00

RECEPTION

Wednesday, March 24th

8:00 – 8:30

REGISTRATION AND CONTINENTAL BREAKFAST

8:30 – 10:00

Selecting the Appropriate Training Approach: Delivery Decision-Making

Dr. Karl Kapp, Professor of Instructional Design and Bloomsburg University

- Adult learning theory applied to your organization
- Method: instructor-led, computer based, OJT, read and understand, etc.
- Introduction to the ADDIE model
- Aligning content and learning approach to your audience

10:00 – 10:15

BREAK

10:15 – 11:00

Assuring Competency and Documenting Success

Dr. Karl Kapp, Professor of Instructional Design and Bloomsburg University

Priscilla Hall, Compliance Education Manager, Ethicon Endo-Surgery

- Knowledge testing
- Skill demonstrations
- Train the trainer
- Establishing success metrics
- Monitoring the training program
- Record-keeping

11:00 – 12:00

Learning Management Systems

Scott Barnard, VP, Business Solutions Group, Kaplan EduNeering

- When is a learning management system (LMS) needed?
- Electronic database Part 11 compliant
- Distribution and competency
- Establishing a tracking and reporting system
- Metrics to drive compliance

12:00

ADJOURNMENT

Important Notice

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