

CAPA Training Workshops

April 20—21, 2010 Doubletree Hotel—Boston/Waltham, MA



CAPA: Effective System Management
One Industry Professional Shares His Expertise

&

Supplier-Related CAPA:
Conducting Effective Root Cause Investigations

Presented by

enKap
ENGAGED KNOWLEDGE APPLICATION

Publisher of



These Training Workshops Feature “Hands On” Application Exercises

7:30 a.m.

Registration/Continental Breakfast

8:30 a.m.—9:15 a.m.

CAPA Regulations: Regulatory Basis

- Understanding current FDA medical device and pharmaceutical regulations
- 21 CFR 820.100
- 21 CFR 211.192
- ISO 13485 Corrective and Preventive Action
- Current trends and expectations from regulated bodies.
- Recent CAPA-related Warning Letters

9:15 a.m.—10:00 a.m.

Effectively Managing a CAPA System: Industry Best Practice - Part I

We will explore the owner's and management's perspectives regarding roles and responsibilities, and present best practice for organizational engagement to ensure a successful CAPA program.

- File management
- Roles and responsibilities
- Issue identification
- Scoping and containment
- Risk evaluation

10:00 a.m.—10:15 a.m.

Break

10:15 a.m.—11:00 a.m.

Effectively Managing a CAPA System: Industry Best Practice – Part I (Continued)

- Investigation
- Approval

- Implementation
- File Linkage verification
- Effectiveness monitoring and dissemination

11:00 a.m.—12:00 p.m.

APPLICATION EXERCISE

To reinforce the information learned, we will develop a compliant CAPA file by selecting the appropriate tools for successful closure.

12:00 p.m.—1:00 p.m.

Lunch

1:00 p.m.—2:15 p.m.

Effectively Managing a CAPA System: Industry Best Practice - Part II

To manage a CAPA system effectively, it is appropriate to have meaningful metrics for management review and for individual file owners to ensure linkage to company goals and objectives.

- What information management wants to see and what you as a system owner need for them to see
- Effectively communicating potential issues that may negatively impact the timeliness and/or effectiveness of your organization's CAPA program
- Understanding one's audience
- Data trending
- Metrics selection
- Escalation
- Presenting issues for positive results

2:15 p.m.—2:30 p.m.

Break

2:30 p.m.—4:00 p.m. APPLICATION EXERCISE

Mock FDA Inspection: CAPA System

To reinforce the information learned today, we will engage in a mock FDA inspection of our CAPA system.

- Set up a CAPA staging team
- Conduct file and system audits
- Evaluate the results
- ISO vs. FDA regulatory differences and approaches

4:00 p.m.—4:15 p.m.

Question & Answer Session

Attendees will have the opportunity to ask the instructor questions. This time can also be used to expand on any topic discussed earlier in the day which may be of particular interest to attendees.

Training Concludes

What Attendees Will Learn In These Workshops

How to develop and manage a CAPA program in their organization and provide supplier-related CAPA support by:

- Establishing thresholds for CAPA initiation to ensure that quality/compliance critical issues are escalated appropriately with adequate justification to resource an issue
- Conducting effective quality root cause investigations for supplier-related deviations
- Developing appropriate timelines and resource management to address CAPAs in a timely manner
- Developing meaningful metrics for management
- Ensuring that all required linkages are identified and bi-directional
- Managing 2nd and 3rd tier supplier corrective actions

- File management from the owner's and management's perspectives
- Understanding one's audience
- Linkage of nonconformities
- Data trending
- Escalation
- Trending and Closure
- Effectiveness monitoring
- File linkage verification

Who Should Attend

Quality assurance, packaging, operations, and manufacturing personnel from pharmaceutical, medical device, biotechnology and other FDA-regulated industry manufacturers. Attendees should have a basic understanding of the following areas: ISO 13485, Quality System Regulation & Good Manufacturing Practice.

General Information

Training workshop fee includes continental breakfast, lunch and all conference materials.



7:30 a.m.

Registration/Continental Breakfast

8:15 a.m.—10:00 a.m.

A Risk-Based Approach for Addressing Supplier-Related CAPAs

- 21 CFR 820.50 (Purchasing controls) and how it relates to 21 CFR 820.100 (Corrective and Preventive Action) to ensure that supplier-related CAPAs are appropriately addressed
- Understanding current expectations for managing supplier-related process/product failures
- How to initiate, conduct and close a CAPA for vendor specific failures
- Understanding the role of a quality agreement as an input to a vendor CAPA
- Setting thresholds to initiate a CAPA file
- CAPA scope management/deciding which organization should own the CAPA
- Linkage of nonconformities at your facility and your vendor's location
- Quality agreement review
- Vendor contact

10:00 a.m.—10:15 a.m.

Break

10:15 a.m.—12:00 p.m.

Conducting an Effective Root Cause Investigation For a Supplier-Related Failure: Part I

We use product supply CAPAs generated from the previous session to complete a root cause investigation of a supplier-related failure. We will conduct scope verification and develop an implementation plan and vendor communication.

- Investigation documentation
- Understanding issue containment
- Selecting related nonconformities
- Selecting investigational tools
- Information evaluation
- Project planning

12:00 p.m.—1:00 p.m.

Lunch

1:00 p.m.—2:30 p.m.

Conducting an Effective Root Cause Investigation For a Supplier-Related Failure: Part II

With completed investigations and implementation plans in place, we review the following areas:

- Execution
- Areas of focus to ensure the success of each file
- Appropriate reasons for changes in scope for a CAPA
- Implementation
- Documenting file status
- Roadblock elevation
- Managing “scope creep”
- Effectiveness monitoring

2:45 p.m. - 3:00 p.m.

Break

3:00 p.m. - 4:00 p.m.

APPLICATION EXERCISE**Verification and Closure**

We will revisit our CAPA inputs, verify that the impacted areas are aware of the final results and ensure that no further nonconformities will be linked to a closed file. To close, we will review the completed CAPAs for feedback from each team relative to the applicable regulations.

- Closed loop communication of file closure via dissemination to internal and external customers
- File linkage verification
- Ensuring that your file is closed in systems linked to CAPA internally and externally

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Training Concluded**What Attendees Will Learn In These Workshops**

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About Your Instructor

William McQuillan is former Global Manager, Change Document and Records Management, Cordis, a Johnson & Johnson Company. He has previously worked for LifeScan, a Johnson & Johnson Company. His experience includes working in CAPA, Product QA and Complaint Investigation departments at both LifeScan and Cordis.

Having worked as a Worldwide CAPA Manager, Will considers deploying global CAPA solutions, improving cycle time and effectiveness of CAPAs in multiple operating companies, and developing international partnerships for the sustained success of a CAPA program to be significant industry accomplishments.

He has conducted training related to understanding CAPA, Good Manufacturing Practice (GMP) practical applications, root cause investigation and the non-conformance process.

He has been involved in multiple FDA inspections, including staging room management, front room auditee and subject matter expert preparation.

CAPA Training Workshop Venue

April 20-21, 2010
 Doubletree Guest Suites Hotel Boston/Waltham
 550 Winter St.
 Waltham, MA 02451
 781-890-6767

[Doubletree Guest Suites Hotel](#)



Mission Statement:

enKap provides an exclusive learning community for professionals in FDA-regulated industry to continuously strengthen and apply their foundation of knowledge related to Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP). Our training workshops are based on the principle of engaging learners through a variety of active learning and instructional activities.



FDA COMPLIANCE DIGEST

To view our November 2009 Sample Issue or November 2009 Premier Issue article excerpts click on the links below.

FDA Compliance Digest November 2009
 Sample Issue: [click here](#)

FDA Compliance Digest November 2009
 Premier Issue article excerpts: [click here](#)

Exclusive GMP, GCP and GLP Editorial Lineup:

The January 2010 Issue will include the following “How To” Meet FDA Requirements Articles, Checklists, SOPs and PowerPoint Training Presentations:

- Complaint Handling
- CAPA
- Ensuring GCP Quality in Your Clinical Trial
- Informed Consent
- Computer Validation Requirements
- SOP on SOPs
- Part 11 Compliance Assessment Checklist
- Good Documentation Practice
- Subpart B of the Drug GMP Regulations
- GLP Regulations

Subject Matter Resource: CAPA Kit

This Kit contains the following subject matter:

Two Instructional Guides

[CAPA: A Guide to Effective Management Practice: Part I CAPA Basics](#)

[CAPA: A Guide to Effective Management Practice - Part II: Datastream Analysis for Identifying CAPA Items](#)

Webinar Recording

[Recording - CAPA: Implementing an Effective Program: Lessons From the Trenches](#)

AND THE NEW...

[CAPA Training and Auditing Reference Materials](#)

... Contains:

- CAPA SOP
- SOP Audit Checklist
- PowerPoint Training Presentation
- Trainer Instructional Notes

[TO PURCHASE THIS KIT - CLICK HERE](#)

Registration Form

CAPA Training Workshops



Please check off which seminars you will be attending

CAPA: Effective System Management: One Industry Professional's Experience	Supplier-Related CAPA: Conducting Effective Root Cause Investigations
<input type="checkbox"/> April 20, 2010 Doubletree Guest Suites Hotel Boston/Waltham, MA Training Workshop Fee - \$550.00	<input type="checkbox"/> April 21, 2010 Doubletree Guest Suites Hotel Boston/Waltham, MA Training Workshop Fee - \$550.00

Four easy ways to register:

1. Call: 561-795-2785
2. Online: <http://www.enkap.com>
3. Fax this completed form: 561-798-8138
4. Mail this completed form: enKap, 125 South State Road 7, Suite 104-222, Wellington, FL 33414

Contact Information

Last Name:		First Name:		M.I.:	
Job Title:					
Department:			Company:		
Mailing Address:					
City:		State/Province:		Zip/Postal Code:	
Country:					
Business Phone:			Fax:		

PAYMENT

Enclosed find my payment of \$ _____
All payments must be in U.S. Dollars. Federal Tax ID #26-4253129

Early Registration Discount: Register for any training workshop by March 5, 2010 and save 10%. After this date, price will be \$550.00 each.

Credit Card

- American Express MasterCard Visa Discover PayPal

Total Amount:		Credit Card Number:			
Expiration Date:		Security Code (found on back of card):			
Name (exactly as it appears on card):					
Billing Address (if different from above):					
City:		State/Province:		Zip/Postal Code:	
Country:					
Billing Phone (if different from above):			Signature:		

Check

- Forward together with completed registration form payable to enKap (checks must be in U.S. dollars and drawn on a U.S. bank). No personal checks will be accepted.

Invoice

- Please mark here to request an invoice from enKap. You are not considered registered until payment is received and a confirmation has been sent from enKap.

Refunds: Refund requests must be made in writing and received by April 1, 2010. You will receive a refund, less a \$200.00 cancellation fee. After the above-mentioned date, no refunds will be approved. enKap's liability is limited to refund of the training workshop registration fee only. **Substitutions:** If you are unable to attend, substitutions can be made anytime. **Group Discounts:** Available for three or more individuals from the same facility. Call the enKap community desk toll-free at 1-877-823-4GXP for more details.