



# Medical Device Software Validation Training Workshops

*Two Workshops—Two Locations!*

March 24—25, 2010 - Hilton Woodbridge-Iselin, New Jersey

May 19—20, 2010 - Doubletree Hotel-Boston/Waltham, MA

Medical Device Software Validation:  
System Definition and Requirements

*Incorporating Effectiveness and Compliance  
in Software Design*

&

Implementing Critical Processes for Effectively  
Supporting Medical Device  
Software Validation Programs

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.**

### Software Validation Overview

Software validation has a distinct definition and set of characteristics within FDA-regulated industry. In industry, however, there are multitudes of terms, methodologies and lifecycle models, even within regulated companies. This session will simplify the language landscape related to software validation and create some common ground on which to build the workshop discussions.

Subject Matter reviewed in this session include:

- Overview of the V-Model
- Verification vs. Validation
- Intended Use
- Regulations vs. Guidance vs. Standards vs. Models
- Key Process Areas

**9:15 a.m. – 9:45 a.m.**

### FDA Requirements for Requirements

What does intended use mean? How does the FDA stratify requirements and specifications? What are FDA's expectations for how requirements relate to one another, their associated tests, and final system? This session will explore these and other topics to establish the regulatory ground rules for the requirements discussions of the day.

Subject Matter reviewed in this session includes:

- Intended Use
- Why FDA Requires Requirements
- Requirements vs. Specifications – Layers of the Cake

- Traceability
- Hazard/Risk Analysis as Requirement

**9:45 a.m. – 10:15 a.m.**

### What Makes a Well-Written Requirement?

This facilitated discussion will collect the various views in the room regarding well-written requirements. In addition, participants will be encouraged to give examples of well-written and poorly written requirements, and to help each other understand the needs of various audiences of requirements.

Questions addressed during this discussion include:

- What are some examples of well-written and poorly written requirements?
- Who are the key stakeholders of various levels of requirements?
- What are the key ideas and words to incorporate into requirements writing?
- What are key ideas and words to avoid when writing requirements?

**10:15 a.m. – 10:30 a.m.**

### Morning Break

**10:30 a.m. – 11:30 a.m.**

### APPLICATION EXERCISE

#### What's Wrong With This Picture?

This exercise will challenge participants to identify issues in samples of real-life requirements. The goal is to enable each participant to apply good requirement documentation concepts by identifying common pitfalls.

**11:30am – 12:30pm**

**Lunch**

**12:30 p.m. – 1:15 p.m.**

### **Connecting the Dots**

This facilitated discussion will explore how the companies represented in the room stratify and label requirements and specifications for systems. The group will further examine the relationship these documents have with each other, with other project/system documents, and with the system itself.

Questions addressed during this discussion include:

- What are different levels of requirements?
- How do various levels of requirements relate to each other?
- Why is traceability important?
- What other documents and activities influence requirements development?
- What other documents and activities are influenced by requirements?
- What are your audit experiences around traceability?

**1:15 p.m. – 2:15 p.m.**

### **APPLICATION EXERCISE**

#### **Building the Correct System**

Using common children's building blocks, this exercise will demonstrate the purpose and importance of user, business/systems analyst, and developer in effectively understanding and communicating system requirements.

**2:15 p.m. – 2:30 p.m.**

**Afternoon Break**

**2:30 p.m. – 3:15 p.m.**

### **Content Elements (User Requirements/Business Process Requirements)**

This facilitated discussion will focus on development, content and use of the highest level of requirements.

Questions addressed during this discussion include:

- Is the highest level of requirement needed for effective system design?
- Who is the intended audience?
- What elements should be documented and at what level of granularity?
- How should this document be used in the overall project work product hierarchy?

**3:15 p.m. – 4:00 p.m.**

### **Content Elements (Software/System Requirements)**

This facilitated discussion will focus on the development, content, and use of the (software/system requirements) document, which, in some organizations, is the set of requirements for a system.

Questions addressed during this discussion include:

- What is the purpose for this level of document, when designing a system?
- Who is the intended audience?
- What elements should be documented and at what level of granularity?
- How should this document be used in the overall project work product hierarchy?

**4:00 p.m. – 4:30 p.m.****Content Elements (Design Requirements)**

This facilitated discussion will focus on the development, content, and use of the (design requirements) document, which may be the least used set of requirements for a system.

Questions addressed during this discussion include:

- Is low-level documented design a waste of time?
- What is the true purpose of documented design documents?
- Who is the intended audience?
- What elements should be documented and at what level of granularity?
- How should this document be used in the overall project work product hierarchy?

**4:30 p.m.****Question and 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 This Workshop**

This workshop is an open forum and training event intended to provide participants with a sound understanding of software validation from “both sides of the V.”

The first half of the workshop will explore system definition and requirements. The second half will address other essential concepts and practices in

software system validation. Incorporating (then moving beyond) lecture, participants will gain the benefit of experience from both the instructor and peers, who share many of the day-to-day challenges of ensuring systems are designed, constructed, and implemented in compliance with internal and external obligations, and in accordance with needs of all stakeholders.

Hands-on exercises will create lasting triggers to allow participants to recall the lessons they learn long after they return to their daily job functions.

**WHO SHOULD ATTEND**

This training workshop is ideal for those individuals in your organization involved in the following functions:

- Business analysts
- Product managers
- Project managers
- Software testers
- Software designers
- Software developers
- Software quality management
- Quality systems change owners
- Influencers or decision makers for new systems

**General Information**

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



**7:30 a.m.****Registration/Continental Breakfast****8:30 a.m. – 9:00 a.m.****Software Process Overview**

Software projects are often seen by practitioners and engineering managers as victims of the software process. The FDA, however, insists that the software process be an integral part of a regulated company's overall process library, and is focusing more attention on this component of company behavior. Several models in industry have shown an impressive return on investment, when a software process is implemented effectively.

Topics covered in this session include:

- The reasonable role of software process in software projects
- Moving process beyond bureaucracy into corporate asset
- Important process areas to consider and why
- A short lesson in effective process development

**9:00 a.m. – 10:15 a.m.****APPLICATION EXERCISE****A Planning Case Study Gone Awry**

Participants will examine a case study of a project that failed as a result of poor planning. The group will spend 45 minutes examining the case and documenting their findings. Thirty minutes will be dedicated to openly discussing findings.

**10:15 a.m. – 10:30 a.m.****Morning Break****10:30 a.m. – 11:00 a.m.****Effective Project Planning**

This facilitated discussion will examine various aspects of project planning as a distinct process area within software engineering. Participants will gain insight into the wide variety of activities and documents which may be used to effectively plan and execute software projects.

Questions addressed during this discussion include:

- What went wrong with the case study we just discussed?
- Why is planning key to project success?
- What planning is necessary for software projects?
- Who is involved in project planning?
- Can you do too much planning, and when do you know you're there?
- What planning work products and activities are important?
- What types of information are in project planning work products?

**11:00 a.m. – 11:30 a.m.****Evaluation/Testing**

This facilitated discussion will review various aspects of software testing and the difference between verification and validation.

Questions addressed during this discussion include:

- What is verification?
- What is validation?
- What is the true purpose of testing?
- Why is testing an important project activity?
- When does testing occur in a project?
- What activities on a project can be considered testing activities?

- What work products should be created through testing activities and what would be the content?
- Who performs testing activities?

**11:30 a.m. – 12:30 p.m.**

**Lunch**

**12:30 p.m. – 1:00 p.m.**

### **Configuration/Change Management**

This facilitated discussion will examine the various aspects of configuration management and change management. Participants will hear their peers cite examples of configuration management activities and work products, issue management processes, change management deliberation activities, and more.

Questions addressed during this discussion include:

- What is configuration management?
- Why is configuration management a key process area?
- How is configuration management the same or different from change management?
- What are the components of configuration/change management?
- When does configuration/change management begin in the life of a system?
- Who is responsible for configuration/change management?
- What are the activities associated with this function?

**1:00 p.m. – 2:15 p.m.**

### **APPLICATION EXERCISE**

#### **Jeopardy!**

Key concepts from the major process areas covered in today's training workshop will be revisited using this popular game show format. Remember to phrase your answer in the form of a question!

**2:15 p.m. – 2:30 p.m.**

#### **Afternoon Break**

**2:30 p.m. – 3:15 p.m.**

#### **Off-The-Shelf and Outsourced Software Projects**

This facilitated discussion will look at the impact of off-the-shelf and outsourced software projects on the various areas discussed previously in this workshop. The group will also address the various types/levels of off-the-shelf software, outsourcing agreements and how to govern the relationship between client and software/service supplier when the FDA holds the manufacturer accountable for compliance.

Questions addressed during this discussion include:

- What is off-the-shelf software?
- What is outsourcing?
- What does the FDA require for purchasers of off-the-shelf software?
- What does the FDA require for those outsourcing software engineering activities?
- What can be reasonably outsourced in a regulated environment?
- What does the purchaser of off-the-shelf software need to know about the supplier?
- What does the client need to know about the outsourced service provider?

- How does off-the-shelf software change the activities within a system's lifecycle?
- What work products should a client expect from a service provider?
- What level of in-process oversight is reasonable for a service provider?
- What are some tips for managing the relationship with an off-the-shelf software supplier and/or outsourced service provider?

### 3:15 p.m. – 4:00 p.m.

#### Spreadsheet Validation

This facilitated discussion will focus on the increasingly hot topic of spreadsheet validation. Spreadsheets are most often created and maintained by those with little or no technology or software process training.

Many spreadsheet "developers" do not realize their activities are part of a company's Quality System and are subject to the requirements of 21 CFR 820.70(i), as a result. Change control also becomes problematic, as both staff and software system sit outside the normal technology infrastructure.

Questions addressed during this discussion include:

- When is a spreadsheet part of the Quality System?
- How do organizations keep track of Quality System spreadsheets?
- How should change control be managed for spreadsheets?
- Do normal development and change control processes fit spreadsheet development and maintenance?
- What validation steps are reasonable and defensible for spreadsheets?
- What training is appropriate to ensure "developers" of spreadsheets comply with FDA requirements?

### 4:00 p.m. – 4:30 p.m.

#### Question and 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 This Workshop

This workshop is designed to give participants the necessary tools to understand and develop processes necessary to implement safe, effective and compliant software systems. Although entire courses are developed around each of the topics discussed during this Training Workshop, the attendee will have a grasp of the fundamentals of key process areas necessary for starting a more detailed exploration.

In this workshop, the following six software validation fundamentals are covered:

- Basic concepts
- Validation planning
- Requirements and design
- Evaluation and testing
- Configuration and change management
- Off-the-shelf and outsourcing impacts on validation

### General Information

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

## WHO SHOULD ATTEND

This workshop is ideal for those individuals in your organization involved in the following functions:

- Business analysts
- Product managers
- Project managers
- Software testers
- Software designers
- Software developers
- Software quality management
- Quality systems change owners
- Influencers or decision makers for new systems

## About Your Instructor

**Eric Henry** is the Sr. Manager of Corporate Software Quality for Boston Scientific.

Previously, he was the Manager of Design Assurance for a medical device company, Director of a Software Quality Management consulting practice, and Director of Test Management for a securities regulator.

Eric holds a BS in Organizational Management and is a Senior Member of ASQ (Biomedical Division and Software Division).

### Boston Scientific

Boston Scientific Corporation is a developer, manufacturer, and marketer of medical devices that are used in a broad range of interventional medical specialties, including cardiology, cardiac rhythm management, peripheral interventions, electrophysiology, neurovascular intervention, endoscopy, urology, gynecology and neuromodulation.

The Company's products are offered for sale principally by three dedicated business groups: Cardiac Rhythm Management (CRM); Cardiovascular, including the Cardiovascular, and Neurovascular businesses; Endosurgery, including the Endoscopy and Urology/Gynecology businesses, and Neuromodulation.

## Software Validation Workshop Venue

### March 24-25, 2010

Hilton Woodbridge  
120 Wood Ave. S.  
Iselin, NJ 08830  
732-494-6200

[Hilton Woodbridge](#)

### May 19-20, 2010

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

[Doubletree Guest Suites](#)

## 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

# Registration Form

Please check off which seminars you will be attending

| Software Validation: System Definition and Requirements  | Effectively Supporting Software Validation Programs  |
|--|--|
| <input type="checkbox"/> March 24, 2010<br>Hilton Woodbridge, Iselin, New Jersey<br><b>Training Workshop Fee - \$550.00</b>          | <input type="checkbox"/> March 25, 2010<br>Hilton Woodbridge, Iselin, New Jersey<br><b>Training Workshop Fee - \$550.00</b>          |
| <input type="checkbox"/> May 19, 2010<br>Doubletree Guest Suites Hotel Boston/Waltham, MA<br><b>Training Workshop Fee - \$550.00</b> | <input type="checkbox"/> May 20, 2010<br>Doubletree Guest Suites Hotel Boston/Waltham, MA<br><b>Training Workshop Fee - \$550.00</b> |

### 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

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

## 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 February 15, 2010 and save 10%. After this date, price will be \$550.00 each.

## Credit Card

American Express       MasterCard       Visa       Discover       PayPal

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

## 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.