

MEDICAL DEVICE DESIGN CONTROL | Implementing An Approach That Works

PRESENTED BY OMBU ENTERPRISES AND FDANEWS

YOUR INSTRUCTOR



Dan O'Leary

President

Ombu Enterprises, LLC

"It was a very methodical approach, enjoyed the examples."

— Randall Lenz,
CQT Consultant / QE,
Stryker Instruments

This conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification.

JUNE 16-17, 2015 | CHICAGO MARRIOTT OAK BROOK, OAK BROOK, IL

Design control in both QSR and ISO 13485:2003 is complicated. Regardless of the complex structure, you need flawless execution. FDA investigators and notified body auditors will take pains to check your work against the regulatory requirements.

This workshop will help you learn the requirements, develop approaches, and execute them. Through examples and case studies you will solidify your understanding of design controls and learn how to develop procedures that define and document your approach.

Many device manufacturers market in the US, the EU, and Canada – the workshop compares and contrasts the requirements to help you develop a comprehensive system.

The workshop uses FDA's Quality System Inspection Technique (QSIT) as a method to ensure correct implementation.

Attend this critical workshop to learn:

- Methods on design planning based on project management techniques
- Developing sources of design input and resolving problems
- The role of design output and methods to ensure it is complete
- How to conduct design reviews that help improve the device design
- Using design verification methods to match design output with design input
- Conducting design validation and its critical elements of software validation and risk management
- Implementing the 5 vital components of design change



Day 1

TUESDAY, JUNE 16, 2015

8:00 a.m. – 9:00 a.m. | **REGISTRATION AND CONTINENTAL BREAKFAST**

9:00 a.m. – 10:15 a.m.

Part A – Statutory and Regulatory Requirements

- Design Control
 - US – Food Drug and Cosmetics Act & 21 CFR Part 820
 - EU – Medical Device Directive (MDD) & EN ISO 13485:2012
 - Canada – Canadian Medical Device Regulations (CMDR) & ISO 13485:2003
- Conformity Assessment Paths
 - US – Premarket Submissions
 - EU – MDD Annex II Technical Files & Design Dossiers
 - Canada – Medical Device License

Exercise – Identify Total Design Control Requirements

10:15 a.m. – 10:30 a.m. | **BREAK**

10:30 a.m. – 12:00 p.m.

Part B – Planning

- Planning Stages
- Interfaces

“The examples given were helpful, and the presentation was very easy to follow.”

— Karyn Schwitters, Regulatory Affairs Specialist, Anderson Packaging, Inc.

- Project Management Technique
 - Action List
 - Work Breakdown Structure (WBS)
 - Gantt Chart
 - Critical Path Method (CPM)
 - Program Evaluation and Review Technique (PERT)
- Developing the Design History File (DHF)

Exercise – Developing a Project Plan

12:00 p.m. – 1:00 pm | **LUNCH BREAK**

1:00 p.m. – 2:30 p.m.

Part C – Design Input

- Requirements for the Procedure
- Resolving design input issues (incomplete, ambiguous, or conflicting requirements)
- Identifying the design input requirements
 - Performance
 - Functional
 - Safety
 - Regulatory
 - Market
- Starting a trace matrix

Exercise – Developing and Resolving Input Requirements

2:30 p.m. – 2:45 p.m. | **BREAK**

2:45 p.m. – 4:30 p.m.

Part D – Design Outputs

- Requirements for the Procedure

- Total finished design output
 - The device
 - Packaging and labeling
 - Device Master Record (DMR)
- Acceptance criteria
- Essential product characteristics
- Continuing the trace matrix

Exercise – Design Output Completeness

4:30 p.m. | **SESSION WRAP-UP, END OF DAY ONE**

COURSE BINDER MATERIALS

- Full slides from the PowerPoint presentations
- A list of design control requirements and their regulatory source
- A checklist for each required design control procedure
- A copy of each interactive exercise worksheet
- Reference documents:
 - FDA guidance on Design Controls
 - FDA Small Entity Compliance Guide on Design Controls
 - FDA guidance on Enhancements and Recalls
 - FDA guidance document on 510(k) changes

SIGN CONTROL | Implementing An Approach

Day 2

WEDNESDAY, JUNE 17, 2015

8:30 a.m. – 9:00 a.m. | **CONTINENTAL BREAKFAST**

9:00 a.m. – 10:15 a.m.

Part E – Design Review

- Requirements for the Procedure
 - What needs to be covered
 - Who needs to attend
 - How to document results
 - Integrating risk management
- Design Review at each Stage
- Creating and Closing Action Items
- Exercise – Identifying and Resolving Problems

Exercise – Identifying and Resolving Problems

10:15 a.m. – 10:30 a.m. | **BREAK**

10:30 a.m. – 12:00 p.m.

Part F – Design Verification

- Requirements for the Procedure
- Design Verification Tools
 - Failure Modes and Effects Analysis (FMEA)
 - Fault Tree Analysis (FTA)
 - Inspections and Tests
 - Document Review
 - Alternate Calculations
 - Similar Designs

- The sample size question
- Continuing the trace matrix

Exercise – Design Verification Methods

12:00 p.m. – 1:00 pm | **LUNCH BREAK**

1:00 p.m. – 2:30 p.m.

Part G – Design Validation

- Requirements for the Procedure
- Initial Products or Equivalents
- Defined conditions or simulation
- Software Validation
- Risk Management (ISO 14971:2007)
- Usability Engineering
- Continuing the trace matrix

Exercise – Examining a Design Validation Plan

2:30 p.m. – 2:45 p.m. | **BREAK**

2:45 p.m. – 4:30 p.m.

Part H – Design Transfer

- Requirements for the Procedure
- Process Controls, 820.70(a)
- Purchasing Data, 820.50(b)
- Process Validation, 820.75

Exercise – Determining When a Process Must be Validated

Part I – Design Changes

- Requirements for the Procedure
- Design change interrelationships — the five important considerations

- When a production change is a design change
- Does the design change create a new Device Identifier?
- Does the design change require an updated 510(k)?
- Does the design change impact the Risk Management File?
- Is the design change an enhancement or a recall
- The design change flow chart shows the picture
- Design change records

Exercise – Classify changes as a design change or a production process change

4:30 p.m. | **ADJOURN WORKSHOP**

WHAT COMPANIES WOULD BENEFIT FROM THIS WORKSHOP

- Device companies
- Diagnostic companies
- Combination products companies
- Kit and repackagers
- Laboratory developed test companies
- Human factor and engineering companies
- Contract design and testing firms

9 Comprehensive Exercises You Can't Afford to Miss!

1. Identify Total Design Control Requirement

— Participants review specific design control requirements, determine their source, and identify implementation methods.

2. Developing a Project Plan — Participants analyze a small example project, identify stages, and develop a Work Breakdown Structure (WBS) and a Gantt chart for the project.

3. Developing and Resolving Input Requirements

— Participants develop a set of design inputs for an example product and use the results to identify missing, incomplete, or ambiguous requirements.

4. Design Output Completeness — Participants review design outputs for an example product and identify essential requirements, acceptance criteria, and gaps in the requirements.

5. Identifying and Resolving Problems — Design reviews systematically examine a design to evaluate its adequacy and capability with the intent to identify problems. Participants critique a design review to determine if it is sufficient.

6. Design Verification Methods — Participants examine paired design inputs and design outputs and determine the best tool for design verification. In some cases the analysis is extended to look specific aspects of the tools.

7. Examining a Design Validation Plan

— Participants critique a design validation that starts with user needs and intended uses. The plan uses production equivalents and simulated use conditions.

8. Determining When a Process Must be Validated

— Some production processes require process validation, while others do not. Participants will determine analyze processes transferred to production and document whether they require process validation.

9. Classify changes as a design change or a production process change

— QSIT informs the FDA Investigator that Production and Process Changes could be Design Changes. This exercise provides participants an opportunity to classify changes and provides insight into the decisions to make in the QMS.

"I thought the presenter was thorough and provided real-world examples in order to enhance the presentation."

— Isabel Hoverman, Quality Engineer, Orthofix, Inc.

ABOUT YOUR INSTRUCTOR



Dan O'Leary

Dan O'Leary has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs. Dan is now President of Ombu Enterprises, LLC a consultancy focused on operational excellence and regulatory compliance serving small manufacturing companies. He has a Masters Degree in Mathematics; is an ASQ Certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is certified by APICS in Resource Management.

"Dan is a wealth of knowledge in regards to all aspects of medical device regulations."

— **Kanan Bhavsar, PV Clinical Trial and Drug Safety Specialist, Merck**

"[Dan is an] Excellent speaker. Great experience and examples. Interactive discussions in particular were very helpful."

— **Brian Ray, Senior Manager Risk Management, Welch Allyn**

"Dan is an excellent speaker who holds a lot of knowledge and experience."

— **Joaquin Bautista, Quality Specialist, Colgate-Palmolive Co.**

"[Dan] has a great approach to teaching a group of professionals with very different backgrounds and experience."

— **Walter Domozych, Principle Quality Engineer, Boston Scientific**

WHO SHOULD ATTEND

- Quality Managers
- Regulatory Affairs Managers
- Engineering Managers
- Quality Engineers
- Production Engineers
- Purchasing Managers
- Purchasing Agents involved in outsourcing production or processes
- Design Engineers
- Project Managers involved in design and development
- Specialists assigned to complaints, corrective actions, or medical device reporting
- Recall coordinators
- Medical staff evaluating risk, safety, or effectiveness
- General/corporate counsel

ATTENDEES WILL LEARN

- The regulatory basis for design controls in the US, the European Union, and Canada
- Methods on design planning based on project management techniques
- Developing sources of design input and resolving problems
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MEDICAL DEVICE DESIGN CONTROL

Implementing An Approach That Works

Yes! Sign me up for the **Medical Device Design Control Workshop**
June 16-17, 2015 | Oak Brook, IL

Attendee 1: Name _____
 Title _____ Email _____ \$1,797

Attendee 2: Name _____ *Call for Discounts*
 Title _____ Email _____

Attendee 3: Name _____ *Call for Discounts*
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www.FDAnews.com/MedicalDeviceDesignControl **TOTAL:**

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PAYMENT OPTIONS:

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HOTEL RESERVATIONS:

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the **FDAnews Workshop** to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. The discounted rate is also available two nights before and after the event based on availability. Hotel may require first night's room deposit with tax. Room cancellations within 72 hours of the date of arrival or "no-shows" will be charged for the first night's room with tax.

Dates/Location:

June 16-17, 2015
Chicago Marriott Oak Brook
 1401 West 22nd Street, Oak Brook, IL 60523
Toll Free: (800) 228-9290 or +1 (630) 573-8555
www.MarriottOakBrook.com
Room rate: \$209.00 plus 9 percent tax
Reservation cut-off date: May 29, 2015
GROUP CODE – 02246838FDA

TUITION:

Tuition of \$1,797 includes all workshop sessions, workshop written materials, two breakfasts, two lunches and daily refreshments.

CANCELLATIONS/ SUBSTITUTIONS:

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund -- less a \$200 administration fee. No cancellations will be accepted -- nor refunds issued -- within 21 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

TWO OR MORE TEAM DISCOUNTS:

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Call +1 (703) 538-7600 for details.

FOUR EASY WAYS TO REGISTER:

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