

Preparing for FDA Regulation of Laboratory Developed Tests

Nov. 12-13, 2015

Chicago Marriott Oak Brook • Oak Brook, IL

The FDA plans to regulate Laboratory Developed Tests (LDT). Whether it's days, weeks or months from now, the agency WILL enter this previously unenforced area. Savvy LDT makers need to prepare, starting *TODAY*.

LDT Manufacturers Challenged to Get Ready NOW

The FDA does not intend to regulate laboratory services, but will treat LTD manufacturers as regulated IVD manufacturers. That means entirely new compliance challenges covering pre-market submissions, device design, manufacturing, adverse event reporting ... the list goes on and on. And don't think for a minute that CLIA compliance will be sufficient. The new framework is not CLIA — far from it. Bottom line: You have a lot of learning to do ... and time may be short.

The most effective approach draws a bright line between the two major LDT aspects. One is test design and manufacture under the Quality System Regulation (QSR) and the other is provision of laboratory services under CLIA. The bright line separates these aspects, even as they occur in the same building.

Ombu Enterprises, the leader in regulatory compliance training for medical device manufacturers, has teamed with FDAnews to craft a hands-on workshop where you learn by doing. By the end of this intensive session, you'll have a jump on —

- Understanding FDA device regulations and how they'll apply to *YOU* ...
- The nitty-gritty of day-to-day compliance ...
- What regulators will be looking for during an Inspection ...



Dan O'Leary
President, Ombu Enterprises

"I enjoyed [Dan's] delivery and experience."

— Laura Meyer, Post Market Surveillance Lead,
Siemens

"Presenter was thorough and provided real-world
examples."

— Isabel Hoverman, Quality Engineer, Orthofix Inc.

"A very methodical approach. Enjoyed the examples."

— Randall Lenz, CQT Consultant/QE, Stryker
Instruments

Preparing for FDA Regulation of LDTs

Nov. 12-13, 2015 • Chicago Marriott

WORKSHOP AGENDA

DAY ONE

THURSDAY, NOV. 12, 2015

8:00 a.m. – 9:00 a.m.

REGISTRATION & CONTINENTAL BREAKFAST

9:00 a.m. – 10:15 a.m.

Part A — FDA's LDT Framework

- The draft guidance documents
- The FDA notification process and its implications
- Device classification based on notification
- QSR implementation timeline
- Exercise A1 — Completing the Notification

10:15 a.m. – 10:30 a.m. REFRESHMENT BREAK

10:30 a.m. – 12:00 p.m.

Part B — Understanding Pre-market Notification

- Device classes in the US regulatory system
- FDA's methods to assign device classes
- Premarket submissions, 510(k) and PMA
- Regulations, Product Codes, and Submissions
- Exercise B1 — Classification of an IVD

12:00 p.m. – 1:00 p.m. LUNCH

1:00 p.m. – 2:30 p.m.

Part C — QSR Overview

- The CFR Parts in the device regulation
- Development of QSR, Part 820
- The 15 Subparts of QSR
- Subparts with particularly important issues for LDTs and IVDs
- Exercise C1 — Supplier Management in QSR

2:30 p.m. – 2:45 p.m. REFRESHMENT BREAK

2:45 p.m. – 4:30 p.m.

Part D — IVD Regulations

- Reagent labels and labeling in Part 809
- Unique Device Identification (UDI)
- Research Use Only (RUO)
- Investigational Use Only (IUO)
- Analyte Specific Reagents (ASR)
- General Purpose Laboratory Reagents (GPR)
- Exercise D1 — Reagent Label Information

4:30 p.m. END OF DAY ONE

DAY TWO

FRIDAY, NOV. 13, 2015

8:30 a.m. – 9:00 a.m.

CONTINENTAL BREAKFAST

9:00 a.m. – 10:15 a.m.

Part E — QSR – Design Controls

- The applicability of design controls
- The structure of design control
- Design inputs
- Design outputs
- Design verification
- Design validation
- Risk analysis
- Design transfer
- Design history file
- Exercise E1 — Establishing performance specifications

10:15 a.m. – 10:30 a.m. REFRESHMENT BREAK

10:30 a.m. – 12:00 p.m.

Part F — QSR – Production & Process Controls (P&PC)

- The applicability of P&PC
- The structure of P&PC
- Production processes
- Change control

- Environmental control
- Personnel health, cleanliness, personal practices, and clothing
- Contamination control
- Equipment
- Automated processes
- Exercise F1 — Equipment maintenance

12:00 p.m. – 1:00 p.m. LUNCH

1:00 p.m. – 2:30 p.m.

Part G — QSR – Process Validation

- Concepts of process validation
- When a process must be validated
- Validating a process (IQ, OQ, PQ model)
- Performing a process
- Changes and deviations
- Exercise G1 — Process validation requirements

2:30 p.m. – 2:45 p.m. REFRESHMENT BREAK

2:45 p.m. – 4:30 p.m.

Part H — Complaints and MDRs

- Complaint files
- MDR reporting for user facilities
- MDR reporting for manufacturers
- Corrections & Removals
- Exercise H1 — A reporting example

4:30 p.m.

ADJOURNMENT

Description of the Exercises

Exercise A1 — Completing the Notification

Participants review notification information for a sample LDT, and then complete a notification worksheet for one of their own LDTs.

Exercise B1 — Classification of an IVD

Participants use existing IVDs and FDA's classification information to understand the system

of Laboratory Developed Tests

riott Oak Brook • Oak Brook, IL

MEET YOUR INSTRUCTOR



Dan O'Leary a favorite presenter at FDAnews conferences and workshops, has more than 30 years' experience in quality, operations and program management in regulated industries, including medical devices and clinical labs. Dan is president of Ombu Enterprises LLC, a consultancy focused on operational excellence and regulatory compliance. He 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] has a great approach to teaching a group of professionals with very different backgrounds and experience."

— Walter Domozych, Principal Quality Engineer, Boston Scientific

COURSE BINDER MATERIALS

- Slides from PowerPoint presentations
- Interactive exercise worksheets
- Draft Guidance — Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)
- Draft Guidance — FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)
- 21 CFR Part 803 — Medical Device Reporting
- 21 CFR Part 806 — Medical Devices; Reports of Corrections and Removals
- 21 CFR Part 809 — In Vitro Diagnostic Products For Human Use
- 21 CFR Part 820 — Quality System Regulation
- CLIA Regulations Excerpts

of premarket submissions, guidance documents, and recognized consensus standards.

Exercise C1 — Supplier Management

QSR has more detailed regulations for supplier management than CLIA. Participants evaluate a hypothetical supplier used for an existing LDT and perform a gap analysis for QSR compliance. This includes both purchasing and acceptance activities.

Exercise D1 — Reagent Label Information

This exercises reviews the label and package insert content required for an IVD and compare it with the requirements for performance specifications in the CLIA regulations.

Exercise E1 — Establishing performance specifications

Participants compare and contrast the QSR design controls requirements (input, output,

and verification) with the CLIA requirements for a laboratory that introduces a test system not subject to FDA clearance or approval, i.e., and LDT.

Exercise F1 — Equipment maintenance

Participants document QSR equipment maintenance requirements based on the CLIA requirements, identify gaps, and develop methods to close the gaps.

Exercise G1 — Process validation requirements

Participants will examine a production process for an IVD and determine if it must be validated. If so, the participants apply the IQ, OQ, PQ model to process.

Exercise H1 — A reporting example

Participants analyze a situation that includes a complaint, a user facility report, a manufacturer's report, and a removal.

WHO WILL BENEFIT

- Project managers involved in design and development
- Design engineers
- Quality engineers
- Manufacturing engineers
- Quality auditors
- Production managers
- Scientists involved in device research and development
- Medical staff evaluating risk, safety or effectiveness
- Quality or regulatory staff assigned to complaint, CAPA or MDR management
- Training personnel
- General/corporate counsel

Preparing for FDA Regulation of Laboratory Developed Tests

Nov. 12-13, 2015 • Chicago Marriott Oak Brook • Oak Brook, IL

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

Nov. 12-13, 2015

Embassy Suites Raleigh-Durham Airport/Brier Creek

1401 West 22nd Street

Oak Brook, IL 60523

Toll Free: (800) 228-9290

+1 (630) 573-8555

www.MarriottOakBrook.com

Room rate: \$169.00 plus 9% tax

Reservation cut-off date: Oct. 21, 2015

TUITION

Tuition includes all workshop sessions, workshop written materials, two breakfasts, two luncheons 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.

TEAM DISCOUNTS

Significant tuition discounts are available for teams of three 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

Online: www.fdanews.com/LDTs

Fax: +1 (703) 538-7676

Phone: Toll free (888) 838-5578 (inside the U.S.)
or +1 (703) 538-7600

Mail: **FDAnews**, 300 N. Washington St., Suite 200
Falls Church, VA 22046-3431 USA

YES! I want to attend **Preparing for FDA Regulation of Laboratory Developed Tests**. I understand the fee of \$1,797 includes all workshop sessions, workshop materials, two breakfasts, two luncheons and daily refreshments.

FDA NEWS

300 N. Washington St., Suite 200
Falls Church, VA 22046-3431

(Please see "Team Discounts" above for tuition discounts when you send a team of three or more.)

Attendee 1: Name _____ Title _____ Email _____

Attendee 2: Name _____ Title _____ Email _____

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization _____

Address _____

City _____ State _____ Zip _____

Country _____

Phone _____ Fax _____

Payment Options

Check enclosed, payable in U.S. funds to FDAnews

Charge to: Visa MasterCard American Express

Credit card no. _____

Expiration date _____

Total amount \$ _____

Signature _____

(Signature required on credit card and bill-me orders.)

Print name _____

Bill me/my company \$ _____

Purchase order # _____

(Payment is required by the date of the conference.)