CfPA
THE CENTER FOR PROFESSIONAL ADVANCEMENT
FOUNDED 1967

Celebrating 50 YEARS 1967-2017

NEW!

LIMS: Applying the SDLC Approach to Implementation

Software Development Life Cycle Approach to Laboratory Information Management Systems

11-12 May 2017 | Amsterdam, The Netherlands

Course Topics Include:

- LIMS platform capabilities
- Retiring, decommissioning and migrating LIMS systems
- Regulatory and business drivers
- Current "hot topics"
- Case study approach

course description

A Laboratory Information Management System (LIMS) is a valuable asset employed to manage the data generated daily in a laboratory. As with all validated systems, an oversight during the implementation period can be costly and slow down business processes for years to come, as well as introduce unwelcomed regulatory risk. This course aims to provide participants with the tools they need to successfully implement a new LIMS platform, decommission a legacy system, or migrate from legacy systems.

This 2-day, **intensive** course will use the Good Automated Manufacturing Practices (GAMP) guidelines and a software development life cycle (SDLC) context to plan for implementation of a LIMS. Each course module will examine a phase of the SDLC, list deliverables required, and describe best practices for applying the approach. During the course, participants will workshop through their own company's processes and LIMS platform, and come out of the course with a usable plan. A case study applying the approach to a LabWare LIMS implementation will also be presented as a reference point.

SAVE $200-Register & Pay by 31 March

www.cfpa.com

who should attend

This course is intended for those individuals responsible for planning and/ or executing all or portions of the LIMS implementation strategy. The rigor of testing will be in alignment with highly regulated industries such as biotech, pharmaceuticals, and medical devices, but the strategies and approach could be applied to any industry. Potential affected departments could include:

• QA/QC • Validation • Engineering • Technical Operations • Information Technology

learning objectives

Upon completion of this course, you will be able to:

- Define the business processes present in a lab, as well as the interface to associated manufacturing areas
- List typical LIMS platform capabilities
- Plan for successful implementation and use of a LIMS system
- Map deliverables required to successfully implement a LIMS system to their software development lifecycle phases
- Assess future state business processes to match LIMS platform capabilities
- Discuss considerations for retiring and decommissioning of legacy LIMS systems
- Describe best practices for transitioning from one LIMS system to another
- Understand the regulatory and business drivers impacting the decisions made during a LIMS platform implementation
- Discuss regulatory "hot topics" such as data integrity, Part 11, and lean laboratory business practices as they pertain to LIMS

course outline

First Day

08.00: Registration/Continental Breakfast

08.30-10.00:
Review of Learning Objectives/Introductions
LIMS Value Proposition
- Icebreaker Exercise: "Voice of the Sample"
- Process flow for samples
- Regulatory & Business Drivers that justify a LIMS system
- LIMS Capabilities

10.30–12.00:
SDLC and Requirements Analysis
- Refresher of Software Development Life Cycle (SDLC)
- Requirements Analysis Phase
- Necessary Deliverables

13.00–14.30:
Design and Specification
- Functional Design Specification
- Hardware Design Specification
- Configuration Specification
- Workshop activity: case study using LabWare

14.45–16.30:
Development
- Software Development Frameworks and Configuration Methodologies
- Integrator Responsibilities
- User Acceptance Testing
- Workshop activity: case study using LabWare

Second Day

08.30–10.00:
Testing
- GAMP Guidelines
- Core/Platform Qualification
- Workshop activity: case study using LabWare

10.30–12.00:
Implementation / Go Live
- System and Process SOP Readiness
- User Training
- Performance Qualification
- Workshop activity: case study using LabWare

13.00–14.30:
Maintenance and Retirement
- System Change Requests
- External Interfaces
- Phased Deployment Planning
- System Decommissioning
- Workshop activity: case study using LabWare

14.45–16.30:
Hot Topics
- Data Integrity
- Part 11 Compliance
- Mobile Execution, etc.

Questions and Answers

Assessment Opportunity

course director

John Wass is a programmatic technical Consultant and Project Manager for Commissioning Agents, Inc., a Certified Pharmaceutical Industry Professional (CPIP). Over the past decade he has participated in most stages of the product development lifecycle from concept to new market commercialization, and has implemented enterprise quality data management and manufacturing process control systems in support of these product processes. He has served as a project executive for both local, single-site and global, multi-site implementations of LabWare LIMS v6 with Pharma Template. During that time he was involved in all areas of implementation including:

- Establishing project management controls
- Business process definition and standardization
- Configuration strategy
- Validation strategy
- Documentation and training strategy
- System administration and configuration

Recently Mr. Wass has been engrossed in the global, multi-site development and validation of a Computerized Maintenance Management System (CMMS), which is also a common interface to a LIMS. Prior to this project he served in a technical project management role leading the technology transfer of a legacy sterile parenteral product to an international greenfield facility where a retrospective QbD approach was employed.

course location

This course will be held in the Amsterdam area. Specific hotel information will be sent to you in your final confirmation package which will be emailed to you approximately three (3) weeks prior to the course start date. Please note that participants must make their own hotel reservations; the cost of the hotel accommodations is not included in the course fee. We recommend that travel/hotel arrangements not be made until final confirmation email is received.

- **Located in downtown area, near shopping, dining and local attractions**

accreditations/recertifications for this course

The Center for Professional Advancement (CfPA) has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 12100 Sunset Hills Rd., Suite 130, Reston, VA 20190. In obtaining this approval, CfPA has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. CfPA is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEUs will be awarded for participation in CfPA's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. This course offers a total of 12 contact hours, or 1.2 CEUs.

who we are—"Celebrating 50 Years"

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately 450 short courses in 15 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more. Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting-edge technology, and current U.S. and European regulations. CfPA courses are offered in a variety of formats to fit you or your company's training needs:

In Person: Away from responsibilities, participants are immersed without distraction

Client Site: Training at your site and at your convenience. For further information, please contact Client Site Programs: +1/732.238.1600, ext. 4547 or E-mail clientsite@cfpa.com

Online: A convenient and cost-effective way to experience our accredited training. For a list of upcoming courses visit www.cfpa.com/onlinetraining

we also offer

Client Site: Training at your site and at your convenience. This course and any of our other courses are available to be customized and brought to your location. For more information visit www.cfpa.com/ClientSite

Online Training: A convenient and cost-effective way to experience our accredited training. Easily access the knowledge you need through the Internet. For a list of upcoming courses visit www.cfpa.com/onlinetraining.

tuition

Early Bird–Save $200–(Must register and pay by 31 March 2017)	$1970
Regular Tuition	$2170

Group Discount: Register 2 or more from the same company, at the same time, for this course and receive a 10% discount off each registration. Tuition payable in US funds net of all charges includes continental breakfast, luncheon, breaks and course notes.

Note: Payment is due 2 weeks prior to course or at time of registration.

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how to register

- Online: www.cfpa.com enter Course ID# into Search. Click Register Now button. Group Rates Available: Save 10% on 2 or more attendees.
- Call Customer Service at 732-613-4500 or email: info@cfpa.com
- Fill out the registration form and email it to: info@cfpa.com

registration form

LIMS: Applying the SDLC Approach to Implementation

course id# 2740 /course offering# 170511EU2740

instructions:

Please complete Registrant Information, Course Information and Payment Sections. Submit one form per individual registrant.

☐ Check here if group discount applies (two or more enrollments for the same course, from the same company)

All fields MUST be completed in order for registration to be accepted.

registrant information

Registration Type: ☐ In Person Attendee ☐ Virtual Attendee (Live or Recorded)

Prefix: ☐ Ms ☐ Miss ☐ Mrs ☐ Mr ☐ Dr ☐ Prof

First Name_____ Last Name_____Designation (i.e.Phd, Jr)_____

Email Address _____ Alternate Email (copy sent here as well) _____

Title_____

Your position in the organization is (please check one)

☐ Corporate ☐ Line Operational ☐ Managerial/Supervisory ☐ Staff ☐ Consultant

Your primary job function is (please check one)

☐ Clinical Practice ☐ Project Management ☐ Design Engineering ☐ Quality Control Assurance

☐ Environmental Safety ☐ Research & Development ☐ Legal or Regulatory Affairs ☐ Technical Information Services

☐ Manufacturing & Operations ☐ Training and/or Education ☐ Marketing or Sales ☐ Other _____

*Primary industry that best describes your area of interest (select maximum of 2)

☐ Analytical Chemistry
☐ Biopharmaceuticals/ Biotechnology
☐ Chemical/ Process Engineering
☐ Clinical/ Non-Clinical
☐ Cosmetics/ Personal Care/ Household Products
☐ Environmental and Safety Technology
☐ Food Technology
☐ Mechanical/ Design Engineering
☐ Medical Devices/ Diagnostics
☐ Packaging Technology
☐ Petroleum Technology
☐ Pharmaceutical Technology
☐ Technical/ Project Management

contact information

Company Name _____

Address _____

Zip/Postal Code_____ City_____ Country_____

Phone _____ Fax _____

course information

Course Title_____

Course ID#/Offering#_____

Tuition

Tuition_____

*How did you hear about us? ☐ Email ☐ Postcard ☐ Colleague ☐ Google Search ☐ Social Media

☐ Trade Show ☐ Advertisement ☐ Course Director ☐ Course Brochure ☐ Other _____

discount code

Discount Code _____

payment information

☐ Credit Card

☐ Visa ☐ Mastercard ☐ American Express ☐ Discover

Card #: _____ Exp. Date: _____ Security Code: _____

Cardholder Name: _____ Signature: _____

Billling Addess (if different from above)

Address _____

Zip/Postal Code_____ City_____ Country_____

☐ Wire Transfer ☐ Purchase order (PO# if applicable _____)

☐ Send Invoice ☐ Check: Payable in US funds to: **The Center for Professional Advancement**

terms and conditions

Payment: Tuition payable in US funds net of all charges. Payment is due at time of registration or upon receipt of invoice. If payment has not been received two weeks before the course, a credit card will be required to guarantee registration.

Discounts/Rates: To receive the Early Bird tuition rate, payment is required at time of registration and/or BEFORE early registration tuition expires or the regular tuition rate will apply. The Virtual Attendee Option does not qualify for Early Bird pricing. If choosing invoice/wire transfer, payment must be received prior to expiration of early registration tuition or the regular tuition rate will apply. All tuition prices are a per person rate. To qualify for the Group Rate discount, registration must be for two or more enrollments registering at the same time, from the same company, for the same course. Please note: Group Rate Discount cannot be combined with any other discount. Multiple discounts not applicable.

Cancellations/Substitutions/FEES: ALL cancellations must be in writing and emailed to: info@cfpa.com. All cancellations are subject to a $300.00 cancellation fee. Applicants may cancel up to four (4) weeks prior to the course start date for a refund less cancellation fee. Applicants that cancel less than four (4) weeks prior to the course will be issued a credit less cancellation fee that can be used towards a future course up to one year from the date of issuance. If you do not cancel and do not attend you are still responsible for the full payment. If for any reason, CfPA decides to cancel this course, we are not responsible for airfare, hotel or other costs incurred by the registrant. Program content, schedule and instructors are subject to change without notice. Substitutions are permitted at any time, must be in writing and emailed to Customer Service at info@cfpa.com.

Confirmation Letters: Before each course begins, all registrants will receive written Final confirmation including detailed information regarding course location – VIA EMAIL. We recommend that travel/hotel arrangements not be made until final confirmation package is received. If confirmation is not received two weeks prior to the course please contact Customer Service at info@cfpa.com.

Course photography / video: By registering and attending a CfPA course, you agree to have your photograph and/or video taken at the course venue, and you do not have any objections to CfPA using these photos and/or videos for marketing or any other CfPA Course and/or promotional purposes. You agree to release CfPA from any kind of claims arising out of copyright or privacy violations. All questions regarding this matter should be sent to Customer Service at info@cfpa.com.

Please note: English will be used in all lectures and course notes. For questions/more information contact Customer Service at 732-613-4500 or info@cfpa.com.

☐ I have read and agree to CfPA's Terms and Conditions