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EVENTS LIST

Risk Based Project Management for the Life Sciences Industry (ntz)

Date : Jan 15, 2018 - 09:00 AM

Event URL : http://www.sfbayeventslist.com/events/risk-based-project-management-for-the-life-sciences-industry-ntz-jan-2018

Organizer : NYMT

Venue :

Location : DoubleTree by Hilton Hotel San Diego Downtown1646 Front StreetSan Diego, CA 92101United States,
San Diego, CA, US, ZIP: 92101

DESCRIPTION

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Project management is a discipline that can be applied to all industries. In the pharmaceutical industry, project management is the key to addressing the unique regulatory, compliance and quality related needs of the industry. The process of clinical research and drug development, coupled with the critical issue of time to market, can use project management techniques to effectively apply scheduling, risk management, and comprehensive quality assurance and control to the process of bringing a drug to market in a safe, effective & cost-efficient way

Every industry has different "stress points"-those points that are most critical to the specific product or service being delivered. The most typical stress points are schedule, cost, and quality. Depending on the project, one (sometimes more) of these stress points directly affects that company's profit, thereby making that point absolutely critical to the success of the product, and the company delivering it. In the pharmaceutical industry, the most important stress point is quality. For example, each year at least one drug company experiences a recall of one of their

drugs, lawsuits from their customers or lawsuits from their competitors. Poor quality in this industry can literally be a matter of life and death, in its worst cases. Being the first to bring a product to market is also critical, though the course of drug development is unpredictable.

Because of the risks involved in the pharmaceutical industry, due diligence is of the utmost importance in terms of quality control measures. So these competing priorities-quality and time to market-must be well managed through careful process in order to reduce the risks inherent in this industry. Another current challenge for pharmaceutical companies is the pressure they are under to increase their productivity, as the number of new products reaching the market has been on the decline over the past few years. This productivity decline has led many to believe that the industry is in need of a new and better approach in its management of clinical research, drug development, and product delivery. The two key challenges in the pharmaceutical industry are quality and schedule, both of which are directly addressed by the tools and techniques used in project management

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The Seminar:

This hands-on seminar provides good practices for project management for a wide variety of project types within the pharmaceutical industry. The Seminar considers how appropriate tools and techniques can support and promote good project management practices and aims to help in sharing of these good practices to facilitate their use within the pharmaceutical industry.

This Seminar aims to:

- provide specific guidance on project management in the pharmaceutical industry
- provide a resource for Project Managers and other professionals who are involved in projects in the pharmaceutical industry
- provide a link to project management bodies of knowledge for industries other than the pharmaceutical industry

The Seminar is specific to Project Management within the global pharmaceutical industry and projects specific to that industry. The concepts, principles, approaches and tools will include product lifecycle as described in ICH Q10, as well as projects for facilities, engineering and IT

Who Should Attend:

- VP of IT
- Director of IT
- Quality Managers
- Project Managers (for CSV / IT)
- Validation Specialists
- Database Administrators
- System Administrators
- Directors / Senior Directors of Discovery

- Directors / Senior Directors of Development
- Directors / Senior Directors of Commercialization
- Document Managers
- Training Managers
- Regulators
- Vendors
- Suppliers
- Outsource Service Providers

Industries:

- Pharmaceuticals
- Biotech
- Medical Device
- Radiological Health
- Blood Products
- Companion Animals
- Food
- Cosmetics
- Tobacco
- Academia

AGENDA

Day 1 Schedule

Lecture 1: **Introduction and Background**

- Introductions / Participants' Understanding / Participants' Objectives for the Course (Please come prepared to discuss)
- Background
- Industry Context
- Key Concepts

Lecture 2: **People Management**

- Introduction
- The Project Manager
- Senior Stakeholders
- The Project Team
- Consultants & Contractors
- Knowledge Management
- Language, Culture & Communication

Lecture 3: **Risk Management**

- Introduction to Risk Management
- Pharmaceutical Risk Types
- Pharmaceutical Quality Risk Management
- Integrated Project Risk Management

Lecture 4: **Project Initiation**

- Introduction
- The Importance of Good Front End Definition - a Cat Story
- Stage Gate Project Approval Process
- Stage 1 - Project Feasibility - Is this a Good Idea?
- Stage 2 - Project Conceptual Development - Identifying the Best Option

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Lecture 5: **Project Delivery Planning**

- Project Sponsor
- Project Scope
- Project Schedule
- Project Cost
- Project Controls
- Project Team
- Communication Plan
- Design Management Strategy
- Technology Strategy
- Procurement Plan
- Implementation Plan
- Testing and Commissioning Strategy
- Project Startup Strategy
- Project Close-Out & Handover Strategy
- Completion of Project Delivery Planning

Day 2 Schedule

Lecture 6: **Design, Planning & Delivery**

- Feasibility Stage
- Conceptual Development Stage
- Budget & Schedule Objectives
- Project Delivery Planning
- Detailed Design Activities
- Exercise
- Completion of Design

Lecture 7: **Implementation: Procurement**

- Strategy
- Planning
- Delivery
- Exercise
- Procurement Completion

Lecture 8: **Implementation**

- Implementation Input
- Pre-Implementation
- Delivery
- Exercise
- Implementation Completion

Lecture 9: **Testing & Commissioning**

- Testing Prerequisites
- Delivery of Testing Phase
- Exercise
- Testing & Commissioning Completion

Lecture 10: **Project Closeout**

- Handover Activities
- Financial & Contractual Closeout
- Knowledge Transfer
- Closeout Checklist

Quiz: Jeopardy!!!!

- Project Management in the Pharmaceutical Industry

SPEAKER

Angela Bazigos

CEO, Touchstone Technologies Silicon Valley

Angela Bazigos is the CEO of Touchstone Technologies Inc. She has 40 years of experience in the Life Sciences & Healthcare Industries. Experience combines Quality Assurance, Regulatory Compliance, Information Technology, Project Management, Clinical Lab Science, Microbiology, Food Safety and Turnarounds. Past employers / clients include Roche, Novartis, Genentech & PriceWaterhouseCoopers, Public Health Service. Positions include Chief Compliance Officer, http://morflearning.com/angelabazigos/, QA Director, Director of MIS. Co-authored & prototyped 21 CFR 11 guidance with FDA. Co-authored Computerized Systems in Clinical Research w/ FDA http://www1.diahome.org/~/media/4FA562336EBD46C58CDC43A8B7773095.ashx. Patent on speeding up software compliance https://www.google.com/patents/US8266578. Recently quoted in Wall Street Journal for using training to bring regulatory compliance to the Boardroom http://blogs.wsj.com/riskandcompliance/2015/07/24/using-training-to-bring-compliance-to-boardrooms/. Comments / collaborates with FDA on new guidance documents. Former President of Pacific Regional Chapter of Society of Quality Assurance. Stanford's Who's Who for LifeSciences: http://www.stanfordwhoswho.com/Angela.Bazigos.7144112.html#overview.

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