Excellence Corridors

Pathway to Organizational Excellence

April 28, 2017
Event Program

7:30am – 8:30am	**Registration, Breakfast & Networking**					
	Quality Management Track		**Lean Healthcare & Operations Track**		**Facilities Management & Maintenance Track**	
8:30am - 10:00am	Guidelines for clean room management and revision of aseptic and cleaning protocols according to the ISO/GMP/FDA new criteria for an efficient and cost effective quality control process.	**Lcdo. Luis E. Ruiz**, B.S. M.T. & Microbiologist, Professional Quality Health Service Corp.	Healthcare operational management	**Dr. Edwin Dávila Aponte**, MBA, Ph.D	LEED based energy audits for maintenance of facilities	**Ing. Jesus Garay**, EIT, LEED AP, PMP
10:00am - 10:30am	**Break**					
10:30am - 12:00pm	Cont.: Guidelines for clean room management and revision of aseptic and cleaning protocols …	**Lcdo. Luis E. Ruiz**, B.S. M.T. & Microbiologist, Professional Quality Health Service Corp.	Developing a Lean Management System for Healthcare Operations	**Prof. Luis A Olivares,** ME, MLSSBB Senior Consultant at QBS	Efficient implementation of energy audits in sustainability projects: case studies	**Prof. Wilfredo Torres** Electrical Engineering Dept. – PUPR Honor Program Director
12:00pm – 1:30pm	**Lunch & Keynote Speaker Technical Lecture**					
1:30pm - 3:00pm	ISO13485-2016 for Medical Devices	**Carlos Manuel Urrutia Ferrer** Engineering Manager, Zimmer Biomet	Regulations, Cyber Security & Identity Management applied to the healthcare industry	**Dr. Chase Cunningham** Director Cyber Threat Research and Innovation at Armor **Urayoán Camacho** Technology Consultant	Project management applied to facilities management	**Prof. Ricardo Suárez** Industrial Engineering Dept. - PUPR
3:00pm - 3:30pm	**Break**					
3:30pm -5:00pm	Quality Management / Internal Audits and Risk Management for quality organizations	**Dra. Janet Irizarry**, Ph.D. Polytechnic University of Puerto Rico	Agile Project Management & healthcare operations	**Nelson Ortiz**, MaEd, PMP CompTIA Project + PMI-ACP	Maintenance and inspection of clean rooms and critical facilities	**Lcdo. Luis E. Ruiz**, B.S. M.T. & Microbiologist, Professional Quality Health Service Corp.
5:00pm	**Cocktail & Networking**					

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Descriptions and topics by tracks:

Quality Management

Guidelines for clean room management and revision of aseptic and cleaning protocols according to the ISO/GMP/FDA new criteria for an efficient and cost effective quality control process.

Duration: 3.0 hrs.

A través de esta conferencia se identifican posibles áreas de riesgo, requerimientos críticos de operaciones y mantenimiento en diferentes facilidades de salud y edificios, y se discuten aquellas regulaciones existentes, las nuevas que están en rigor y que requieren la implementación de procedimientos específicos para control de calidad en facilidades.

Como parte del seminario se identifican parámetros críticos de condiciones ambientales, los requerimientos de utilidades para equipos, los recursos disponibles de monitoreo ambiental en áreas de mucho transito de personal, y como desarrollar un protocolo de mantenimiento para el control de calidad de acuerdo a necesidades, experiencias y situaciones de falta de mantenimiento y el establecimiento de un programa de mitigación.

ISO13485-2016 for Medical Devices

Duration: 1.5 hrs.

In this innovative session participants will have a general overview the new key factors to be implemented in order to comply with this ISO 13485: 2003.

ISO 13485: 2003 embodies expected international requirements that medical device manufacturers must incorporate into their management systems. Though based on ISO 9001, 13485 remove 9001's emphasis on continual improvement and customer satisfaction. In its place is an emphasis on meeting regulatory as well as customer requirements, risk management and maintaining effective processes.

13485 is in part designed to produce a management system that facilitates compliance to the requirements of customers and-preeminently-various global regulators. While being certified to 13485 does not fulfill the requirements of foreign regulators, the certification aligns an organization's management system to the requirements of the FDA's Quality System Regulation (QSR) requirements as well as many other regulatory requirements found throughout the world. Therefore, 13485 certification serves to create a base for any management system that can be thought of as a framework on which to build compliance to various regulatory and customer requirements.

Furthermore FDA has expressed their acceptance of the ISO 13485 as part of the International Standards recognized by the agency.

Quality Management / Internal Audits and Risk Management for quality organizations

Duration: 1.5 hrs.

This course will cover an Introduction and update of the Internal Audit requirements for the regulated operations. The course will detail the Subpart B – from the 820.22, explaining the FDA perspective and some of the industry adaptations for compliance. Also the course will show the relation between FDA and ISO 9000 requirements. Topics will include:

- Development of Quality Audit program
- Management Responsibility
- 6 Sigma & Lean Manufacturing
- Good documentation practices
- Internal Audit trending and analysis
- Do's and Don'ts when facing external auditors
- Quality System Inspection Technique (QSIT) training
- Development of Change Control SOP
- Management Responsibility
- Good documentation practices and technical writing concepts

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Descriptions and topics by tracks:

Lean Healthcare & Operations

Healthcare operational management

Duration: 1.5 hrs.

En esta presentación, se identificaran las principales variables que dificultan las operaciones hasta el mantenimiento preventivo de los equipos médicos y facilidades. Se expondrán ejemplos de situaciones reales en un ambiente de cuidado de salud y se harán recomendaciones dirigidas a un mejor manejo de tan importantes herramientas de trabajo.

Developing a Lean Management System for Healthcare Operations

Duration: 1.5 hrs.

Continuous improvement must be at the core of efforts for any Healthcare operations by identifying and solving problems following several key principles:

1. focus on patients and design care around them
2. identify value for the patient and get rid of everything else (waste);
3. minimize time to treatment.

Let's understand the methodology and tools critical to this effort.

Agile Project Management & healthcare operations

Duration: 1.5 hrs.

This innovative conference will give participants additional methodologic tools to integrate them with Lean Healthcare.

Agile is basically a model containing process groups run sequentially within a defined period of time or "iteration," and with a feedback loop to the customer for solution validation. The solution can be "discovered" or defined in detail through iterations that deliver functions and features of the solution. Thus, agile project management is an approach that leverages this iterative model to define and control the project work.

The combination of Agile Project Management and Lean Healthcare will enhance implementation of strategic projects within your organization.

Regulations, Cyber Security & Identity Management applied to the healthcare industry

Duration: 1.5 hrs.

How organizations are confusing security with compliance?, How Organization really know what are the latest cyber threats and how can affect the operations?, How complicated it's to keep up with compliance and implementing new technology solutions?, How organizations are dealing with fraud waste and abuse of healthcare services and institutional fraud?, How can organizations prepare themselves to mitigate New Cyber Threats? What technology solutions and skillsets are required, to build an effective Information Assurance lifecycle? How can organization innovate and be flexible taking in consideration organizational information security controls and governance?

It is the intention of our team to explain in a comprehensive what are some of the real challenges, what technologies are available in the market for various of these issues and how organization can start to prepare to mitigate cyber threats while achieving and exceeding compliance.

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Descriptions and topics by tracks:

Facilities Management & Maintenance

LEED based energy audits for maintenance of facilities

Duration: 1.5 hrs.

Las guías de auditoria energética de "Green Building Council" para evaluación energética nos dan no solo los requisitos óptimos para determinar la eficiencia de una facilidad existente, sino que nos sugiere y recomienda a llevar la facilidad a una optimización de recursos energéticos.

Se identifican los parámetros críticos que afectan los mantenimientos y operaciones eficientes de edificios y lo que sugieren las agencias regulatorias para incorporar un monitoreo efectivo, los procedimientos de implementación de un programa predictivo y la implementación de estándares para certificación de la facilidad como una facilidad verde según LEED (Leadership in Energy and Environmental Design).

Efficient implementation of energy audits in sustainability projects: case studies

Duration: 1.5 hrs.

To be provided soon.

Project management applied to facilities management

Duration: 1.5 hrs.

En esta conferencia se discuten los conceptos de buenas practicas en gerencia de Proyectos con énfasis específico en planificación, manejo y fases de control para diversas facilidades en edificios que resultan ser críticas para su mantenimiento

Se dará énfasis en la necesidad de la gerencia de proyecto para atender un plan predictivo efectivo en facilidades, así como las herramientas más recomendadas que deben usarse en el rol activo del Ingeniero de proyectos o de facilidades para una gerencia efectiva de facilidades.

Se incluye la discusión del ciclo de vida del proyecto, planificación, fundamentos de Manejo de presupuesto de proyectos de renovación, y fundamentos de gerencia de riesgo en diversos tipos de edificios y servicios y los conceptos de auditoria de facilidades y control de costos.

Maintenance and inspection of clean rooms and critical facilities

Duration: 1.5 hrs.

A través de esta conferencia se identifican posibles áreas de riesgo, requerimientos críticos de operaciones y mantenimiento en diferentes facilidades de salud y edificios, y se discuten aquellas regulaciones existentes, las nuevas que están en rigor y que requieren la implementación de procedimientos específicos para control de calidad en facilidades.

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