



2022-2023 Educational Webinar Series

Implementing Quality Managing Program

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Speaker:

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Director, Clinical Engineering



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HEALTHCARE TECHNOLOGY SOLUTIONS
ENHANCING THE CLINICAL EXPERIENCE



About the Moderator



Nader Hammoud, BE, MBA, CHTM
Biomedical Engineering Manager
John Muir Health

Nader Hammoud is currently the Biomedical Engineering Manager, at John Muir Health.

- Biomedical Engineer with 3 degrees in Biomedical Engineering and an MBA
- International Experience
- Active member of the HTM community
- Member of the Technology Management Council at AAMI
- ACCE Education Committee Co-Chair
- California HTM of the year for 2018
- Recognized by ECRI and FDA for efforts in the domain

Logistics

- ❖ All attendees have their microphones muted during the presentation.
- ❖ Questions to the panelists must be submitted via the “Q&A” feature in Zoom at any time. They will be addressed at the Q&A portion.
- ❖ If there is any urgent issue, please use the “chat” feature to communicate with the host/moderator.
- ❖ Please remember to complete the webinar evaluation after attending. A link will be provided at the end.

About the speaker



Mike Powers, MBA, AAMIF, CHTM, CDP, CMDA



Mike Powers is a Clinical Engineering Director at Intermountain Healthcare, headquartered in Salt Lake City, Utah. Intermountain is a health network including 32 hospitals, a medical group, ambulatory surgery centers, insta-care clinics, and imaging centers. He co-leads a task group for the Health Sector Coordinating Council on Legacy Medical Device Cybersecurity. He is a vice chair of the AAMI Healthcare Technology Leadership Committee. Prior to Intermountain, he was the Clinical Engineering Quality Manager at ChristianaCare Health System. He has an MBA in Healthcare Administration from Wilmington University and is a Certified Medical Device Auditor.

Session Description

Why Quality Management Systems

- May 2018 FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices
- What QMS are available
- Improve & focus a critical eye on our processes
- Drive our process towards being metric measured
- Continuous Improvement
- High Quality Service, and better patient outcomes

Formal Quality Management per ISO13485 vs ISO9001


- Continuous improvement – JC & 9001
- The Definition of Risk 9001 in 13485
- Compare 13485 & 9001

May 2018 FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices

- <https://www.fda.gov/media/113431/download>
- 1. Promote the Adoption of Quality Management Principles;
- 2. Clarify the Difference Between Servicing and Remanufacturing;
- 3. Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices; and
- 4. Foster Evidence Development to Assess the Quality, Safety and Effectiveness of Medical Device Servicing.



What QMS are available?

- 21 CFR 820
 - ISO 9001 – 2015
 - ISO 13485 – 2016
 - MITA QMS Standard
 - MDSC QMS Proposal
 - DNV GL
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Improve and Focus a Critical Eye on our Processes

Improve Quality of Service Provided

-more selective about vendors

-commitment to continuous assessment and improvement

-tracking new metrics like repeat failures

At the Core of our Business is Increasing Customer Satisfaction

-Surveys are Required

-Surveys as a feedback channel, opens other feedback channels to address long running issues

Describe Understand Communicate our Processes

-metrics

-quality objectives

-turns data into information

Drive Processes toward being Metric Measured



Tracking new metrics like repeat failures, projects managed, and parts ordering, not just device service



New proposals have a defined method for consideration and implementation



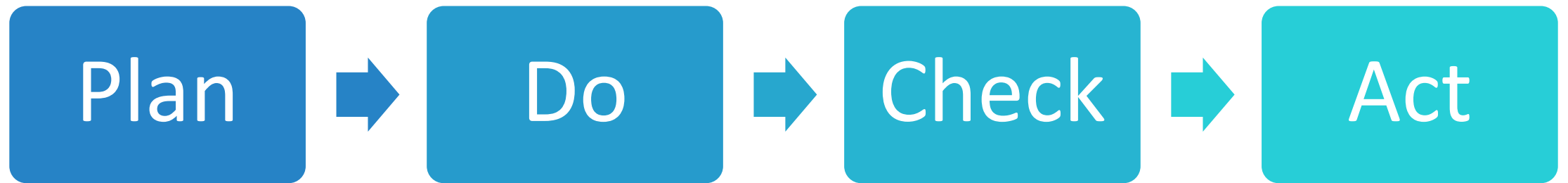
With better quality and reduced variation, regularly attain objectives:

Customer satisfaction goes up
Costs go down



With metrics team knows “what is important” and where to focus their energy

Continuous Improvement



High Quality Service = Better Patient Outcomes

- Professional Culture yields Better Morale
- better defined processes
- solicit needed improvement
 - CMMS codes
- ability to share feedback on a job from end users
- "right the first time" attitude

Formal QMS 9001 vs 13485

Continuous Improvement – Joint Commission Requirement

- Written Performance Improvement Plan
- This new requirement is in both the Hospital manual and the Behavioral Healthcare & Human Services manual.
- TJC now requires a written PI Plan.
 - Specifically, it needs to include details about your PI methods,
 - PI projects,
 - and how you'll measure and sustain improvement
 - Please reference PI.02.01.01 EP1, EP2 & PI.04.01.01 EP3

9001 - Risk

- The Definition of Risk 9001 - risk is the “effect of uncertainty on an expected result.”

13485 - Risk

- The Definition of Risk 13485 - anything which could impact the safety or performance of the device, or the device's ability to achieve market approval.

Compare 9001 & 13485 – the Similarities

MEASUREMENT, ANALYSIS and IMPROVEMENT.

Management of customer feedback and complaints

Internal Auditing

Develop a Planned Audit Schedule

QMS data analysis

Improvement Process Developed – When Identified by
Data Analytics

Compare 9001 & 13485 – the Similarities

Identify the processes that make up the QMS and show the interconnectivity and controlled through a risk-based approach

Document the QMS in a Quality Manual

All records must be kept and controlled according to a documented procedure

Requires LEADERSHIP to show a commitment to establish and maintain an effective Quality Management System.

Requires LEADERSHIP to define and document responsibilities and authorities for effectively operating the HTM program as defined in the QMS.

Requires LEADERSHIP reporting out on the effectiveness of the QMS program via formal Management Reviews held at planned intervals

Compare 9001 & 13485 – the Similarities

This means establishing a quality policy and objectives for the entire HTM program

Defines the resources needed for an effective QMS.

- Requires the organization to provide the infrastructure and environment needed to ensure medical device safety and performance, such as health, cleanliness, and perhaps any clothing requirements (ie. Scrubs for OR environments or PPE for clinical lab) where those issues could affect product quality.
- Requires that people and resources (for their work duties) are identified who affect product quality and ensure they are competent

Compare 9001 & 13485 – the Similarities

Policies and procedures of the program

Purchasing Controls – often called conformity to specification, and taking the guise of vendor auditing

Requirements around contamination control

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Unique to 13485

- Each medical device must have a unique medical device record

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Unique to 9001

- Establishing processes to prevent contamination – this concept extends to the need for Parts Segregation
- Set objectives for key processes, and include organizational charts
- Establish processes for communications with customers and authorities having jurisdiction
- Establish planned and corrective maintenance procedures
- “broken devices” – called non-conforming have to be identified and isolated. This is tracked in a Non-Conformance Log

Discovered Value Adds



Development and publication of a qualified vendor list

Reporting (internal advertising) via required Management Reviews

By interacting with key concepts, and working the plan, the ability arises whereby data can be manipulated into information.

Questions & Discussions

Enter your
questions
to the Q&A
window

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