Medical Devices and Quality: An Opportunistic Match

Condensed Version

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Learning Objectives

• Enlighten  - Share some of my experiences/stories in the medical device field and the connection to quality

• Motivate  - Make you aware of opportunities with ASQ, including certifications, technical communities (divisions), and networking

• Encourage  - Point out how medical device design and manufacturing can synergize with the quality sciences to improve people’s lives
Interesting Facts About Medical Devices

- Global medical technology industry => ~$430B USD

- The US makes up (producer and consumer) ~50% of the global market

- Global R&D spending in 2019 => ~$31B USD

- Strongest device businesses include IVDs, cardiology, diagnostic imaging and orthopedics
Education and training should be on-going

• Never stop learning

• Part of continuous improvement

• “Use it or lose it”
“Training increases skill and competence and teaches employees the “how of a job”. Education increases their insights and understanding and teaches the “why”.

The continual pursuit of education/training and problem solving often leads to or creates various opportunities.

- 3M Post-it Notes
- Sony Digital Versatile Disc (DVD)
- Raytheon Microwave Beam
Opportunities

• Don’t fear them
• Choose strategically (wisely)
• Learn and grow from them
• One path leads to another
Couple more quotes

“Life opens up opportunities to you, and you either take them or you stay afraid of taking them.”

Jim Carrey

“Opportunities multiply as they are seized.”

Sun Tzu
Making the Connection

Began to realize and appreciate the association of medical device design and manufacturing with the quality sciences

- Optimize design for customer needs
- Design for manufacturability
- Minimize process variation
- Continuous improvement
ASQ Certification

• Great way to demonstrate proficiency in a specific quality sciences area
• May lead to higher compensation
• Increased peer respect and recognition
ASQ Offers 18 Different Certifications

Certified Quality Engineer, CQE (1968) (19,092)
Certified Quality Technician, CQT (1970) (25,637)
Certified Reliability Engineer, CRE (1972) (3,539)
Certified Quality Auditor, CQA (1987) (18,172)
Certified Manager of Quality/Organizational Excellence, CMQ/OE (1995) (9,503)
Certified Software Quality Engineer, CSQE (1996) (2,056)
ASQ Certifications

Certified HACCP Auditor, CHA (2000) (895)
Certified Quality Improvement Associate, CQIA (2001) (14,430)
Certified Six Sigma Black Belt, CSSBB (2001) (11,144)
Certified Biomedical Auditor, CBA (2002) (1,273)
Certified Calibration Technician, CCT (2003) (1,134)
Certified Quality Process Analyst, CQPA (2005) (3,373)
Certified Six Sigma Green Belt, CSSGB (2006) (20,859)
ASQ Certifications

Certified Pharmaceutical GMP Professional, CPGP (2009) (586)
Certified Master Black Belt, CMMB (2010) (124)
Certified Six Sigma Yellow Belt, CSSYB (2014) (1,938)
Certified Supplier Quality Professional, CSQP (2016) (838)
Medical Devices & Technical Communities

- Biomedical Division ↔ Medical Devices (~4,000)
- Food, Drug and Cosmetic Division (~5,000)
- Healthcare Division (~4,700)
Get more involved …………

- Pursue ASQ certifications
- Support your local section
- Volunteer for technical community (division) work
- Attend conferences
- Network, network, network
Networking is basic to business

“Succeeding in business is all about making connections.”

- Richard Branson

“The richest people in the world look for and build networks, everyone else looks for work.”

-Robert Kiyosaki

www.EnlightenedNetworker.com
Networking is a process, not a tally

“Your network is the people who want to help you, and you want to help them, and that’s really powerful.”
- Reid Hoffman

“Networking is more about ‘farming’ than it is about ‘hunting’. It’s about cultivating relationships.”
- Dr. Ivan Misner
Networking can lead you to opportunities . . .
Invite and encourage each of you . . .

Think outside of the box
Invite and encourage

Step out of your comfort zone

“Rise to new heights by daring to leave your comfort zone.”
Career Strategic Planning

Five Tasks of Strategic Planning

1. Forming a strategic vision
2. Setting objectives
3. Crafting a strategy to achieve the desired outcomes
4. Implementing and executing the chosen strategy
5. Evaluating performance, monitoring new developments, and initiating corrective adjustments

www.studyMarketing.org
If aligned with your strategy, don’t hesitate... the opportunity may not present itself again.
Proceed strategically ……………

Avoid

Reach for

Rest or return to catch your breath
How can we make better medical devices?

Medical Devices  

Quality Sciences  

Highly reliable, quality medical devices
Synergy

A mutually advantageous conjunction or compatibility of distinct business participants or elements (such as resources or efforts).

Merriam-Webster definition
Synergistic Strategy

Take advantage of the quality sciences during medical device development and manufacturing.

Reliability Engineering
QFD
FMEA
Benchmarking
DOE

Statistical Analysis
6σ
Supplier Quality
PDCA

Manufacturing
ASQ

SPC
Lean
Quality Auditing
The Future of Medical Devices

• Move toward more holistic solutions for patients

• Increase in options for non-invasive procedures

• Focus on ex-US markets => e.g. China
The Opportunity In Front of Us

One group of authors uses the three “Rs”

Reinvent  =>  QFD, shift focus from “cost” to “value”
Reposition =>  new entrants, technologies and markets
Reconfigure =>  strengthen the entire supply chain
List of references


The Potential of Medical Device Industry in Technological and Economical Context, PMC4599058, US National Library of Medicine, 2015-10-03.

Summary

Embrace your involvement with medical devices

Increase your ASQ member value by getting more involved

Go forth and design/manufacture better medical devices to improve people’s lives
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Comments or Questions?
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Thank you for the opportunity to make this presentation.

Enjoy the rest of your day and have a great weekend.