AAMI 2017
Conference & Expo
June 9–12, Austin, TX

Development Environment for Medical Devices in Japan and the US: ***Impact on Current Activities and the Roles of Clinical Engineering***

Sunday, June 11, 8:00 a.m. - 9:00 a.m.

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Objectives

- Review the practice of clinical engineering profession in the US
- Medical device market global overview and roles of Clinical Engineers in manufacturing and associated technologies
- Opportunities for clinical engineers in the current innovative and fast-developing technology
- Closing Comments

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US Clinical Engineers

- **Profession by the title of Clinical Engineer (CE)**
  - Coined in mid 1960s by Cesar Caceres, MD, later AAMI Board member
- **American College of Clinical Engineering began in 1990**
  - *"A Clinical Engineer is a professional who supports and advances patient care by applying engineering managerial skills to healthcare technology."* - ACCE Definition, 1992, see http://accenet.org/
- **Education**
  - Typically has at least a baccalaureate (4-year) degree in engineering or engineering technology from an accredited college or university
  - Of ACCE Individual members*, 60% have masters or doctoral degrees
- **Certification & Licensing**
  - CE Certification desirable after 3 years of experience; 31%* have CCE
  - Licensing as a professional engineer (PE) not required

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US Clinical Engineers

Number*

- USA CEs est. 20,000
- ACCE members ~800

Work Place**

- Hospitals 70%
- Consultant 15%
- Industry 10%
- Academia 5%

***Sources:** PayScale.com, Bureau of Labor Statistics, and CNNMoney research, 2012
**ACCE Body of Knowledge (BOK) 2015 Survey re Health Technology (HT) Definitions & Practices

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US CEs: *Activities & Knowledge Base*

Categories of CE Work	% Time
1.HTM	30
2.Service Delivery Management	20
3.General Management	15
4.Risk Management / Safety	10
5.CE-IT (Information Technology)	8
6. Education of Others	7
7. Facilities Management	6
8. Testing, Evaluation, Modification	4

CE Knowledge Category

1.Regulatory Standards/Codes

2.Physiological Monitoring

3.General Med./Nursing Equipment

4.Surgical Equipment

5.Medical Device Integration (CE-IT)

6.Anesthesia

7.Presentation Skills

8.Respiratory Therapy

9.Computers, Networking, Information Tech. (CE-IT)

10.Medical Imaging

Source: ACCE Body of Knowledge (BOK) 2015 Survey

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Global Overview: *Medical Device Market 2017*

- **US --** Companies are trying to figure out what will replace the soon-to-be-dismantled Affordable Care Act and what this means for their long term sales prospects in the world's largest healthcare market (world market $398B (Visiongain, London))
- **Europe --** The introduction of strenuous new medical device regulations and ongoing currency exchange differential has some smaller American device companies pulling out of the market
- **Brazil --** Stagnating economy continues to take some shine off what used to be the brightest market in the western hemisphere
- **China --** Regulations seem to appear out of nowhere with immediate effect, leaving many scratching their heads about how to comply with the Chinese FDA (CFDA)

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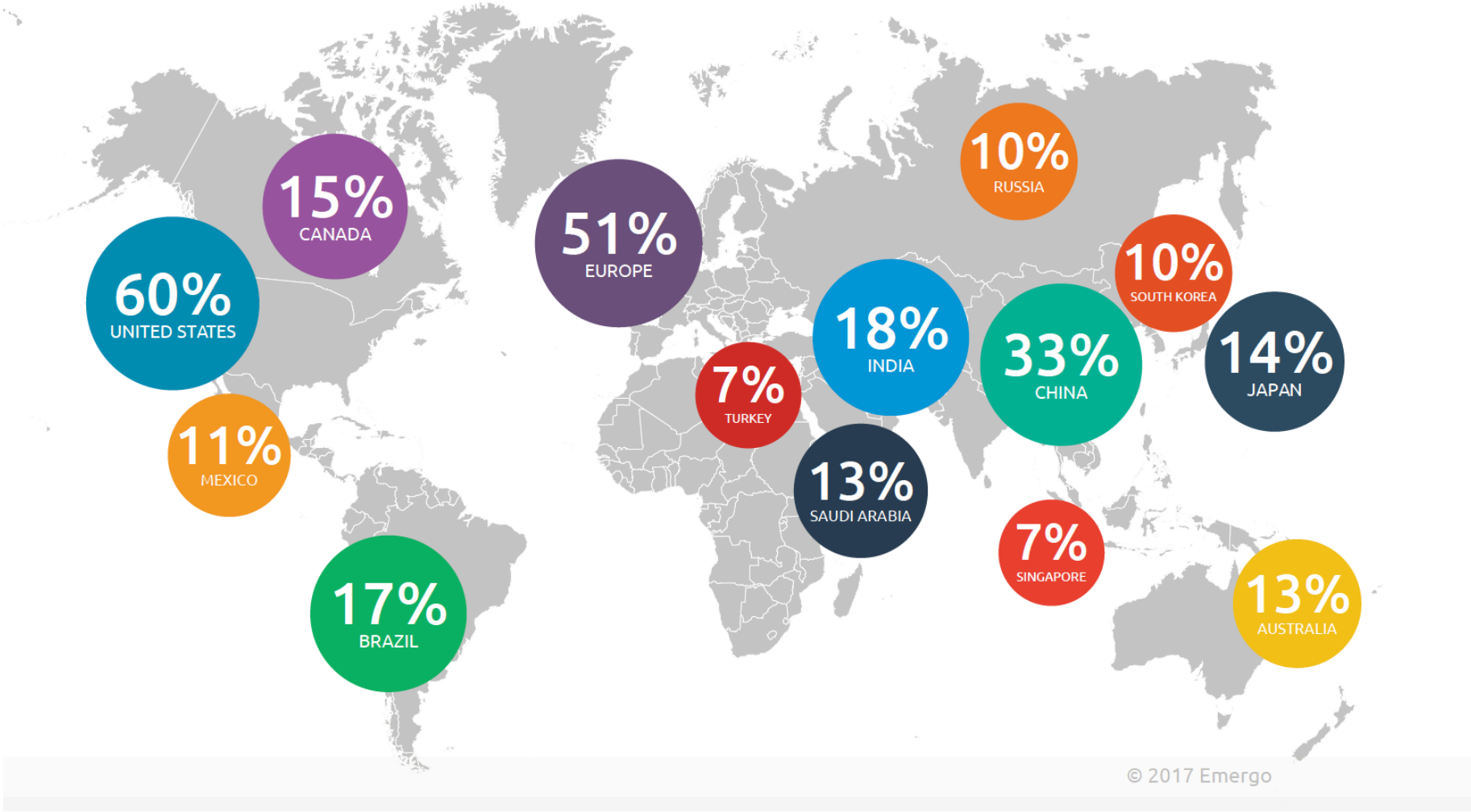
Estimated Growth in Medical Device Market



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Clinical Engineers' Roles

- Health Care Delivery
- Health Care Administration
- Academia
- Health Care Commerce
- Health Care Manufacturing – Medical Devices
- Health Care innovation –Start ups

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US Clinical Engineers in Different Roles

Jenniffer Jackson

Director of Clinical Engineering & Device Integration at Cedars-Sinai Medical Center,
Los Angeles, CA

Payman Roshan

Senior Vice President at Kaiser Foundation Hospital/Health Plan
Kaiser Permanente
Panorama City, California

Frank R. Painter

Healthcare Technology Consultant and UCONN Professor
University of Connecticut - Clinical Engineering Program
University at Buffalo,
Greater New York City Area

Carla Gallegos

Vice President of Healthcare Solutions Sales, at Enlighted Inc.
Advanced Technologies, Innovation, and Transformation,
San Francisco Bay Area

James Welch

Executive Vice President Product Development, Quality Systems and Regulatory Affairs at Sotera Wireless, Inc.
Orange County, California Area

Tracy Rausch

Founder, CEO of DocBox Inc.
Innovative platform that integrates medical device and Health IT,
Greater Boston Area

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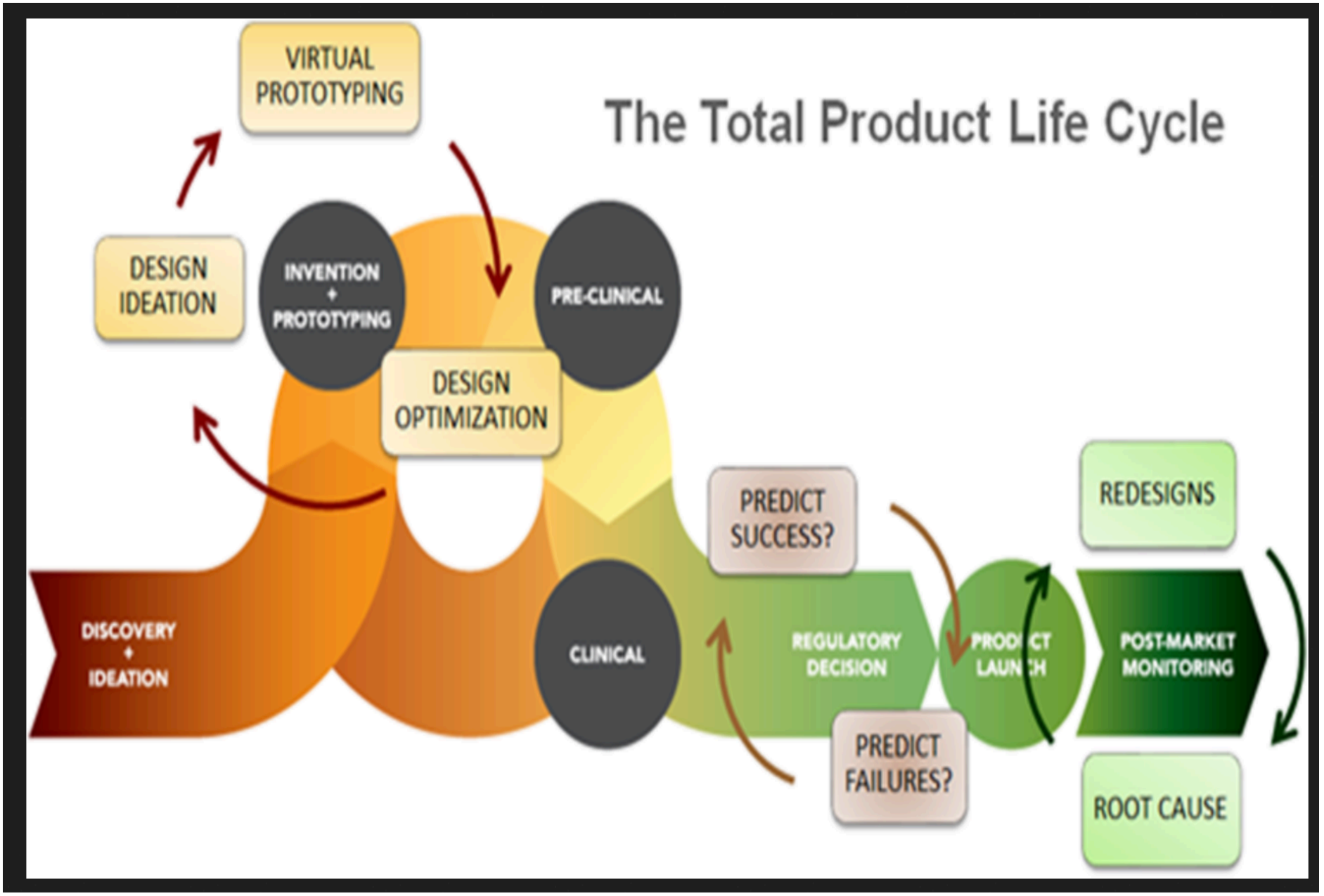

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Role of Clinical Engineers in Manufacturing

- Point of care consultants and advisors – Individual, Focus Groups, Survey Participants.
- Value added point of care – build upon deployed technology. Integration, formal evaluation/assessment, purchasing process
- Part of medical device life cycle teams – Design, production, market, product improvement.
- Entrepreneurs, Innovators, Company founders / owners

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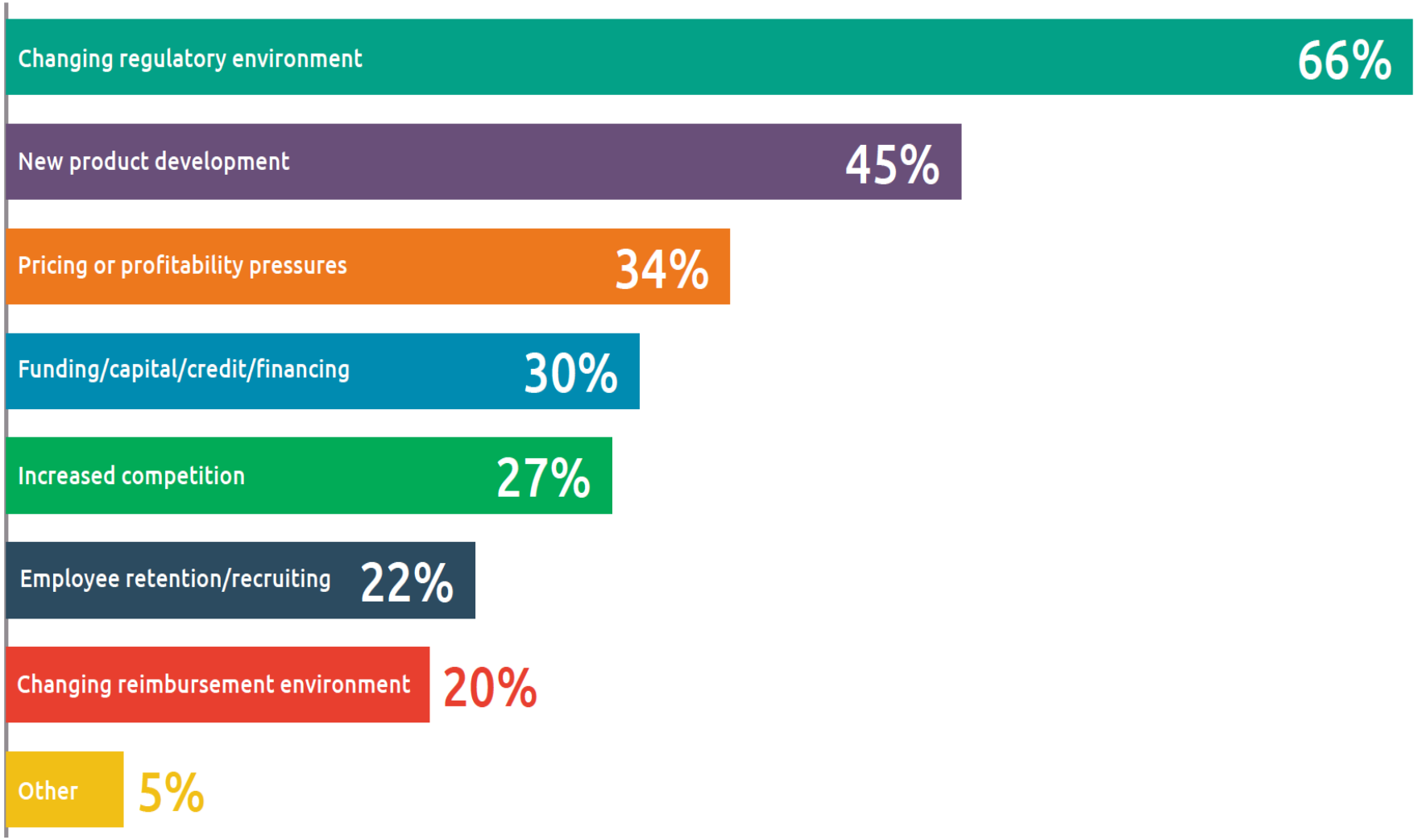
Biggest Challenges for Medical Device Manufacturers 2017



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Traditional Role of Clinical Engineering

Sustaining Innovation

- Technology acquisition and installation
- End user education
- Technical support
- Life cycle management

Disruptive Innovation

- Same sustaining elements of support
- New clinical application support
- Performance feedback to developers

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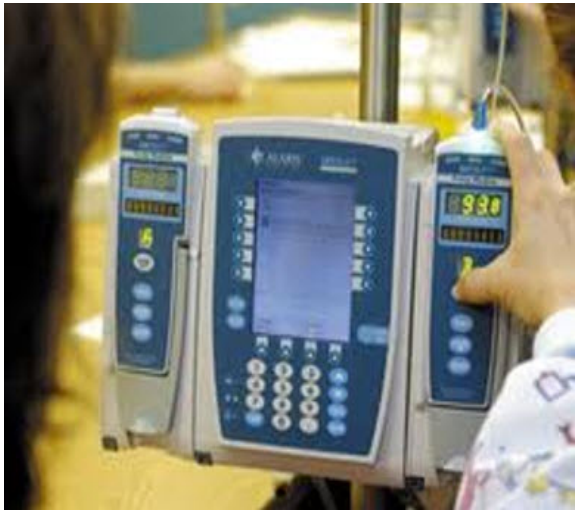
US CE Case Study 1: *Infusion Pump Systems*

Emerging Role for assisting Disruptive Innovation CE-IT related devices



Delivery System CE Roles:

Design Challenges

- Several FDA alerts re design, software-SW/firmware, cleaning/infection control, equipment PM, &and other issues
- Over-infusion Incidents supplier follow-up
- Warranty & Post-warranty support concerns
- Add additional alarms, eg ,tubing setup
- Artifact interference in certain clinical settings

CE-IT Requirements Challenges

- Wireless challenges for CQI downloads and SW change management ; took 2 years to re-design and correct wireless card
- Eventually hit limit and need to exceed 2500 programmable drugs for all use cases
- Security protocols for all device use cases

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US CE Case Study 2:

Alarm Management Systems (AMS)

More Disruptive Innovation

Delivery System CE Roles:

Design Challenges

- Scalable solutions not fully developed so initially server overloads & intermittent system shutdowns; supplier purchased smaller company but had not fully assessed current product and capabilities
- Reduction of monitoring techs by Customer before Alarm response protocols worked out became a patient safety issue
- Different subsystems gaining significant national scrutiny as The Joint Commission (hospital accreditation) national patient safety goal emerged

CE-IT Requirements Challenges

- A secondary alarm notification tool; not optimized for primary notification
- KP has conducted end-to-end testing and invested significantly to build up IT infrastructure to support enterprise-wide approach
- More readily monitor and adjust individual device AMS configurations

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US CE Case Study 3:

Digital (Integrated) OR Systems (DOR)

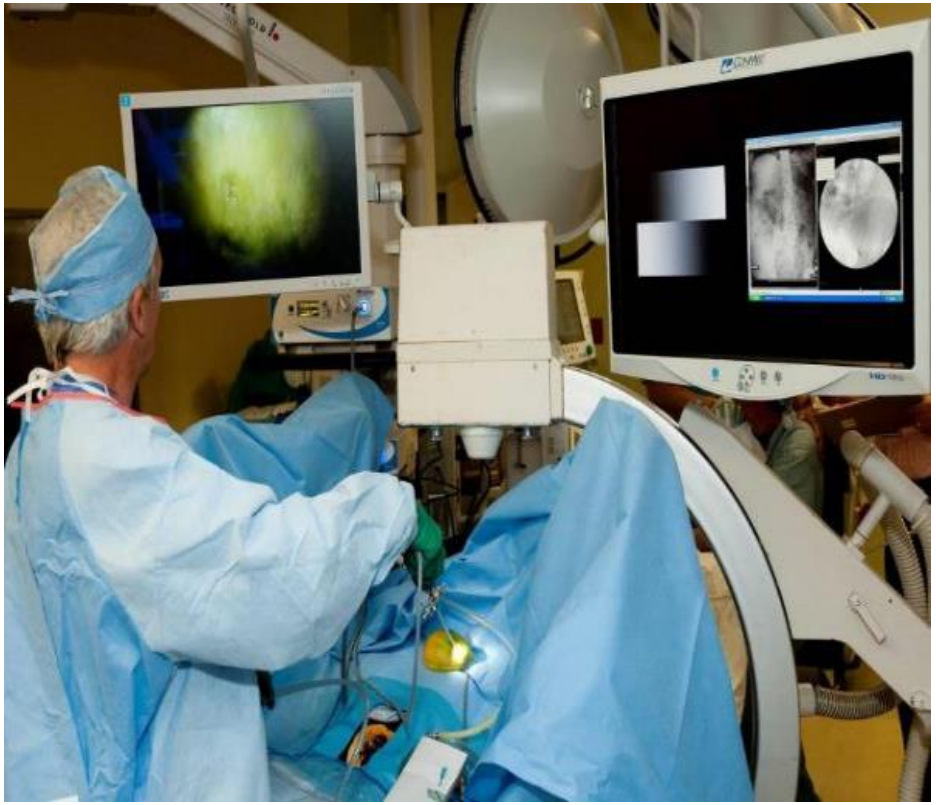
Delivery System CE Role:
Design Challenges

- Device interoperability ensuring image quality when using different DOR and Rigid Endoscopy suppliers
- Storage and retrieval of surgical images with appropriate privacy and security compliance
- Reliability, reprocessing, and durability of surgical video Endoscopy

CE-IT Requirements Challenges

- Different image capture / management strategies for different surgical sub-specialties
- Sending images to mHealth platforms - SmartPhones, Tablets - while still meeting needed privacy and security
- Wireless image transfer and fidelity
- Ongoing testing of image quality

More Disruptive Innovation



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US CE Case Study 4: *Tracy Rausch, CCE*

- Early CE-IT leader in her delivery system
  - Started own small company 10 years ago
- Now has implemented a very innovative device for intensive care …
  - Being used in India integrating clinical and CE-HTM information in a world-class fashion; presented at WHO's recent Forum, approved in USA by FDA as well
  - This system is changing how clinical practice and CE-HTM combine together to improve quality & efficiency
  - Tracy is speaking in the 2nd hour for JSMI-JACE this morning.

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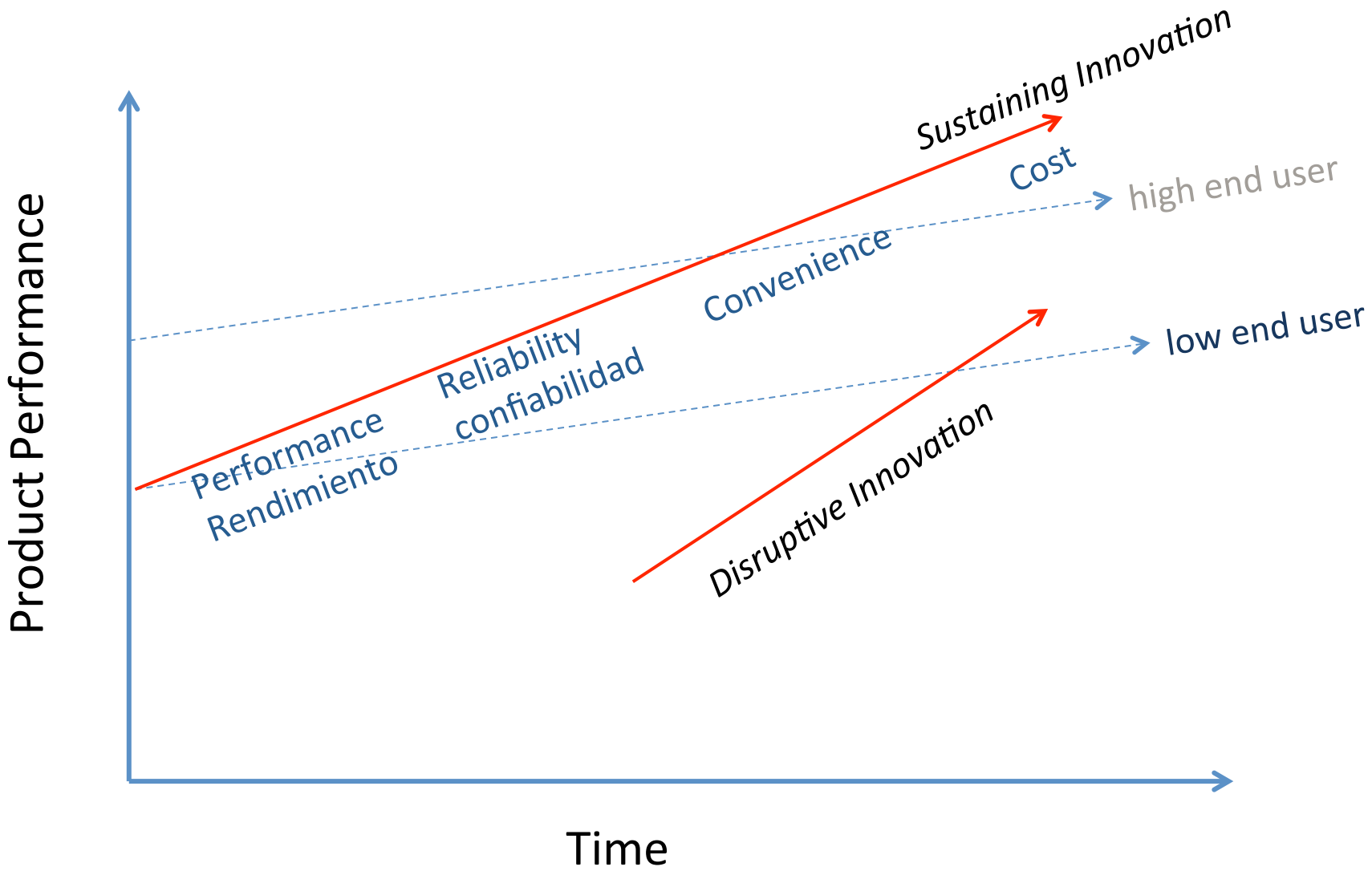
What is Innovation…?



The Innovator's Dilemma. Clayton Christensen. HBRPress 1997

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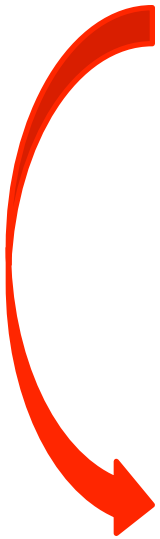
Innovation

The innovators dilemma



Sustaining Innovation

- Adds new capabilities to existing users
- Driven by most demanding customers
- Dominated by existing market leaders

Disruptive Innovation

- Provides solutions for new users
- Developed by new entrepreneurial companies
- Adds capability over time
- Creates new business ecosystem

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Disruptive Technology Introduction Challenges

Disruptive technologies address the needs of new users (non-consumers)

- Traditional device in-service (how to use) may not be sufficient
- Are new user policies or practices required?
- What new risks are introduced into the system (unintended consequences)?
- What role does the clinical/biomedical engineer play?

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Ultrasound Imaging

Product Performance

high end user

low end user

Time

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Opportunities for Clinical Engineers in Manufacturing

- Specialization In Regulatory affairs
- Professional Association participation
- Embrace innovation as part of Body of Practice
- Participate in incubators for innovative technology and new product development
- Embrace “leading from where you practice”

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Remaining part of the Future

- Innovation in healthcare is unavoidable. If we are not prepared we may find ourselves obsolete.
- IT enterprise with medical devices is a fact
  - Ubiquitous wireless connectivity rapidly becoming reality
  - New standards will follow innovation, not lead it.
- The creative destruction of the current healthcare model will be replaced by the merging of wellness devices with medical devices.
- CEs can embrace the creation, production, and application of the medical devices of the future.

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