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# Mobile Apps in Healthcare

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# Big challenges in healthcare

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## Information Gap

Data can be sparse and segregated, and insights that could improve care are missed

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## Decision Gap

Provider visits are infrequent, but decisions happen weekly, daily, hourly

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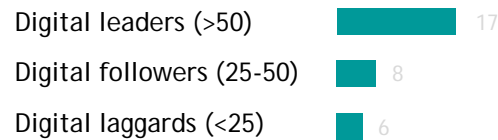
## Quality Gap

Healthcare costs are trending upwards without corresponding increases in quality and outcomes

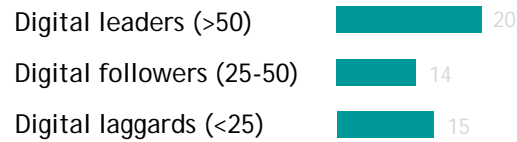
## Companies with Digital Quotient Score over 50 have performed Across industries

Financial performance vs DQ  
Over the past 5 years,  
Analysis in Jan 2016 (n = 107)

5-year revenue CAGR,<sup>2</sup> %

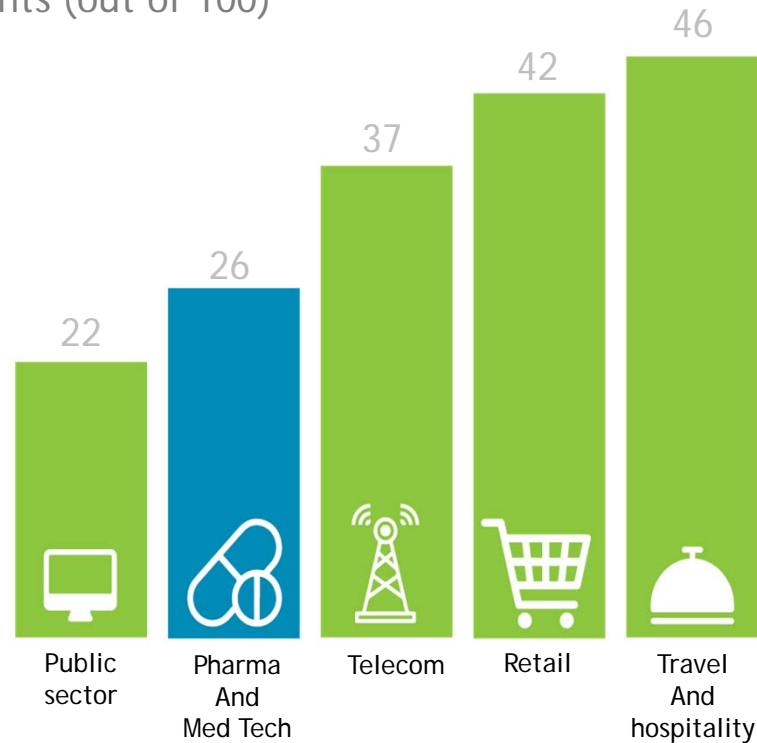


5-year total return to shareholders CAGR, %



## Pharma and medical-device companies lag other industries in their DQ

Digital Quotient scores by industry globally  
Points (out of 100)



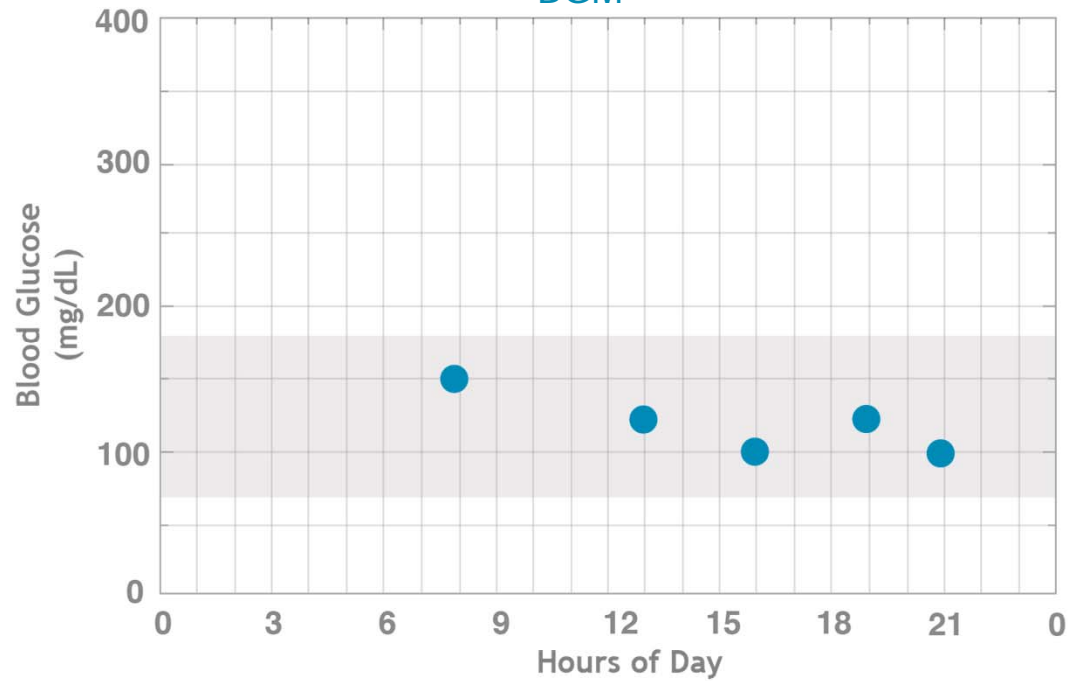
Source: McKinsey

# Technology Push



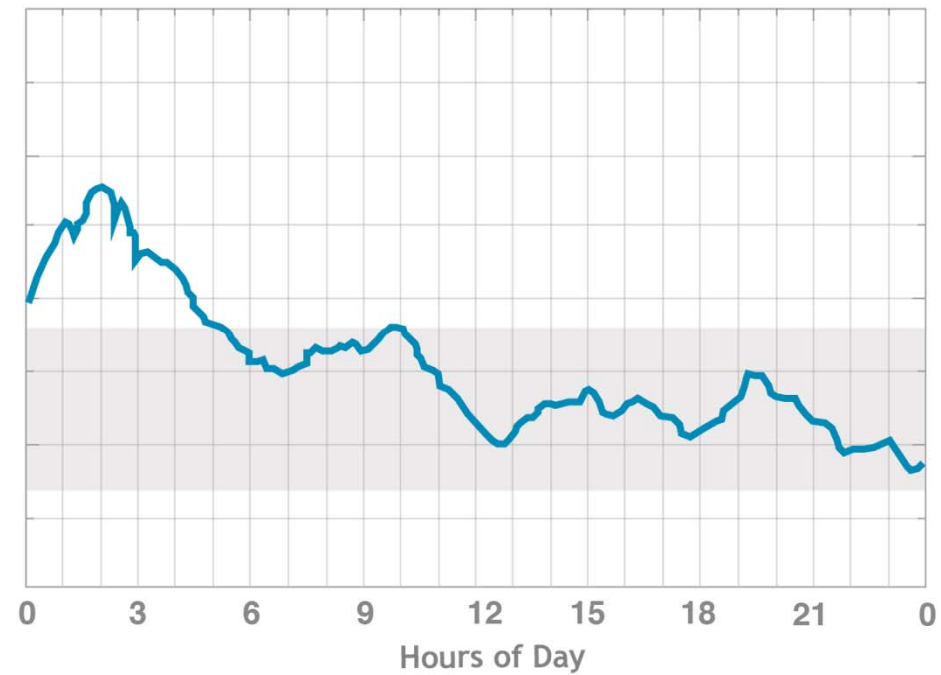
# A more Complete Picture

BGM



1-5 daily time points

CGM



~300 daily time points

# Clinical Grade Wearables



Any Internet-enabled device

# The P's

## Precision

More accurate actionable data  
Timing for an intervention

## Personalization

"Small Data"  
Specific to the Individual

## Prevention

Get ahead of their condition  
Lifestyle  
ID Disease Progression

## Prediction

More complete datasets  
More Insight, machine learning

## Participation

Ownership of Condition  
Patient Education  
Patient Engagement

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## SaMD Categories:

- Generic Risk and Assessment apps:  
Apps that take patient specific data and determine disease progression/prognosis.
- Diagnostic Simulators:  
Apps that take patient specific data and determine a specific diagnosis
- Drug Adherence apps:  
Apps that facilitate or improve drug adherence
- Product Integrated apps:  
Apps that communicate with a drug delivery device and provide a myriad of features including device performance, medication reminders, adherence reports, and data transmittal to a HCP.



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# Software is Different

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## Productising and codifying science

In that reduction do you lose the fidelity  
Illusion that you can address an unmet need faster

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## Never Defect/bug free

Continuously in development  
Better with time ...  
PMS efforts are significant

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## Phone not ideal Device

Hardware Target you do not control  
High Risk - Complexity  
Skills Challenge

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# Regulatory Landscape

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## Medical Device Directive (MDR) Rule Part 11

“Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- Death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- Serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

# Quality & Compliance

## Compliance ≠ Quality



**“...one device manufacturer can meet FDA requirements  
and *still* make a poor quality device whereas  
a second manufacturer may not comply with all FDA requirements  
and yet make a high-quality device”**

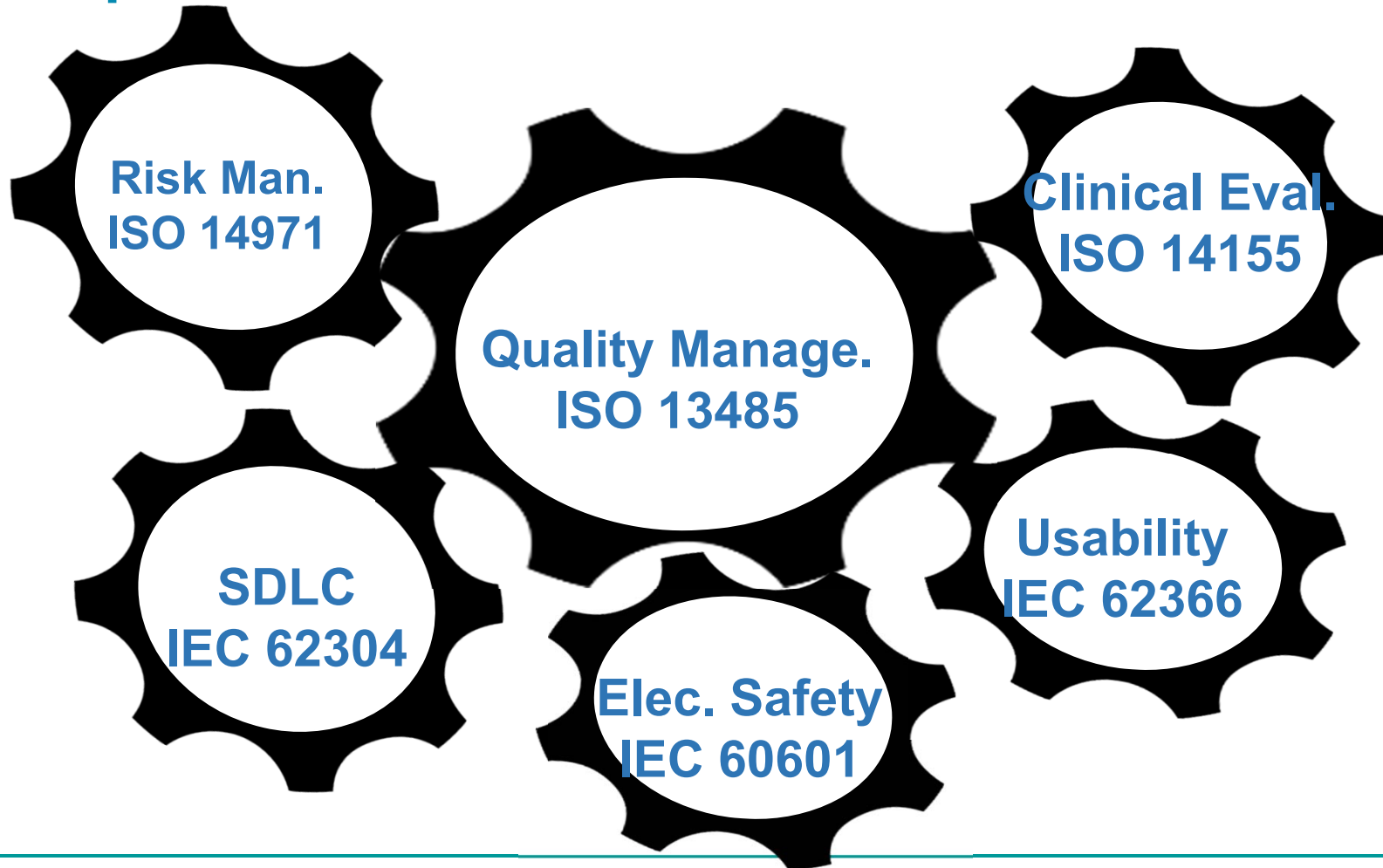
*Jeff Shuren, M.D., J.D.,  
Director CDRH*

**\*\*\*NOTE: Compliance to regulations is still important, as it is required – a high quality product is not a substitute for a compliant product under our current statutory situation**

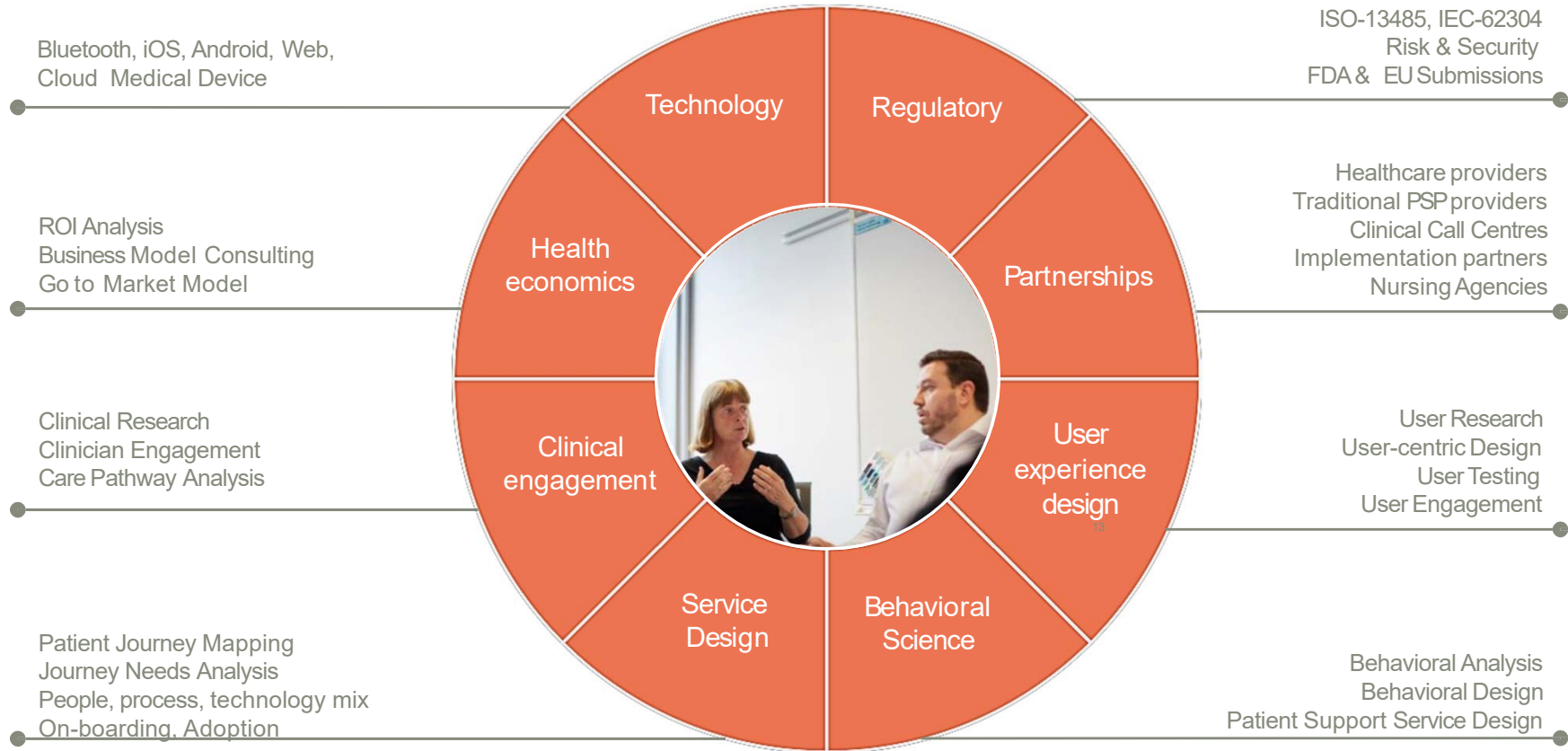
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm>

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## Require Blended Skills for SaMD



# The Total System



# Welcome to Your Digital Future

Digital filled with hype, but also lots of promise

Companies get rewarded for digital transformation

Hardware, meet software

Mechanical engineer, meet data scientist

Get on the train or get left at the station

Digital is where the Invest is

Combinations are even better

Technology innovation is as much cultural as technical

New thinking will need additional new people

