

Powering the Future  
of Healthcare ▶

 **CitiusTech**

# Medical Devices

Shifting Focus, Regulatory Compliance  
and Technology Outlook



[www.citiustech.com](http://www.citiustech.com)

## Who we are

As a strategic partner to some of the world's largest healthcare and life sciences organizations, we play a deep and meaningful role in accelerating digital innovation, driving sustainable value and helping improve outcomes across the healthcare ecosystem.



Gartner



healthcare  
innovation  
PEOPLE. PROCESS. TECHNOLOGY TRANSFORMATION

CitiusTech is uniquely positioned to address complex MedTech industry challenges, accelerate digital innovation, drive rapid adoption of value-based care models, enhance patient engagement and empower healthcare organizations to deliver better care.

**2,800+**

Engineering & QA  
professionals

**30+**

Healthcare  
technology clients

**400+**

Medical devices  
experts

**4.5/5**

Client satisfaction  
score

# Medical Device Industry: Emerging Trends

## In-hospital

- Patient Surveillance
- Connected Equipment
- RTLS
- Smart QR



## In-clinic

- Handheld Devices
- Ambulatory Therapies
- Lab-on-a-chip
- Co-ordinated care

## On-body

- Smart Devices
- Implants
- Wearables
- Peripherals

## In-home

- Digital Assistants
- Activity Monitoring
- Telehealth Consultations
- Home Medical Devices

## Trends

- ▶ The COVID19 pandemic has accelerated the need for remote device management and servicing solutions
- ▶ Consumers are increasingly turning to wearables and mHealth apps to drive physical and mental wellness
- ▶ Connected medical devices and advancements in software that capture and analyze device data has led to improved delivery of care and new product development
- ▶ Adoption of emerging technologies is essential to drive digital transformation in the medical device industry

**\$602 Bn**

Global medical devices market

**\$1.1 Tn**

Remote monitoring healthcare market

**CAGR >39%**

Wearable medical devices market

**\$289 Bn**

mHealth industry valuation by 2025

# Shifting Focus: Medical Device Industry

*One size fits all approach*



***Personalized medicine***

*Fragmented, one-way information flow*



***Integrated, two-way information exchange***

*Centralized, hospital-based locations*



***Decentralized, community-based***

*Individual, expert-based decision making*




***Protocols and analytics driven***

*Treating sickness*



***Preventing sickness***



***By 2040, it is estimated that two-thirds of health care spending will be related to well-being and the early detection, prevention, and curing of disease***

# Medical Devices: Key Regulations & Standards

The **FDA's** Center for Devices and Radiological Health (CDRH) regulates medical devices in US. All devices are classified into **3 classes** & **16 medical specialties / panels** (defined in 21 CFR 800-898)

## Device Regulations

### Digital Health Software Pre-certification Program

- Part of FDA's Digital Health Innovation Action Plan
- Identify manufacturers - quality & organizational excellence
- Streamline the FDA approval processes

### Draft Regulation for AI/ML based SaMD

- New regulation for adapting evolving AI/ML devices
- New controls: SaMD Pre-Specifications (SPS) & Algorithm Change Plan (ACP)

### ISO/TR 80002-2:2017 Medical Device Software - Part 2

- Validation of software for medical device quality systems

## New Laws

### Regulatory Standards

- FDA Section 506J - Mitigate medical device shortages during a public health emergency
- USA: FDA Title 21, CFR Part 11, Part 820
- EU: MDR & IVDR (replacing 90/385/EEC; 93/42/EEC; 98/79/EC)

### Impact of 21st Century Cures Act

- Medical device & reporting exemptions to select software & accessories respectively
- Quick review of "Breakthrough Devices"
- Updated device clinical trial requirements
- Changes to safety / effectiveness clauses of devices

## Standards

### Subchapter H - Part 800 (Devices)

- Device classification
- Medical devices – approvals, packaging, and reporting
- Quality systems regulations

### Product Standard

- IEC 60601-1/2, IEC 61010-1: Medical Elec. Equipment Safety

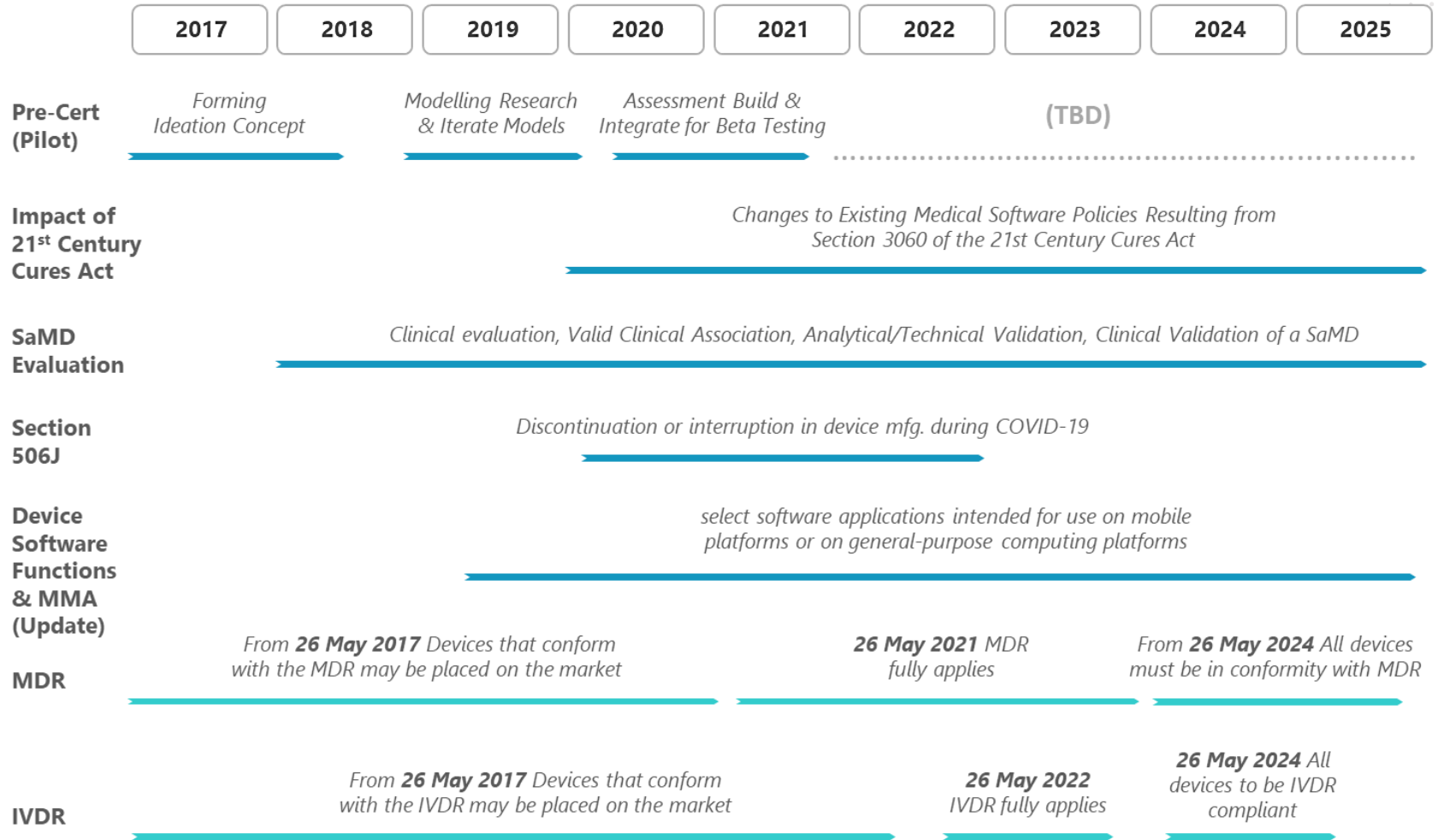
### Quality & Risk Management

- ISO 13485 based QS regulation
- ISO 14971 risk management
- ISO 31000:2018 principles & generic guidelines on risk mgmt.

### Process Standards

- IEC 62304: Medical Device Software Lifecycle

# Timeline: Medical Device Regulations



# Emerging Technology: Use Cases (1/2)



## Smart Devices & Wearables

- Smart IoT enabled devices & wearables with decision support alerts for enhancing clinical workflows
  - AI-based SaMD development for disease diagnosis, care management and therapeutics
- 



## Patient & Provider Engagement

- Mobile medical apps including chatbots for teleconsultation, patient education and surveys
  - Apps for care coordination, wellness management and personalized care
- 



## Legacy Device Digitization

- Digital enablement through robust connectivity with data platform and cybersecurity
  - Software modernization, cloud migration with microservices, containerization, etc.
- 



## Remote Monitoring

- 24x7 access to patient vitals using remote monitoring devices can drive clinical interventions
  - Track trends in device utilization, connectivity, battery level, performance, etc.
- 



## Intelligent Automation

- Automated status tracking of documents and compilation of records necessary for regulatory submissions
- Adverse event reporting and recalls management using RPA bots



# Emerging Technology: Use Cases (2/2)



## Proactive Device Maintenance

- Predictive analytics for proactive device maintenance and service scheduling
  - Streaming device data analytics to drive remote device configuration and updates
- 



## Smart Surgery

- Simulators for surgery planning and smart wearables for health monitoring post surgery
  - Telesurgery using remote surgery robots
- 



## Digital Twin

- Digital simulations of device twin to provide risk free virtual environment for device testing
  - Digital implant prototypes for accurate design, optimal size to fit patient, saving time & cost
- 



## Medical Imaging

- VR and AR medical Imaging apps for pain management, virtual environment for physical therapy
- Image analysis for lung cancer risk quantification by processing raw CT / MR images from modalities

## Emerging Digital Therapeutics: Use Cases (1/2)







Therapeutic Area	Healthcare decision	Use case
<b>Pulmonology</b>	Diagnose	Perform analysis of cerebrospinal fluid spectroscopy data to diagnose tuberculosis meningitis or viral meningitis in children
<b>Pulmonology</b>	Drive Clinical Management	Use the microphone of a smart device to detect interrupted breathing during sleep and sound a tone to rouse the sleeper
<b>Pulmonology</b>	Inform Clinical Management	Collect output from a ventilator about a patient's carbon dioxide level and transmit the information to a central patient data repository for further consideration
<b>Oncology</b>	Diagnose	Calculate the fractal dimension of a lesion and surrounding skin and build a structural map that reveals the different growth patterns to provide diagnosis or identify if the lesion is malignant or benign
<b>Infectious Disease</b>	Diagnose	Combine data from immunoassays to screen for mutable pathogens / pandemic outbreak that can be highly communicable through direct contact or other means
<b>Dermatology</b>	Diagnose	Diagnose if a skin lesion is malignant or benign by taking pictures and monitoring the growth over time


## Emerging Digital Therapeutics: Use Cases (2/2)

Therapeutic Area	Healthcare decision	Use case
<b>Cardiology</b>	Inform Clinical Management	Use data from individuals for predicting risk score for developing stroke or heart disease for creating prevention or interventional strategies
<b>Nephrology</b>	Drive Clinical Management	Calculate bolus insulin dose based on carbohydrate intake, premeal blood glucose, & anticipated physical activity reported to adjust carbohydrate ratio and basal insulin
<b>Audiology</b>	Treatment	Provide sound therapy to treat, mitigate or reduce effects of tinnitus for which minor therapeutic intervention is useful
<b>Audiology</b>	Inform Clinical Management	Use hearing sensitivity, speech in noise, and answers to a questionnaire about common listening situations to self-assess for hearing loss
<b>Cardiology, Nephrology</b>	Diagnose	Integrate and analyze multiple tests to provide recommendations for diagnosis in certain clinical indications, e.g., kidney function, cardiac risk, iron & anemia assessment
<b>Cardiology, Pulmonology</b>	Drive Clinical Management	Receive data from wearable health sensors for patients with multiple chronic conditions, transmit data to monitoring server, and identify higher-level information such as tachycardia and respiratory infections and communicates this information to caregivers

# CitiusTech Medical Device Offerings

CitiusTech Medical Device offerings cover the end-to-end development, testing, clinical integration, security and support aspects of the product lifecycle.

<b>Engagement Solutions</b>  <ul style="list-style-type: none"><li>▪ Patient / Provider engagement digital platforms</li><li>▪ SMART Mobile Apps &amp; Telehealth</li><li>▪ Smart Device Management</li></ul>	<b>Connectivity</b>  <ul style="list-style-type: none"><li>▪ Device / IoMT Interfaces to HIT Systems</li><li>▪ Device / IoMT Cloud Enablement</li><li>▪ Standards based and Custom Data Exchange – IHE, FHIR, HL7, DICOM etc.</li></ul>	<b>Engineering</b>  <ul style="list-style-type: none"><li>▪ Medical Device Software &amp; SaMD</li><li>▪ Digital therapeutics</li><li>▪ V&amp;V and Automation</li><li>▪ Serviceability</li></ul>	<b>Recent Engagements</b> <ul style="list-style-type: none"><li>▪ Infusion Pumps Integration using IHE</li><li>▪ Product Identification IoT Platform</li><li>▪ ML Dose Optimization SaMD with 510(K) submissions for SaMD</li><li>▪ Embedded Development for CRRT Device</li><li>▪ Surgeon iPad application for Medical Device Data System</li><li>▪ DoD &amp; FDA compliance on cybersecurity for CT Scan devices</li></ul>
<b>Compliance &amp; Security</b>  <ul style="list-style-type: none"><li>▪ Vulnerability / Penetration testing</li><li>▪ Legacy device security testing</li><li>▪ DoD, FDA &amp; CE Mark Compliance</li></ul>	<b>Data Management</b>  <ul style="list-style-type: none"><li>▪ Scalable health data platforms</li><li>▪ Data standardization and curation</li><li>▪ Streaming device data processing</li></ul>	<b>Automation &amp; Analytics</b>  <ul style="list-style-type: none"><li>▪ Remote Device Analytics</li><li>▪ Clinical Decision Support</li><li>▪ Supply Chain Analytics</li><li>▪ Intelligent automation across value chain</li></ul>	

 <b>Customer Value</b>	<i>Accelerated Smart Devices Ecosystem</i>	<i>Improved Patient Monitoring</i>	<i>Clinical Decision Support</i>	<i>Reduced device downtime</i>	<i>Fast Track Regulatory Compliance</i>
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## About CitiusTech

With 6,500+ healthcare technology professionals worldwide, CitiusTech helps leading healthcare and life sciences organizations reinvent themselves by accelerating digital innovation, leveraging next-gen technologies, and driving data convergence across the healthcare ecosystem.

We provide strategic consulting, digital engineering, data, analytics & AI, specialized platforms and end-to-end solutions to over 130 organizations across the payer, provider, medtech and life sciences industries. Our key focus areas include healthcare interoperability data management, quality performance analytics, value-based care, omni channel member experience, connected health, virtual care delivery, real-world data solutions, clinical development, personalized medicine and population health management.

Our cutting-edge technology expertise, deep healthcare domain expertise and a strong focus on digital transformation enables healthcare and life sciences organizations to deliver better outcomes, accelerate growth, drive efficiencies, and ultimately make a meaningful impact to patients.

**100%**  
healthcare focus

**130+**  
healthcare clients

**50M+**  
lives touched

**4.5/5**  
client satisfaction score

**\$340M+**  
worldwide revenue

# Key Contacts



## **Dhaval Shah**

Exec. Vice President  
Healthcare Technology  
CitiusTech

20+ years of experience in healthcare technology, spanning various domains including healthcare interoperability and enterprise application architecture. At CitiusTech, Dhaval heads strategic partnership management for large healthcare organizations.

Prior to CitiusTech, Dhaval worked with leading healthcare organizations and across multiple technology and business-focused roles.

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## **Shujah Dasgupta**

Asst. Vice President  
Healthcare Technology  
CitiusTech

15+ years of experience in developing and designing healthcare products. Leads Interoperability and Imaging practice at CitiusTech.

Shujah has driven multiple digital and product engineering engagements at CitiusTech, including managing large programs, setting up the medical imaging consulting practice, managing strategic customers and driving new business development.

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