

Powering the Future
of Healthcare ▶

 **CitiusTech**

Medical Devices

Shifting Focus, Regulatory Compliance
and Technology Outlook



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.



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

300+

Medical devices experts

4.5/5

Client satisfaction score

Medical Device Industry: Emerging Trends

Medical device companies are diving into the infinite possibilities of IoT technology, device connectivity and data-driven intelligent devices

Technology Trends



Mobile Medical Apps (MMA)

Wearable technology and IoMT integration have enabled access to medical records, personalized care, Remote monitoring, etc.



Extended Reality: AR, VR

VR and AR can help surgeons plan therapy, drive training to enhance accuracy and ease of procedures, educate patients before and after surgeries



Predictive Maintenance

Automated tracking solutions for device anomalies, Remote Device Upgrades, etc.



Digital Platforms on Cloud

Cloud-connected systems are rapidly emerging bridging the gaps in access to longitudinal health records, real time CDS and device insights



Medical Robots

Support minimally invasive procedures, frequent monitoring for driving intelligent therapeutics etc.



5G Technologies

Super-fast connectivity, ultra-low latency, and widespread coverage drives enhanced patient, monitoring, virtual care, etc.

\$495.46 Bn

Global Medical Devices Market, 2022

5.5%

CAGR of Medical Devices Market

\$718.92 Bn

Projected Global Medical Devices Market, 2029

Key Challenges

Supply chain and logistics

Cybersecurity for legacy products

Reimbursement challenges for digital tools

Regulatory challenges

Rising healthcare costs

Key Enablers

Smarter forecasting solutions

Personalized Medicine

Software as a Medical Device

Accelerated integration of AI/ML

Device connectivity accelerators

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



Pre-Cert (Pilot)

Assessment build and integrate for beta testing



Impact of 21st Century Cures Act

Changes to existing medical software policies resulting from section 3060 of the 21st Century Act



CDSS Law

FDA has released new guidance to further define the scope of the agency's oversight of clinical decision support (CDS) software developed for providers, patients, and caregivers.



Cyber-security

The 2022 guidance covers software and firmware or programmable logic, including SaMD, regardless of whether it is connected to a broader environment



Device Software Functions & MMA Update

Select Software applications intended for use on mobile platforms or on general purpose computing platform



MDR

*From **26 May 2017** devices that conform with the MDR may be placed on the market*

*From **26 May 2021** the MDR fully applies*

*From **26 May 2024** All devices must be in conformity with MDR*



IVDR

*From **26 May 2017** devices that conform with the IVDR may be placed on the market*

***26 May 2022** IVDR fully applies*

***26 May 2024** All devices to be IVDR compliant*



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
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Patient & Provider Engagement

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

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

- Simulators for surgery planning and smart wearables for health monitoring post surgery
 - Telesurgery using remote surgery robots
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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
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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
Pulmonology	Diagnose	Perform analysis of cerebrospinal fluid spectroscopy data to diagnose tuberculosis meningitis or viral meningitis in children
Pulmonology	Drive Clinical Management	Use the microphone of a smart device to detect interrupted breathing during sleep and sound a tone to rouse the sleeper
Pulmonology	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
Oncology	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
Infectious Disease	Diagnose	Combine data from immunoassays to screen for mutable pathogens / pandemic outbreak that can be highly communicable through direct contact or other means
Dermatology	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
Cardiology	Inform Clinical Management	Use data from individuals for predicting risk score for developing stroke or heart disease for creating prevention or interventional strategies
Nephrology	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
Audiology	Treatment	Provide sound therapy to treat, mitigate or reduce effects of tinnitus for which minor therapeutic intervention is useful
Audiology	Inform Clinical Management	Use hearing sensitivity, speech in noise, and answers to a questionnaire about common listening situations to self-assess for hearing loss
Cardiology, Nephrology	Diagnose	Integrate and analyze multiple tests to provide recommendations for diagnosis in certain clinical indications, e.g., kidney function, cardiac risk, iron & anemia assessment
Cardiology, Pulmonology	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.

Engagement Solutions

Patient / Provider engagement digital platforms | SMART Mobile Apps & Telehealth | Smart Device Management

Device Connectivity

Device / IoMT Interfaces to HIT Systems | Device / IoMT Cloud Enablement | Standards based and Custom Data Exchange – IHE, FHIR, HL7, DICOM etc.

Device Engineering

Medical Device Software | Software V&V | Modernization & Sustainance | Regulatory documentation

SaMD

Apps for diagnosis, remote monitoring & condition mgmt. | Digital therapeutics & personalized care | AI/ML model development & operationalization

Device Platform

Cloud-based device platforms | Data standardization and curation | Streaming device data processing

Analytics & Automation

Remote Device Analytics | Clinical Decision Support | Operations Analytics | Intelligent automation across value chain

Compliance & Security

Vulnerability / Penetration testing | Legacy device security testing | DoD, FDA & CE Mark Compliance

Supply Chain Management

Supply chain digitization | Process re-engineering – requisition, recalls, etc. | Inventory optimization, Demand prediction & fulfilment

Salesforce

Salesforce Implementations & Business transformation | Customer engagement and support portals | Sales and operations insights

Recent Engagement

SaMD mHealth App for Insulin management in T2D Patients

Product Identification IoT Platform

Enterprise MLOps framework to operationalize digital services

Bi-directional FHIR interoperability for CRRT Device

Supply chain automation for equipment requisition, inventory mgmt., recalls, etc.

About CitiusTech

With 7,500+ 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

\$420 M+
2023E 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

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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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