The medical device industry will face a series of regulatory challenges in 2021. Staying abreast of emerging technology & regulatory trends can help organizations better navigate the evolving regulatory changes and stay competitive.

- Industry trends and focus areas
- Classification of medical devices
- Key standards and regulations
- Emerging technology use cases
Medical Device Industry: Emerging Trends

**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.

**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

**Market Statistics**

- **Global medical devices market**: $602 Bn
- **Remote monitoring healthcare market**: $1.1 Tn
- **Wearable medical devices market**: CAGR >39%
- **mHealth industry valuation by 2025**: $289 Bn
Shifting Focus: Medical Device Industry

- Personalized medicine
- Integrated, two-way information exchange
- Decentralized, community-based
- Protocols and analytics driven
- Preventing sickness
- One size fits all approach
- Fragmented, one-way information flow
- Centralized, hospital-based locations
- Individual, expert-based decision making
- Treating sickness
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)

<table>
<thead>
<tr>
<th>Device Regulations</th>
<th>New Laws (2020)</th>
<th>Standards</th>
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</thead>
</table>
| 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  | Regulatory Standards  
- FDA Section 506J: Mitigate medical device shortages during a public health emergency  
- USA: FDA Title 21, CFR Part 11, Part 820  
- Device classification  
- Medical devices: approvals, packaging, and reporting  
- Quality systems regulations  |
| 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)  | 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  | Product Standard  
- IEC 60601-1/2, IEC 61010-1: Medical Electrical Equipment Safety  |
- Validation of software for medical device quality systems  | Quality & Risk Management  
- ISO 13485 based QS regulation  
- ISO 14971 risk management  
- IEC 62304: Medical Device Software Lifecycle  |
### Timeline: Medical Device Regulations

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2017</td>
<td>Forming Ideation Concept</td>
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<tr>
<td>2018</td>
<td>Modelling Research &amp; Iterate Models</td>
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<tr>
<td>2019</td>
<td>Assessment Build &amp; Integrate for Beta Testing</td>
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<tr>
<td>2020</td>
<td>(TBD)</td>
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<tr>
<td>2021</td>
<td>Impact of 21st Century Cures Act</td>
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<tr>
<td>2022</td>
<td>Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act</td>
</tr>
<tr>
<td>2023</td>
<td>SaMD Evaluation</td>
</tr>
<tr>
<td>2024</td>
<td>Clinical Evaluation, Valid Clinical Association, Analytical / Technical Validation, Clinical Validation of a SaMD</td>
</tr>
<tr>
<td>2025</td>
<td>Discontinuation or Interruption in Device Mfg. During COVID-19</td>
</tr>
</tbody>
</table>

**Pre-Cert (Pilot)**

- **Pre-Cert (Pilot)**
- **Impact of 21st Century Cures Act**
- **SaMD Evaluation**
- **Section 506J**
- **Device Software Functions & MMA (Update)**
- **MDR**
- **IVDR**

### MDR

- From **26 May 2017** Devices that Conform with the MDR may be Placed on the Market
- **26 May 2021** 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
- From **26 May 2024** All Devices to be IVDR Compliant
Emerging Technology: Use Cases (1/2)

**Smart Devices**
- Smart IoT enabled devices with decision support alerts for enhancing clinical workflows
- AI-based SaMD development for disease diagnosis and care management

**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

**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.
Emerging Technology: Use Cases (2/2)

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

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

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

Smart Surgery
- Simulators for surgery planning and smart wearables for health monitoring post surgery
- Telesurgery using remote surgery robots
CitiusTech’s medical device solutions cover the end-to-end development, testing, clinical integration, security, and support activities across the product lifecycle.
About CitiusTech

CitiusTech enables healthcare organizations to drive clinical value chain excellence, across integration & interop, data management (EDW, Big Data), performance management (BI / analytics), data science (predictive analytics, AI, ML) and digital engagement (cloud, mobile, IoT).

CitiusTech Medical Device Solutions

CitiusTech has a dedicated Medical Device Practice that works with some of the world’s leading healthcare technology companies to solve key industry challenges such as interoperability, patient monitoring, and analytics.

The Medical Device practice has deep clinical data expertise. It has executed multiple projects dealing with massive amounts of clinical and operational data generated by connected devices across expansive ecosystems and deploying AI / Machine Learning models to enhance clinical performance.

- **400+** Medical device experts
- **Top 5** Medical device companies as clients
- **500+** HL7, FHIR certified professionals
- **$205+ Mn** in revenue
- **4,000+** healthcare IT professionals
- **40 Mn+** lives touched
- **69+** NPS - highest in the industry!
- **110+** healthcare customers