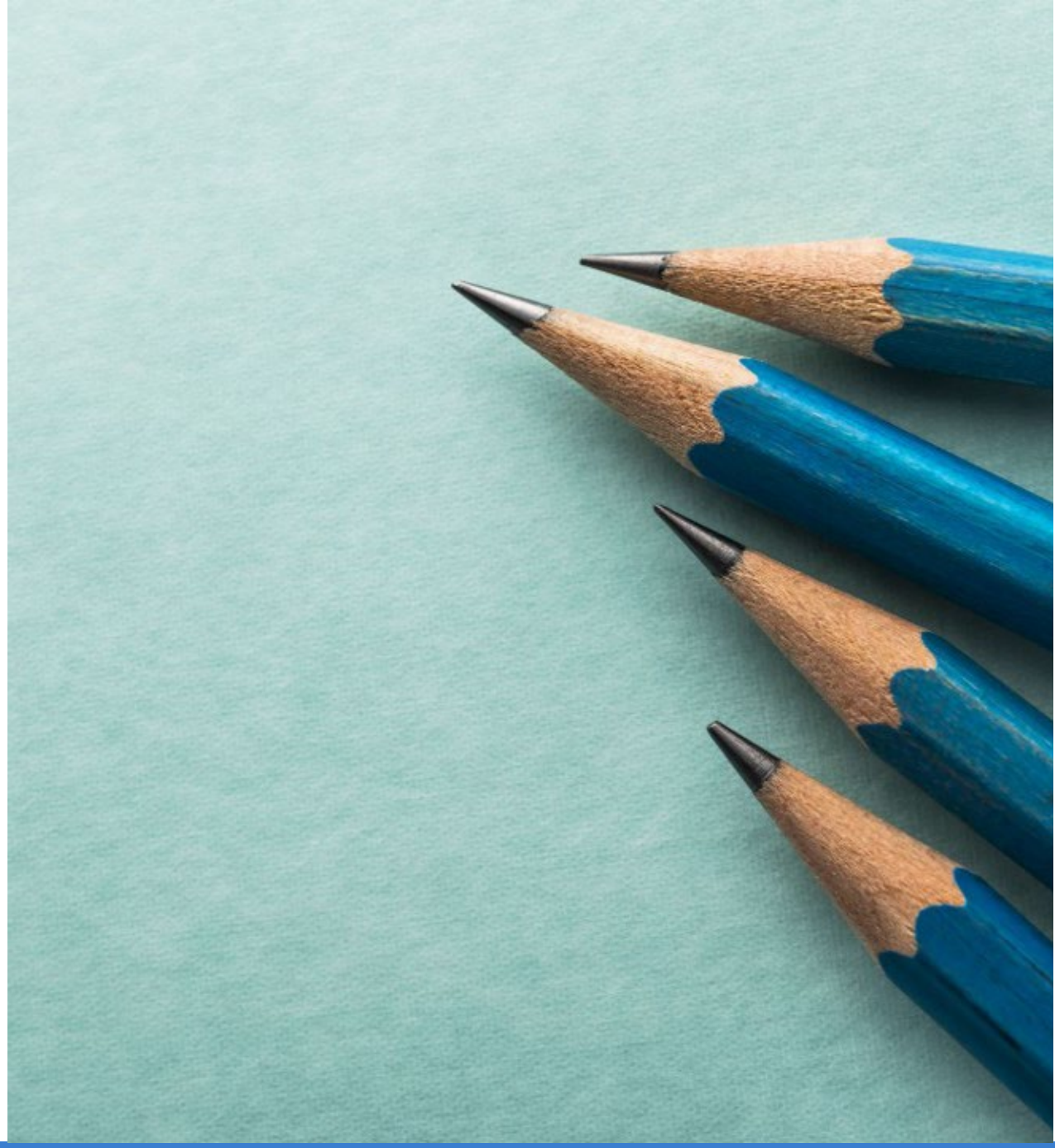
Digital Health Technologies (DHT) and Software as Medical Device (SaMD)

Webinar - January 30, 2026

Housekeeping

A few things before we start…

- This Webinar is being recorded and will be available on the MEC website: ***www.medicalengineeringconsultants.com***
- The Presentation deck will be sent to registered participants and will also be available on the MEC website.
- **During the live Webinar:**
  - Please use Teams “Chat” for questions.
    - We will review questions at the end.
    - We will also follow-up directly with participants on any questions not covered, where possible.



WEBINAR OBJECTIVES

In today's session we will:

- Review the digital health technology landscape and common use cases
- Clarify regulatory scope for wellness tools, CDS and SaMD
- Highlight key elements of recent FDA guidance documents
- Discuss practical implications for development, quality & cybersecurity

Medical Engineering CONSULTANTS

Medical Engineering CONSULTANTS

WHAT WE DO

Medical Engineering Consultants (MEC) is dedicated to helping our clients provide safe and effective medical devices, diagnostic devices and pharmaceutical products.

MEC offers contracting & staffing resources, consulting services and training to deliver operational excellence.

MEC achieves client service excellence by utilizing

- Effective talent acquisition processes
- Consistent solution delivery resources
- Efficient operations infrastructure

Every MEC resource has access to our full suite of internal resources and to the expertise of the full MEC team.

About the Presenter

Supriya Lagu is a Solution Delivery Lead and Digital Health subject matter expert at Medical Engineering Consultants. She helps MedTech and Biopharma organizations design, validate, and launch digital health solutions that are both innovative and compliant. With 25+ years spanning R&D, Quality, and Regulatory leadership, Supriya brings a dual lens — building digital and data solutions and embedding the regulatory, cybersecurity, and QMS rigor that sustain them. Supriya's work bridges digital health product development (SaMD, AI/ML, wearables, decentralized trials) with global compliance frameworks (FDA, EMA, ISO, IMDRF). She leads cross-functional programs that take products from concept to market — ensuring patient safety, data integrity, and inspection readiness.

Digital Health Technology[1] (DHT)

A system that uses computing platforms, connectivity, software, and/or sensors for healthcare and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products.

1: Source: From U.S. Food and Drug Administration. (2023). *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations, Guidance for Industry, Investigators, and Other Stakeholders*. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations.

Medical Engineering CONSULTANTS

Uses of Digital Health Technologies

Key Technologies Enabling Digital Health

Use Cases (Patient Care, Diagnosis, Wellness)

Applications & Intelligence (Apps, CDS, AI/ML, Analytics)

Platform & Trust (Cloud, Interoperability, Cybersecurity)

Medical Engineering CONSULTANTS

Why DHT? Why Now?

FDA Digital Health Center of Excellence (DHCoE)

- Centralized digital health strategy (since 2020)
- Focus areas: **SaMD, CDS, AI/ML, cybersecurity**
- Outcomes: **faster, clearer, more consistent guidance** for industry

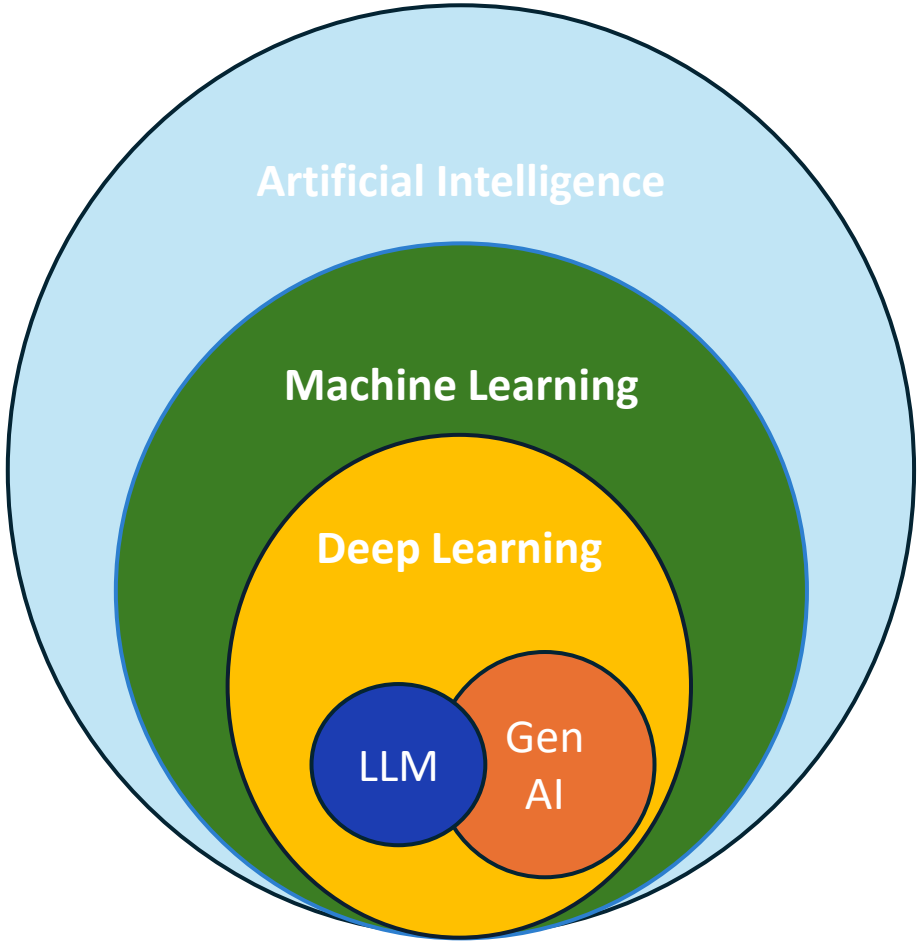
1) https://www.fda.gov/medical-devices/digital-health-center-excellence
2) https://www.fda.gov/medical-devices/digital-health-center-excellence/guidances-digital-health-content

Medical Engineering CONSULTANTS

Baselining AI Concepts (Shared Language)

AI is an overarching concept. ML focuses on learning from the data, LLMs specialize in language tasks and Gen AI excels at creating new content.

- Artificial Intelligence (AI) --> Machine Learning (ML) --> Deep Learning
- Large Learning Models (LLM)
- Gen AI



Medical Engineering CONSULTANTS

DHT Types for this Discussion

Wellness App

- Software that promotes **general health or lifestyle behaviors**; no diagnosis or treatment intent
- Generally non-FDA regulated
- Low-risk, lifestyle or wellness focus

CDS

- Software that **supports clinical decisions**; may be regulated depending on transparency and autonomy
- Context-dependent
- Non-FDA if clinicians can independently review the basis of recommendations
- FDA-regulated if opaque, autonomous, or time-critical

SaMD

- Software intended for a **medical purpose** (diagnosis, treatment, disease management), operating **independently of device hardware**
- Usually FDA-regulated
- Independent of device hardware

SiMD

- Software **embedded in or controlling a medical device**, regulated as part of that device
- Always FDA-regulated
- Embedded in or controlling a medical device

Medical Engineering CONSULTANTS

FDA January 2026 Digital Health Updates – What Changed

Title: FDA Updates (Jan 6, 2026): Wellness + CDS — Clearer Lines, Risk-Based Oversight

Wellness tools (Low-risk):

- FDA reiterates **"general wellness + low risk" → not regulated as a device**
- Emphasis: **claims + risk profile** drive scope (not "AI" itself)

CDS software (Potentially non-device):

- CDS may be excluded only if it supports clinicians and they can **independently review the basis** of recommendations
- Opaque/black-box or autonomous decision-making trends toward **regulated device**

Medical Engineering CONSULTANTS

FDA Pilot - TEMPO (Access + Real-World Evidence)

Title: TEMPO Pilot — What the FDA is Testing (and Why It Matters)

- FDA launched TEMPO to **expand access to certain digital health devices for chronic disease technologies** and gather real-world evidence
- FDA plans to select **up to ~10 manufacturers in each of 4 clinical use areas**; statements of interest begin **Jan 2, 2026**
- **So what?** FDA is signaling that **evidence generation + outcomes** are becoming as strategic as clearance routes

Medical Engineering CONSULTANTS

Other Considerations

Non-FDA regulated tools may require compliance with other regulations.

- **Patient Data Requirements**
- Health Insurance Portability and Accountability Act (HIPAA) – U.S.
- General Data Protection Regulation (GDPR) – EU
- System and Organization Controls 2 (SOC 2) for Software as a Service (SaaS) tools
- Health Information Technology for Economic and Clinical Health Act (HITECH)
- Local data protection laws
- **Clinical Accuracy & Validation**
- **Transparency & Explainability**
- **Bias & Fairness Audits**
- **Cybersecurity & IT Governance**
- **Ethical & Legal Considerations**

Medical Engineering CONSULTANTS

Software as a Medical Device (SaMD) - Deep Dive

Software is classified as a SaMD if it:

- Performs a medical functions such as diagnosis, treatment recommendation or monitoring a disease
- It operates independently of a medical device (e.g. mobile application, cloud-based AI diagnostics)
- It impacts clinical decision making or patient care

If the Software is classified as SaMD,

- It must follow Medical Device Regulations based on the intended use of the device.
- It must meet Cybersecurity submission requirements for applicable cyber devices.

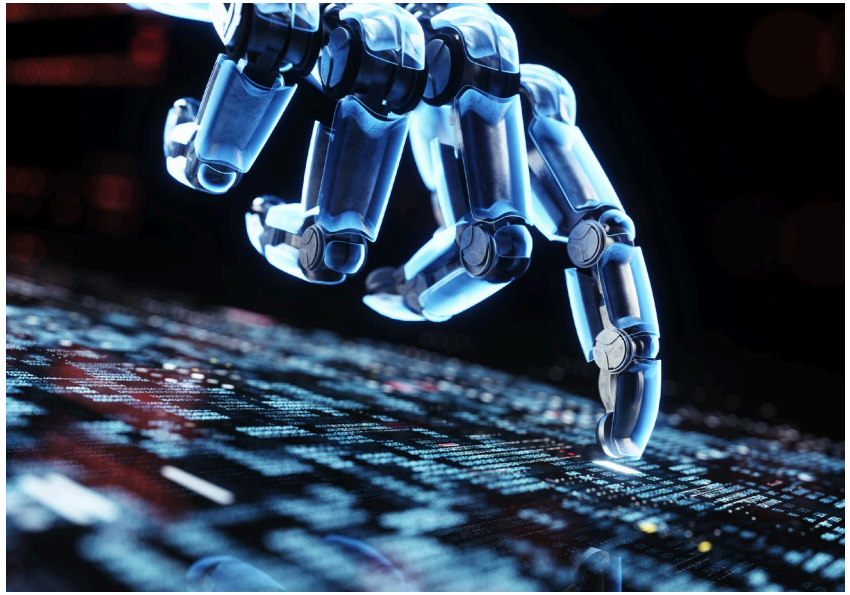
SaMD Categories State of Healthcare Situation or Condition	Significance of information provided by SaMD to the healthcare decision		
	Treat or Diagnose	Drive Clinical Management	Inform Clinical Management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Medical Engineering CONSULTANTS

AI-based & Non-AI based SaMD

AI-based SaMD products leverage machine learning and advanced analytics to identify patterns, predict outcomes, and support or automate clinical decisions—for example, algorithms that detect cancers in imaging scans, predict arrhythmias from ECG data, or personalize treatment pathways based on patient-specific factors.

Non-AI SaMD products include rule-based clinical calculators, image processing software, and digital therapeutics that deliver standardized interventions, all operating on fixed algorithms and deterministic logic.



Medical Engineering CONSULTANTS

SaMD and Medical Device Lifecycle Similarities

Planning

Both start with clinical and business justification, regulatory & risk categorization, Development planning and Go/ No-Go criteria.

Design & Development

Translate user/ clinical needs into requirements, Risk Management, cybersecurity & data risks.

Verification & Validation

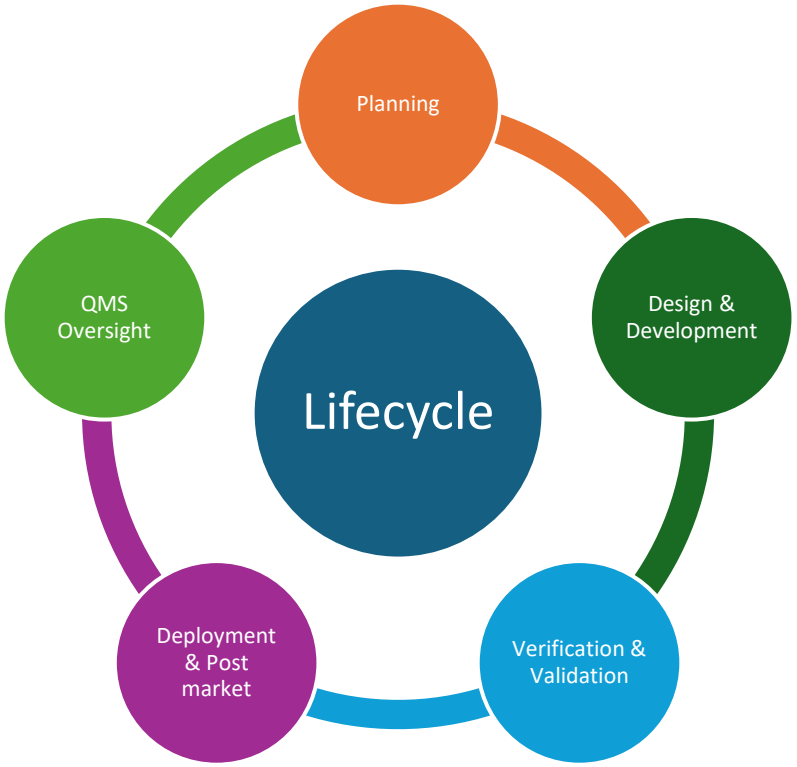
Confirm design outputs meet requirements, Software testing, unit/ integration testing & clinical evaluation. Regulatory emphasis on performance against user needs and intended use.

Deployment & Post-market Surveillance

Submission content (e.g. labeling, risk analysis, V&V results) is similar in structure, PMS, field actions, vigilance and post-market clinical follow-up.

QMS Oversight

Quality system ensures consistency, traceability and compliance.



Medical Engineering CONSULTANTS

Unique Considerations for SaMD

Area	Consideration	Regulatory Expectations
Cybersecurity & Data Integrity	Protect software from vulnerabilities, unauthorized access, and data corruption	Threat modeling, SBOM, secure SDLC, vulnerability handling; scale controls to risk; ongoing patching
Software Lifecycle Management (change control, release/patch cadence)	Establishing processes for secure design, coding, verification, updates, and maintenance	Documented processes for development, verification/validation, release, maintenance; security integrated into lifecycle.
Adaptive AI/ML	Ability to address risks from continuously learning or adaptive algorithms (performance, drift, bias)	Up-front plan for model updates; monitoring for drift; evidence of generalizability and risk controls
Interoperability & Usability	Ensure SaMD works safely across platforms, operating systems, and user settings	Demonstrate safe integration with other systems; minimize use error via human-factors engineering

Medical Engineering CONSULTANTS

Why Cybersecurity Is Now Core to DHT & SaMD

Key Message

- Cybersecurity is no longer an IT concern — it is a **product quality & patient safety requirement**

Why Now

- Increased connectivity (cloud, APIs, remote updates)
- AI/ML model updates & continuous learning
- Expanded post-market monitoring expectations

Regulatory Signal

- FDA treats cybersecurity as part of **safety & effectiveness**, not an add-on
  (Applies across SaMD, AI/ML, CDS, connected devices)

Medical Engineering CONSULTANTS

FDA Cybersecurity Expectations — At a Glance

FDA Expects

- Secure development lifecycle (SDLC)
- Threat modeling & risk management
- SBOM transparency for third-party software
- Vulnerability monitoring & coordinated disclosure
- Post-market surveillance tied to cybersecurity signals

What Changed

- Shift from “point-in-time controls” to **continuous lifecycle oversight**

Medical Engineering CONSULTANTS

Cybersecurity by Role — Where Teams Struggle

Executives

- Cybersecurity impacts launch timelines & liability
- Needs governance, ownership, and funding

Product / R&D

- Secure architecture & design tradeoffs
- AI model updates vs regulatory change control
- Third-party software & cloud dependencies

QA / RA

- Integrating cybersecurity into QMS
- Evidence generation for audits & submissions
- Post-market signal triage & CAPA linkage

Medical Engineering CONSULTANTS

Cybersecurity Across the SaMD Lifecycle

Lifecycle Stage	Cybersecurity Focus
Planning	Intended use, threat modeling, risk classification
Design & Development	Secure SDLC, code analysis, access control
V&V	Security testing, penetration testing
Deployment	Secure release, patch strategy
Post-Market	Vulnerability monitoring, incident response
QMS	Governance, training, documentation

Medical Engineering CONSULTANTS

SaMD Validation in Perspective

- **The use of SaMD is expanding rapidly,** from non-AI applications (rule-based calculators, imaging tools, digital therapeutics) to AI-enabled solutions for diagnostics, prediction, and decision support.
- This growth introduces **unique validation challenges**: data quality, algorithm transparency, bias, interoperability, and cybersecurity.
- Despite these new complexities, **SaMD is still built on the same medical device lifecycle** — planning, design, verification & validation, risk management, and postmarket surveillance.
- What has changed is the **level of rigor and continuous monitoring now expected**, especially for AI/ML-based SaMD.
- To keep pace, **organizations must develop new competencies**: AI/ML fundamentals, data governance, and cybersecurity — enabling safe, effective, and compliant SaMD products.

Medical Engineering CONSULTANTS

Wrap-Up – Key Takeaways

- Digital Health Technologies span **wellness to clinical care**, with varying regulatory expectations.
- FDA oversight is **risk-based** and driven by **intended use, transparency, and user reliance.**
- Recent FDA guidance clarifies scope for **wellness tools and clinical decision support.**
- **SaMD and SiMD** remain subject to full lifecycle, quality, and cybersecurity expectations.
- Successful teams align **product design, quality, and cybersecurity** early in development.

Medical Engineering CONSULTANTS

How Companies Typically Approach This Work

- Start with clarity on intended use and risk
- Assess gaps in processes, evidence, and governance
- Update QMS and lifecycle controls incrementally
- Build cross-functional capability across Product, QA/RA, and Security
- Use external expertise selectively where depth is needed

Medical Engineering CONSULTANTS

QUESTIONS

We asked participants for specific questions they'd like addressed during the webinar:

1. What would be the first thing(s) you recommend to a small startup company to get started in this area?

2. Should all software be considered medical device or just for specific devices?

THANK YOU!

For further information or support contact:

Supriya Lagu

s.lagu@medicalengineeringconsultants.com

www.medicalengineeringconsultants.com