Identifying Your Role in driving Regulatory Strategy for Digital Health Products

Which of the three key stakeholder groups driving regulatory strategies for digital health products do you best identify with?

Stakeholder Archetypes

The archetype examples shared below are not job titles, but rather a way to help identify your role in the context of digital health regulations as part of your product development and deployment.
**Decision-Makers | Primary Audience**

**ARCHETYPES**

- C-Suite/Executive leader at a small startup making commercial decisions based on regulations that apply to their products.
- Venture Capitalists (VCs) making decisions to invest in a company based on their regulatory strategy.
- Head of strategy at a digital health company using regulatory strategy as a differentiator for market positioning.
- Product chief within an industry with regulatory information evaluating and planning for new product development for portfolio strategy and management.
- Technical/product founder of a digital health startup making a decision about what features/functionality to build into their product that may impact decisions about the regulatory pathways.
- Healthcare grant-making organization (non-VC) making decisions to invest in the company based on the organization’s regulatory strategy.
- Head of regulatory affairs at a life science company charged with assigning resources to support product development.
- R&D executive at a MedTech device company developing the company’s first digital device with limited regulatory experience in digital health.
- Executive or product team lead developing the company’s first Digital Health Technology (DHT) that could be regulated as an FDA medical device.
- Digital health startup executive making commercial decisions for product capabilities in the health, wellness, and consumer health market.
- Life science organization product team lead developing DHTs and/or partnering a DHT for use with a drug product in a commercial use or clinical trial setting.
- Teams or organizations with limited experience developing combinational (drug+device) products, software-based medical products, etc.
- Research groups and academic organizations interested in developing digital health products.

**Help to decide or make decision(s)**

Individuals, teams, and/or organizations that are primarily responsible for proposing or permitting decisions about their digital health products and/or portfolios.

**MUST READ RESOURCES**

1. **Navigation tool**: DiMe’s U.S. RegPath tool
2. **Decision Map**: Digital health product class
3. **Value guide** for digital health regulations
4. **Flowchart** of Digital Health Regulatory Pathways
5. **Regulatory Strategy Toolkit** for digital health products
Informers | Secondary Audience

Help influence or inform the decision(s)

Individuals, teams, and/or organizations that directly or indirectly inform and/or influence digital health regulatory decisions but are not final decision-makers

MUST READ RESOURCES

1. DiMe’s Library of digital health regulations
2. Flowchart of Digital Health Regulatory Pathways
3. Digital health pathways toolkit
5. Value guide for digital health regulations

ARCHETYPES

- Legal and regulatory teams at an organization in a specific focus area (medtech, tech, life science, etc.) advising top leadership in support of regulatory decisions.
- Digital health project management teams at an organization that inform other teams about regulatory proceedings for their products.
- Trade associations and professional societies influencing regulatory decisions.
- Non-FDA federal agencies in the US [e.g., The Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), The Office of the National Coordinator for Health Information Technology (ONC), etc.] that maintain awareness of various FDA regulatory paths a digital health innovator may pursue.
- Regulatory consultants both in and outside of the US that advise medtech and digital health companies on US regulatory strategy.
- Academic research organizations and think tanks conducting research on improving evidence generation that meets the needs of regulatory decision-makers.
- Patient groups influencing product development strategies (e.g. product format, functions, etc.) in early phase development.
Implementers | Secondary Audience

Help to execute decision(s) into action

Individuals, teams, and/or organizations that execute and implement the regulatory decisions to develop products, educate stakeholders, etc

MUST READ RESOURCES

1. Flowchart of Digital Health Regulatory Pathways
2. Toolkit for interacting with US regulators
3. Digital health pathways toolkit
5. 5-Step Approach to Classifying your Digital Health Product in the US

ARCHETYPES

- Product development teams at medtech industry organizations executing regulatory decisions to build new products.
- Software engineer at a small, early-stage startup upgrading tech capabilities based on regulatory controls and decisions shared by their product executive leads.
- Health system partnering with a new digital health vendor and evaluating whether the vendor’s digital health product is regulated (and more).
- Investors mentoring and advising portfolio companies about commercialization plans based on a company’s product and regulatory strategy.
- Accelerators and incubators guiding early-stage organizations at the beginning of their product development cycles.
- Regulatory consultants both in and outside of the US supporting medtech and digital health companies with regulatory applications in the US.
- Regulatory team at a company with a specific focus area (medtech, tech, life science, etc.) responsible for developing regulatory strategy and managing regulatory submissions.
- Quality assurance and quality control leads at companies with specific focus areas (tech, life sciences, digital health, etc.) responsible for the development of a product in accordance with applicable regulatory status (e.g., design controls, etc.).
- National Institutes of Health (NIH) sponsors of extramural research to help guide grantmaking and funded device development programs.
- Contract Research Organizations (CROs) implementing research programs and advising on regulatory issues across the product and device development lifecycle.
- Clinicians making evidence-based clinical decisions using regulated and non-regulated digital health products.
Access DiMe's Digital Health Regulatory Pathway Resources

- **Identify** your regulatory pathway
- **Build** your regulatory strategy
- **Interact** with regulators

Digital Health Regulatory Pathways | [Access the resources](#)