



Digital Health: Overcoming Regulatory and Practical Pitfalls

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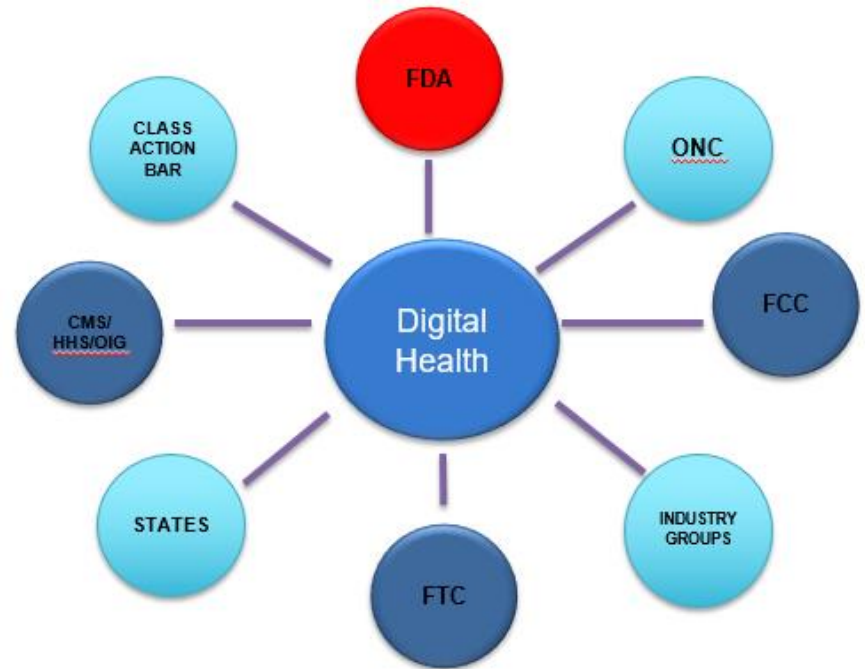


Agenda

1. Overview and Introduction of Hypothetical
2. Addressing Common FDA Product Development Challenges
3. Product Security: The New Frontier for Quality Management
4. Navigating the Coverage and Payment Landscape

Digital Health Regulatory Landscape

- Several regulators with either express authority or significant influence
- Different and sometimes conflicting laws and regulatory priorities
- Regulatory landscape slow to evolve and adapt to the speed of innovation
- Tradeoffs by regulators and industry may be required to balance priorities, manage risk and navigate regulatory challenges



Our Hypothetical....

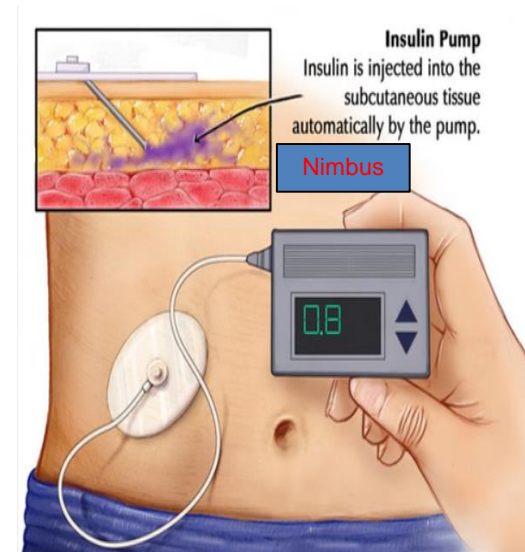
- ABC Health, Inc. is a global medical product manufacturer with 20,000 employees worldwide and \$10 billion in annual revenue
- ABC's headquarters are in San Francisco. It has manufacturing facilities in New Jersey, Puerto Rico and the UK
- ABC markets leading therapies in diabetes treatment and chronic care



Nimbus

Diabetes Management System

- Wi-fi enabled, programmable, automated insulin delivery system for Type 1 diabetes
- Approved for patients 12 and older
- Drug and pump developed and manufactured by ABC Health
- ABC Health partners with DigiTech, Inc., a start-up digital health company in Mountain View to develop mobile applications and clinical decision support tools for the Nimbus system




Introducing *Nimbus Mobile*...

- ABC and DigiTech develop two Nimbus Mobile Applications
- **TrackMe App** for patients to track what time the medication was taken, daily activity, diet, blood pressure, heart rate, and blood glucose
- **TrackPt CDS software** for healthcare providers (“HCPs”) to program dosing schedule and parameters, detect patterns of non-adherence, address and adjust the patient’s therapeutic regimen and prepare patient-specific medication counseling points


Nimbus Mobile!

Revolutionizing Drug Delivery and Adherence for Chronic Care

- Integrated treatment and care solution for diabetes
- Our mobile app is proven to provide better outcomes in patient monitoring and adherence
- Real-time updates for physicians and caregivers
- Easy to use and customizable



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Advising ABC Health and DigiTech...

- As a part of its product development and launch strategy, ABC is seeking advice regarding:
 1. FDA regulatory implications of the planned mobile app launch
 2. Data and Cybersecurity implications
 3. Payment and Reimbursement issues related to the software
 4. Other practical considerations to manage its collaboration and relationship with DigiTech

Addressing Common Product Development Challenges

FDA's Regulatory Priorities

1. New pathways to market for innovative products

- Particular emphasis on oversight of wearables, mobile apps, and clinical decision support (CDS)
- Traditional 510(k), de novo, and PMA pathways vs. Digital Health Precertification Pilot program
- Use of Real World Data (RWD) and Real World Evidence (RWE) to support labeling claims and regulatory decisions

2. Interoperability and cybersecurity for “connected” devices

- Emphasis on ensuring that connected devices are tested and validated to work and perform when connected to or through other devices, hardware or software
- Cybersecurity is an emphasis for pre-and post-market compliance due to recent “hacking” incidents

3. Quality and Performance

- Realigning Quality Systems Regulation and cGMP principles for digital health
- IMDRF Guidance documents describing quality and performance standards for clinical software

4. Advertising and Promotional Claims

- FDA emphasizing new approaches to validating claims and complying with labeling requirements
- Emphasis on ensuring that labeling and instructions for use are clear and appropriate, particularly for novel or innovative devices
- Emphasis on preventing fraudulent “cures” or deception of consumer or healthcare providers
- FTC, State AGs and other regulators increasing enforcement of consumer-facing apps and solutions that FDA no longer regulates

Regulatory Considerations for **Nimbus** App Launch

Threshold Issues	FDA Guidance/Solutions
What is the regulatory Status of the Mobile Applications and what are the available market pathways?	<ul style="list-style-type: none">• <i>Final Guidance: Clinical and Patient Decision Support Software (Dec. 2017)</i>• <i>Prescription Drug-Use Related Software Framework (Nov. 20, 2018)</i>• <i>Medical Device Accessories- Describing Accessories and Classification Pathways (Jan. 30 2017)</i>• <i>Mobile Medical Apps Guidance (Feb. 2015)</i>
How do the parties access and exchange data need for premarket and postmarket obligations?	<ul style="list-style-type: none">• <i>Draft Guidance: Multiple Function Device Products: Policy and Considerations (April 27, 2018)</i>• Assess and the define “field” and scope of exclusivity for use of IP needed for regulatory submissions and other regulatory reporting obligations• Define expectations regarding access to partner and third party data and IP
Who is responsible for quality management and compliance?	<ul style="list-style-type: none">• <i>IMDRF Quality Management System for Software as a Medical Device (SaMD) Framework (Oct. 2015)</i>• <i>Draft Guidance on Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices (2016)</i>• <i>Draft Guidance: Content of Premarket Submissions of Management of Cybersecurity in Medical Devices (Oct. 2018)</i>• <i>Postmarket Management of Cybersecurity in Medical Devices (December 2016)</i>

Common Challenges and Solutions

Challenge	Potential Solution
Absence of appropriate predicate devices for digital health devices	Consider De Novo Pathway to classify novel devices of low to moderate risk for which no valid predicate/comparator exists
Software developers unable to access proprietary data or code from partner or vendor's platform or device to validate performance or safety of software	Platform developers may be able to provide data to FDA in a proprietary Device Master File (DMF)/ Technical Master File (TMF) that developers can "reference" in their submission
How do I apply traditional medical device labeling compliance requirements to software	Develop content for start menu, home screens, settings, and options, instructions, Pop-ups, ratings and user-generated content on website, social media platforms Leverage End User License Agreements (EULA), privacy and disclosure policies, other policies requiring user click through to accept terms and conditions to provide required content
Absence of concrete guidelines for mobile apps and software design, validation and verification	Consider General Principles of Software Validation: Final Guidance for Industry and FDA Staff (2002)
Cannot obtain large enough patient population for traditional clinical investigation to determine safety or effectiveness	Consider novel approaches to clinical trial design to establish key performance parameters or safety and effectiveness endpoints (e.g., use of real-world evidence and real world data)

Compliance and Risk Management Checklist

- ❑ Develop decision-trees, processes or protocols for assessing and documenting decisions regarding regulatory status of proposed apps
- ❑ Develop product design and development protocols, to reduce the risk of defects or “bugs” that may lead to user injury or product malfunctions
- ❑ Create processes for documenting and investigating product complaints
- ❑ Develop systems for assessing the potential impact of significant software “updates” or “patches” designed to improve or alter the app’s performance
- ❑ Ensure that labeling and instructions that clearly articulate the intended use
- ❑ Conduct legal, regulatory or medical review of promotional materials, labeling, and advertising for apps
- ❑ Provide clear and conspicuous disclosure of warnings, contraindications, and disclaimers, especially where such language may limit the scope of express and implied warranties
- ❑ Train developers, sales personnel and vendors, suppliers, and service-providers

Compliance and Risk Management Checklist, Cont'd

- ❑ Develop acceptance and certification criteria for third-party vendors, suppliers, and service-providers
- ❑ Ensure that agreements address regulatory status of products and regulatory obligations of partners, distributors and customers
- ❑ Ensure appropriate Reps and warranties regarding the standard of work, conformity to specifications and documentation, support and service level agreements (particularly in Software-as-a-Service Agreements)
- ❑ Address Reps and warranties regarding regulatory issues (including compliance with law, such as the Anti Kickback Statute, if applicable)
- ❑ Ensure appropriate audit rights (financial, support, data security, regulatory, as applicable) and appropriate limitation of liability, indemnification and insurance provisions
- ❑ In addition to the Development Agreement consider whether Business Associate Agreements, Safety Data Exchange Agreements, or Quality Agreements are necessary or acceptable
- ❑ Address ownership of IP for improvements or changes to technology by users or partners

Product Security: The New Frontier for Quality Management

Product Security in the QMS

- What are we working on?
- What can go wrong?
- What are we going to do about it?
- Did we do a good job?

What Can Go Wrong?


Areas of Consideration:

- Web Application
 - ePHI/PII
- Wi-Fi/Connectivity
- Automated Injection
- Third Party Vendor Management

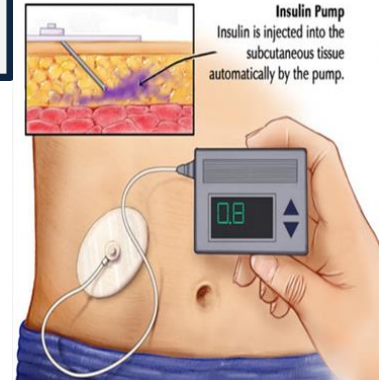
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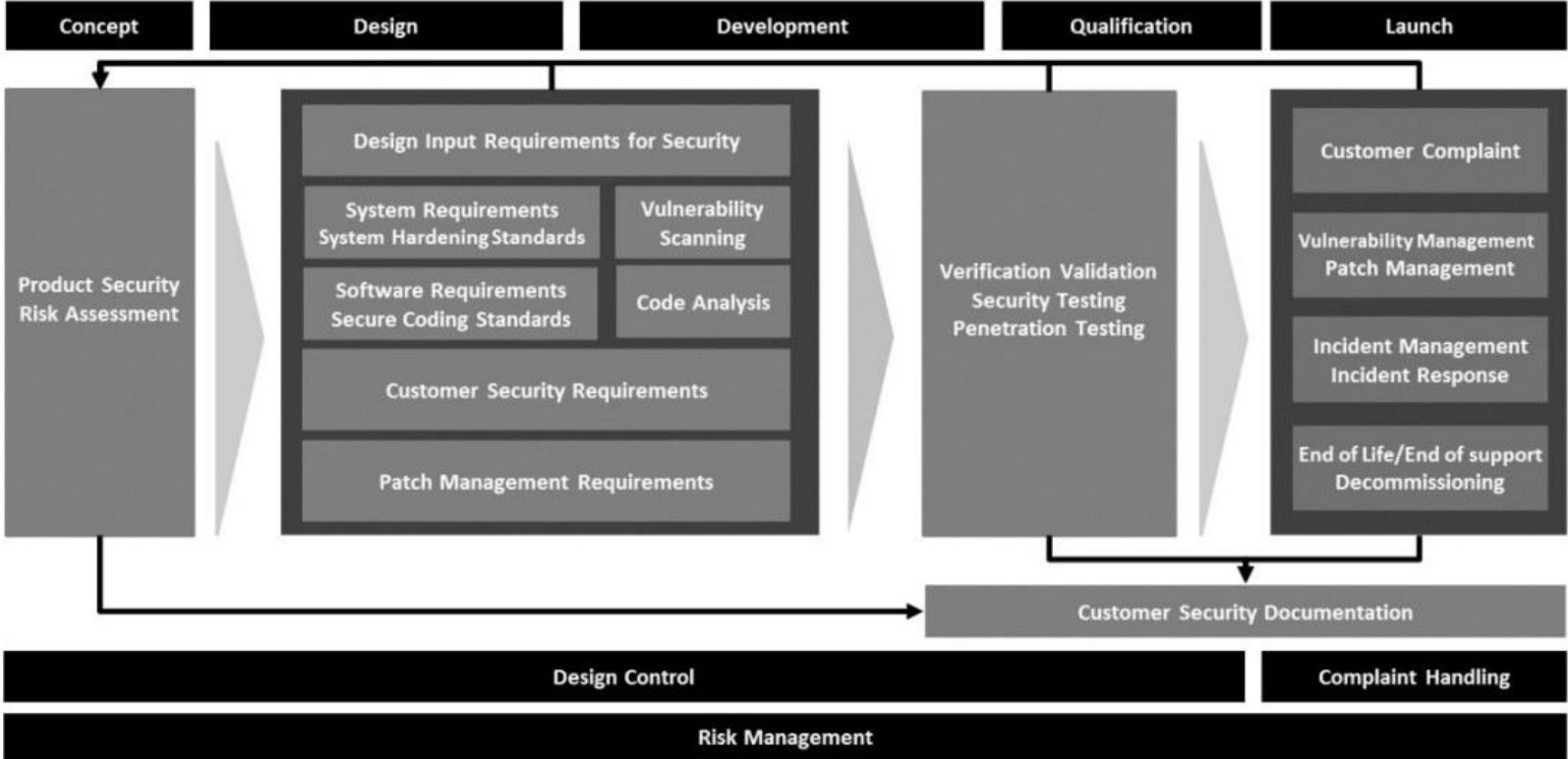
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Product Security in the QMS



Did We Do A Good Job?



Navigating the Coverage and Payment Landscape

CMS vs. FDA

CMS	FDA
“reasonable and necessary”	“reasonable assurance of safety and effectiveness”
65 years of age/older	Broad population/not age specific
CMS coverage determination (formal or informal)	FDA-approved labeling
Focus on health benefits	Focus on device function and clinical risk vs. benefits
Economic data are important	Economic data are irrelevant
Superiority endpoint required	Non-inferiority endpoint acceptable
Focus on Medicare beneficiaries	Focus on intended population
Public processes	Generally not public processes
Publishes proposed decisions	Does not publish proposed decisions



CMS Framework: Key Issues

- Coverage: Will Medicare pay?
 - Benefit Category: Does one exist?
- Code: Does the service or item have one?
 - Is the item cleared or approved by the FDA?
- Venue: Inpatient/Outpatient/ASC/Home?

Benefit Categories

What's In:

- Provider services
- Durable Medical Equipment
- Home Health
- Ambulance
- Preventive services
- Therapy (physical, speech, occupational)
- Mental Health services

What's Out:

- Alternative Medicine
- Cosmetic Surgery
- Hearing aids
- Eye glasses

Codes – The Essentials

- Codes need to tell a story to support coverage and payment
 - But, having a code does not guarantee coverage
- The entity submitting the claim needs to answer:
- Why did you do it? (ICD-10 Diagnosis Codes)
- What did you do? (CPT Codes/ICD-10 Procedure Codes)
- How did you do it? (HCPCS Codes, e.g., drug, device, DME, supply, etc.)
- Who did the work? (clinicians/facilities)

Our Hypothetical: Nimbus Diabetes Management System

- ABC Health, Inc.: Automated insulin delivery system
 - Benefit Category?
 - Code?
- DigiTech: Mobile apps
 - Eligible for Coverage?
 - Separately payable?
 - TrackMe App
 - TrackPt CDS software

Discussion and Questions