Regulatory Strategy 101
Catalyze

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Agenda

Regulatory Strategy

Your Questions

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Experience

- Over a decade @FDA (Former Deputy Division Director)
- Expertise: SaMD, Cardiovascular, Ophthalmology, General Hospital, Infection Control, Dental, Anesthesia, Respiratory
- Vice President Regulatory Affairs / Quality Assurance @Danaher (Fortune 150 Company)
- Lecturer @UCLA
- Advisor @NIH

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Regulatory Strategy

Arena (FDA? EU?)
Vehicle(s) (Applications, Good Manufacturing Practices)
Staging (Timeline)
Differentiation (Consultant? FTE?)
Economic Logic (Speed to market)

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Considerations

- Device landscape
- Specific problem(s)
- Timing engagement w/ stakeholders
- Economic logic (Use of Funds)
- Talent management

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Problems

- Is my regulation correct? 510(k)? DeNovo?
- How long will it ***really*** take to gain clearance?
- How many patients do I ***really*** need?
- How do I prepare for an FDA meeting?

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Poll: What is Your Problem?

1. I want to know the right FDA application
2. I want to know the time it will take to get my application authorized/cleared/granted/approved
3. I want to know the clinical study I need to do

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Regulatory Risk Classes & Data

Class	Risk	Example	Description/Data Requirements
I	Low	Band Aid	No FDA Application Good Manufacturing Practices
II	Moderate	Prescription Digital Therapeutic	Application Horizontal and Vertical Guidance and Test Standards Bench and/or Animal Clinical <1,000 patients
III	High	Pacemakers	Life Sustaining or Supporting Bench, Animal and Clinical Clinical 400 - 1,200

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510(k) vs PMA

510(k) **1-3MM**

- 1-2 years
- <70 pt study

PMA **3-25MM**

- 2.5-3.5 years
- >100 pt study
- Consultants => FTEs by year 3

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Regulatory Path (Timeline) Digital Health Solution

1. Regulatory Strategy
2. Clinical Strategy
3. Verification

1. >500 pts
2. Multi-Site
3. Geographic Diversity
4. Patient Population Diversity

1. Breakthrough Designation?
2. Reanalysis of data
3. Post Market Data Collection

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Regulatory Intelligence/Landscape

Where can we get information about our product and predicates?

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Product and Predicate Resources

- Guidance Document Search
- Product Classification Database (TPLC Report)
- Product Classification Key Word Search
- CDRH Device Advice

- Competitor(s) websites
- Pubmed
- Consultants
- Recalls Database Search
- Warning Letter Search

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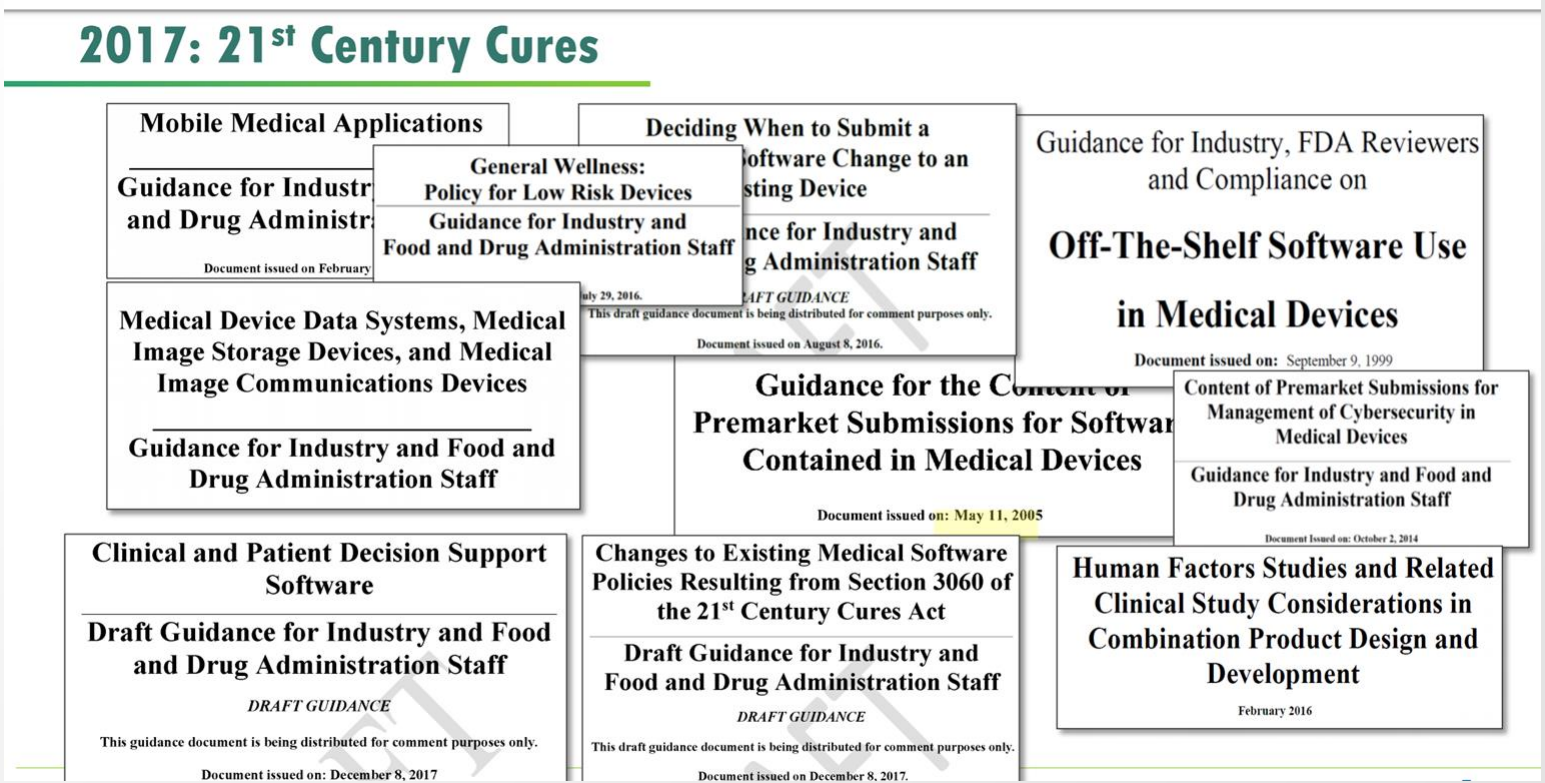
Digital Health Landscape



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Timing Engagement

Should we start talking to FDA now?

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Should we start talking to FDA now?

Yes if:

- Want to clarify pathway
- Have questions on testing needs
- Want to clarify product code
- Have the time

Risks

- Time for FDA feedback (~60 Days)
- Unfocused discussion (Requirement creep)

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Clinical Considerations

- Endpoints
- Biostatistician
- Cash to execute on testing
- 12-24 months
- US data / OUS data
- CRO

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Should we start talking to an ISO 13485 Contract Manufacturer Now?

Yes if:

- Not a wellness device
- Plan to launch in EU

Risks

- Cash burn
- Skill to evaluate

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Meeting Framework

How do I prepare?

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Best practices & Mistakes to avoid

- Minimize the page count (e.g. max 25)
- Ensure time for discussion
- Drive follow up actions/decisions
- Have a good notetaker for minutes
- Build enough time to analyze and respond to FDA written feedback before meeting
- Know the deciders in the room
- Evaluate who should attend from the company

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Control the Narrative

How best to communicate your story in the submission

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How best to communicate your story in the FDA submission

- Consistent
- Concise
- Complete
- Direct them to information
- Provide rationale (e.g. Why you have test data on multiple product versions?)

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Submission Response Plan

What should I expect during the process?

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How best to communicate with FDA during the review process. What to expect?

- Refuse to Accept
- Quick email or phone call for clarification
- Prepare for requests with quick turnaround time (e.g. < 48 hours)
- Interactive vs. Hold letter

- "4 Part Harmony" deficiencies
  - What was provided
  - Why the information provided is not sufficient
  - What additional information is needed
  - Why the requested additional information is needed

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Communication Maintenance

What are best practices for maintaining communications?

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What are best practices for maintaining communications?

Basics

- Understand why
- Answer the question directly and succinctly
- Retell past interactions
- Make the information easy to find

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Discussion

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