

Regulatory Strategy Forum for Medical Devices

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Regulatory Strategies: Where to Start

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Begin with Questions...Not Answers

- **What is a good catch-all response to any regulatory strategy question?**
- **Good regulatory strategy:**
 - Cannot be created in a vacuum
 - Often requires balancing competing priorities
- **Assemble a cross-functional product team as appropriate for the project under consideration:**
 - Internal: Regulatory, Marketing, Medical/Clinical, Engineering, Reimbursement, Manufacturing, Quality
 - External: Partner Companies, Key Suppliers, Consultants



“Peel the Onion”

- What is the device intended to do?
- How is it intended to be used?
- What claims would your company like to make?
- What is the current & anticipated regulatory landscape?
- What are the main target markets?
- Is there a multi-generational plan?
- What Agency concerns are likely to emerge?
- Are any jurisdictional issues anticipated?
- What kind of preclinical & clinical testing is needed?
- What are the postmarket considerations?



First, Let's Understand the Device

- What is the device intended to do?
- How is it intended to be used?
- Does the device have any unique features/ functionality?
- Who are the intended users (surgeons, patients)?
- Will it be used for a new type/subset patient population?
- Is it used for a rare condition?
- What is the intended use environment (home, hospital, ambulance, Rx vs. OTC, etc.)?
- Is the mechanism of action well understood?
- Will it require any unique accessories?
- Are there any novel or controversial materials?
- Is it single use, reusable, serviceable?



What are the Claims?

- **Claims are things you want to be able to say about your product, ideally for competitive advantage**
- **Device claims may involve:**
 - **Clinical:** Prevents SCD, Improved mobility
 - **Safety:** Biocompatible, Infection-free
 - **Characteristics:** Lubricious, Flexible
 - **Functional:** Accurate, Sensitive
 - **Cost-related:** Time savings, efficient, cheaper
- **Claims are reflected in product labeling (instructions for use, patient labeling, promotional materials)**
- **Some regulatory authorities may be concerned about some claims and not others**



What Claims Would You Like to Make?

- **How will your company distinguish this device in the market to gain competitive advantage?**
- **Which claims are most important (must-haves)? What are the “nice to haves”?**
- **What kind of data will you need to support your claims?**
- **Do you need these claims at time of approval?**
- **Does your company want aggressive claims, or “lighter” claims but faster approval?**
- **How will you get alignment on claims within your company?**
- **How will you get alignment on claims with regulatory agencies worldwide?**



Get Internal Alignment on Claims

- **Start early in development**
- **Expect different needs/wants**
 - **Clinical** - **Engineering**
 - **Marketing** - **Reimbursement**
 - **Partner Companies**
- **Educate team members on regulatory processes and requirements**
- **Set realistic expectations**
 - **What claims are clinically meaningful**
 - **What claims can be demonstrated**
 - **Tradeoffs (claims, data, and approval timeframes)**



What is the Regulatory Landscape?

- **What other kinds of devices are like yours?**
 - **If no exact fit, what aspects are presented by other products?**
 - **What was required for their regulatory approval?**
- **What successes/pitfalls did competitors experience?**
- **Are guidance documents available?**
- **Have panel meetings been held for similar products or for products used for similar conditions?**
- **Is positioning as PMA a desirable option?**
- **Recommendation: conduct detailed comparison to other related devices for all key characteristics that are significant from regulatory perspective**
 - **How does your device differ?**
 - **How will you resolve regulatory issues raised by those differences?**



What are the Target Markets?

- What are the must-have first countries to get approval?
- What are the 2nd tier countries?
- Do any target markets require another country's approval?
- What are the language requirements for labeling/interfaces?
- Are there any mandatory product standards?
- What are the regulatory application fees?
- Will clinical studies be required in a country as condition of approval there?
- What countries will require facility inspections?
- Will the study endpoints vary based on particular country requirements (e.g., need to show cost effectiveness in addition to s/e)?



Is There a Multigenerational Plan?

- What are the long-term regulatory objectives?
- Does the regulatory strategy for a 2nd generation depend on approval of certain aspects in the 1st generation?
 - To simplify future studies
 - To establish regulatory predicate/precedent
- Does the company even want to market the 1st generation, or is the 1st generation mainly of interest for regulatory purposes?
 - Will bridging data be necessary for 2nd generation?



What Agency Concerns May Emerge?

- **Use research, intuition, contacts to anticipate:**
 - What concerns might Agency have about this device or use?
 - Are there particular features that might require unique studies?
 - Might off label use be a concern?
 - What stumbling blocks did competitors encounter?
 - How have other Agencies regulated products for this condition?
 - Might this product raise unique concerns (e.g., ReGen, Plan B)?
 - Does the product represent a sea change in medical practice?
 - Does it involve a special patient population?
- **How might the Agency review team be constituted?**
 - Are there any “pet” concerns of the review branch or Division?
 - Might consulting expertise outside of CDRH be needed?
- **How will you mitigate these concerns?**
 - Agency meetings, studies, etc.

Is Jurisdiction an Issue?

- **Is your product a straightforward device, or might a jurisdictional issue be raised?**
 - Liquids, gases, etc. sometimes challenged as devices
 - Tissues or devices used with HCT/P or blood
 - Main determinant: chemical or metabolic action
- **Is your product a combination product?**
 - What is its primary mode/mechanism of action?
 - How will you determine lead Center/agency?
 - Even if regulated as device, review input from drug and/or biological product reviewers should be expected
 - Will two marketing applications be necessary?
 - How will GMPs and AER be handled?
 - Do you have the right expertise (e.g., CMC)

What Kind of Testing Will be Required?

- What kinds of bench, animal, biocompatibility, software, EMC, sterility studies will be needed at investigational phase? For marketing application?
- What existing data can be leveraged, and where will new studies be needed?
- Will new test methodologies need to be developed?
- What are the clinical study endpoints? What follow-up duration will be required?
- Will foreign data be acceptable? Should data be collected in specified geographies?
- Will data to support reimbursement be necessary?

What are the Postmarket Concerns?

- Will post-approval studies be necessary (e.g., longer follow-up, patient subset, answer lingering questions)?
- Is the necessary infrastructure in place?
 - Is the device a type that may require more MDR/MPR/vigilance reporting for company?
 - Is the device a type that may require servicing by company personnel?
 - Is the company prepared for possible field corrections (e.g., device type more likely to be subject to recall)?
 - Would device tracking to patient level be necessary?
- Will stability testing/retention samples be necessary?

Recommendations

- **Begin with questions, not answers**
- **Peel the onion**
- **Do the right research**
- **Look beyond what's fastest**
- **Consider downstream issues**
- **Define and document the strategy**
- **Get the regulator's perspective**
- **Confirm the strategy**
- **Be prepared for changes!**