Good Guidance Practices
Increasing Value
Improving Process

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Background and Disclosures

University of Minnesota Law School	• Professor of Practice • Teach FDA and corporate compliance • Supported in part by NSF and NIH Grants
Counsel, Faegre Baker Daniels	• Advise clients on FDA regulatory matters, compliance issues and regulatory policy issues • Work with 510(k) Coalition
CEO – MR3 Medical LLC	• Start up medical device company • Probably PMA pathway if product successful

Key Guidance Topics

Guidance development

- Transparency and input
- Timing

Use of guidances

- Draft guidances
- Final guidances

Regulatory agenda

- Input process
- Specific suggestions

Overview

- Guidance documents are highly valuable
  - Valuable to all stakeholders
  - But should not be used in lieu of regulation
  - Understanding appropriate use of guidances is key
- We encourage development of new guidances
- Guidance drafting is resource intensive
  - Need to avoid non-value added time
  - Draft guidances should reflect real-life and realistic approaches
- Precision in drafting is critical
  - Stakeholders must read literally and strictly
- All stakeholders part of improving guidances
- Guidances “age” just like everything

Guidance Development Key Challenges

- **Challenge**: Pre-draft process
  - Need to avoid drafts with major unintended issues
  - Limited pre-draft stakeholder input increases issues
- **Possible solutions**: Obtain stakeholder input prior to release of a draft
  - Solicit high level idea, issues or concerns on specific topic
    - 2-3 page overviews
    - Thought piece for drafters
  - Public workshops
  - Stakeholder outreach
  - Use of on-going working groups

Guidance Development Key Challenges

- **Challenge:** Process transparency
- **Solutions:** Add process information
  - Publish list of guidances actually under development
  - Provide time frames for actions
    - Next major action or step
  - Publish current status of drafts
    - Within CDRH, Agency wide, HHS, OMB

Guidance Development Key Challenges

- **Challenge:** Identifying need for new guidances and revisions to existing guidances
- **Solutions:** Added stakeholder input
  - Annual regulatory agenda forum
  - Stakeholder identification of needs
  - Stakeholder identification of “aging” guidances

Key Guidance Challenges

- **Challenge:** Developing guidances of highest value to all stakeholders
- **Solution:** Expanded input into regulatory agenda
  - Annual regulatory/guidance forum
  - Defined process for submitting proposed guidance topics and substance
  - Defined criteria for determining when a new guidance is appropriate
    - Multiple similar questions or requests
    - Implementation of new regulations or statutes
    - Fundamentally new product types

Guidance Development Key Challenges

- **Challenge:** "Perpetual" draft status leads to uncertainty and obsolescence
- **Solution:** "Term limit" drafts
  - After a preset time (24-30 months?) a draft guidance must
    - Be withdrawn
    - Have a re-opened comment period
  - Provide transparency in status of draft review

Guidance Development Key Challenges

- **Challenge:** Keeping guidances current
- **Solutions:** Improved process for updating
  - Stakeholder input of need to update
  - Streamlined process for administrative and consistency updates
  - Formal, periodic reassessment of any guidance
    - Every 5-10 years
    - Develop a stream-lined, resource sensitive process
    - Guidance remains in place during reassessment (absent special circumstances)
    - Stakeholder input via automatic comment period

Key Guidance Implementation Challenges

- **Inappropriate use of draft guidances:** Many treat draft guidances as final
- **Solutions:** Eliminate uses of draft guidances
  - Separate draft guidances from final guidances on the website
  - Mark every page as “draft”
  - Prohibit use of draft guidances in regulatory decisions, inspections, enforcement decisions and other guidances
  - Training of both Center and ORA
  - Prompt escalation process
  - Stakeholders must likewise not use draft guidances

Key Guidance Implementation Challenges

- **Challenge:** Lack of usability
- **Solution:** Improve accessibility and usability
  - Improve searchability
  - One topic/one guidance
  - Clear, descriptive titles
  - No “surprise” off-topic statements
  - Greater citation to guidance documents in regulatory decision, including deficiency letters, 483s and denials
  - On-going Center, ORA and stakeholder education and communication

Key Guidance Challenges

- **Challenge:** Determining the applicability of external standards and regulatory frameworks
- **Solution:** Ensure open assessment
  - To the extent international standards are consistent with US law and policy, adoption of international standards should be encouraged
  - If possible, inform stakeholders of opportunities to provide input into such external framework development

Possible Guidance Priorities

- 510(k) Paradigm/Program
- 510(l)
- 510(m)
- When Does Product Subject to Recall Require 510(k)
- Recall Classification
- Closing and Timeframes for 483s, Warning Letters and Recalls
- Risk/Benefit for 510(k)
- Defining Claims and Data Requirements
- Definition and Process for Withdrawing Submissions
- Unique Device Identifiers
- Finalize 510(k) Transfer of Ownership
- Finalize Infusion Pump
- Finalize *de novo*
- Finalize Anti-Microbial

Conclusion

- Guidances are highly valuable
- Agency and stakeholders commit substantial resources to the development and implementation of guidances
- Processes should maximize high-quality and current guidances
- Draft guidances are just that—draft
- Guidances are just that—guidances
- All stakeholders must be knowledgeable and engaged