Deficiency Writing for Third Party Reviewers

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Benefits of Clear Communication

• Efficiently identify outstanding issues
• Clearly identify expectations
• Reduce multiple rounds of addressing the same issue
• Lead to faster, timely review decisions
How to Use this Presentation

1. Deficiency Writing for Third Party Reviewers
2. Examples and Knowledge Checks
Learning Objectives

• Describe guiding principles of deficiency writing
• Understand four-part harmony format
• Differentiate between major and minor deficiencies
Guiding Principles of Deficiency Writing
Background of Deficiency Writing

• Third Party Reviewers evaluate 510(k) submission
• Additional information may be needed to make final recommendation
  – Requests for additional information are known as deficiencies
  – Communicated through deficiency letters
Relevant Guidance Documents

- **Developing and Responding to Deficiencies** in Accordance with the Least Burdensome Provisions

- **The Least Burdensome Provisions**: Concept and Principles

- **The 510(k) Program**: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
Guiding Principles

• Only include information necessary to make regulatory decision

• Consider and suggest alternative approaches
Guiding Principles

• Deficiencies should request:
  – minimum (that is, least burdensome) amount of information
    • necessary to adequately address the issue
    • in the most efficient manner
    • at the right time
Four-Part Harmony
Benefit of Four-Part Harmony

• Ensures understanding of request
• Facilitates FDA review of Third Party recommendations
• Improves efficiency and timeliness of 510(k) process
Part 1: What Was Provided

- Identify what was provided
- Acknowledge any information the sponsor provided relevant to the deficiency
Part 2: What Is Deficient

• Explain what is deficient in submission
• Be specific about why current information is deficient or not adequate
• Cite references from submission
Part 3: Why Is It Needed

• Explain reason why information is needed
• “Why” may not be understood by audience with diverse backgrounds
  – Scientist, Regulatory Affairs, Business
  – Explicitly identifying reason helps to understand issue
• Reference applicable section of final rule, guidance, or FDA-recognized standard
Part 4: What Is Needed

• Identify what is needed
• Be succinct and specific
• Use directive statements such as:
  – “Please provide”
  – “Please justify”
  – “Please clarify”
Part 4: What Is Needed

• Avoid “Shall” or “Must”

• Avoid questions, for example:
  – “Why did you...?”
  – “What if you...?”

• Suggest alternative ways of addressing the issue
Four-Part Harmony

1. What was provided
2. What is deficient
3. Why it is needed
4. What is needed
Major and Minor Deficiencies
What are the Terms?

• **Major Deficiency**
  - Will lead to a “Not Substantially Equivalent” recommendation if not resolved

• **Minor Deficiency**
  - Can be resolved in a straightforward manner, but needs to be addressed

• **Additional Considerations**
  - Not expected to preclude a favorable decision
Major Deficiencies

• Time- or resource-intense requests (e.g., new testing or analysis)

• Should only be included if their resolution is necessary for the final decision

• Written in four-part harmony
Minor Deficiencies

• Still need a response, but straightforward (e.g., labeling statements)
• Related to potential misbranding or adulteration
• Written in four-part harmony
Additional Considerations

• Is it needed for the decision?
  • If no, it is an additional consideration
• No response from sponsor is needed
• They do not need to be written in four-part harmony
Tips for Good Deficiencies

• Be as detailed as possible
  – cite page numbers, paragraphs, sections of submission

• Provide context for very specific deficiencies

• Prioritize in order of significance
Summary

• Clearly communicating deficiencies is key to efficiently completing the review of an application

• Best practices in deficiency writing incorporate least burdensome and four-part harmony principles

• Organize deficiencies into major, minor, and additional considerations sections
  – and prioritize in order of significance
Your Call to Action

1. Apply the principles described in this presentation

2. View the companion CDRH Learn module for specific examples of deficiency writing