

# 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

[www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions)

- [The Least Burdensome Provisions](#): Concept and Principles

[www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles)

- [The 510\(k\) Program](#): Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

[www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles)

# 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-intensive 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



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