Deficiency Writing for Third Party Reviewers

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Welcome to the CDRH Learn module on Deficiency Writing for Third Party Reviewers. I'm Ksenia Blinova at the FDA's Center for Devices and Radiological Health.

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This training is about clear communication and its benefits for the medical device applicant, third party reviewers and the FDA. The four-part harmony approach to writing deficiencies allows for the efficient identification of outstanding issues in medical device submissions, and the FDA, or Third Party Reviewer, expectations for resolving those issues. Ultimately, the approach that I'll be talking about today may reduce the need for multiple rounds of discussion of the same issue and will hopefully lead to faster, more streamlined review process and decision making.

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This training consists of two separate modules, which I recommend you view in order. In this first module, I will describe deficiency writing in accordance with the least burdensome guiding principles. The second module provides device-specific examples and gives you a chance to check your knowledge and understanding of the material I cover in this first module.

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Let's review the learning objectives for this module. I'll start by describing the least burdensome guiding principles for writing deficiencies and relevant FDA guidance documents. Then, I'll introduce and explain the specific format for deficiency writing, called four-part harmony. I'll then describe the difference between major and minor deficiencies, and how to include them into the additional information requests.

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Let's start with the guiding principles behind writing deficiencies.

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Third party reviewers evaluate 510(k) submissions and provide their recommendation to the FDA. When reviewers identify the need to request for additional information, such requests are called deficiencies. These are communicated through deficiency letters.

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FDA has developed a guidance document titled "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" that was published in September 2017. This guidance lays the foundation of today's training, by outlining an approach to developing and responding to deficiencies. Deficiency writing, as well as other FDA processes, should occur in accordance with the least burdensome provisions covered in the second guidance. Finally, the last guidance covers the entire 510(k) program. I've included links to all three guidances on this slide for your future reference.

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According to the principles outlined in these guidances, you should only request for information necessary to make a regulatory decision**.** Alternative approaches to resolving regulatory issues should be considered to optimize the necessary time, effort, and resources involved in developing a response. For example, can postmarket information play a role?

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The deficiencies should request the minimum, that is, least burdensome, amount of information necessary to adequately address the identified issue, in the most efficient manner, at the right time.

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FDA has adopted a specific format for deficiency writing, called four-part harmony. Let's take a closer look at this right now.

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Following the four-part harmony format in writing deficiencies helps the applicant to fully understand any requests for additional information - why the information is being requested and what specifically needs to be submitted. Writing in four-part harmony facilitates FDA review of Third Party recommendations because the FDA reviewer will not have to look beyond your memo written in this clear and recognizable format. Ultimately, writing in four-part harmony improves the efficiency and timeliness of the 510k process.

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As the name suggests, there are four parts to the four-part harmony. Part 1 is to restate what was provided in the original submission. This is a short acknowledgement of any information the applicant may have provided relevant to the deficiency. This acknowledgement is necessary to show that certain relevant information was reviewed and was not ignored. This is also the place to reference a specific part of the submission relevant to the regulatory question.

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Part 2 is to describe what is deficient. It should specifically state what is missing in the information provided. Again, it helps to include references to the relevant chapter, paragraph or page in the submitted document.

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Part 3 is to explain why the additional information is needed. Although a reviewer may fully understand why additional information is necessary, this might not always be clear to the recipient of the deficiency letter. Remember, the recipient might be a regulatory affairs specialist, a scientist, a business person, or have any multitude of backgrounds, and as a result, might not completely understand the reason for the request.

Explain the relevance of the requested information to the substantial equivalence determination, including, when appropriate, the reference to an applicable section of final rule, guidance, or FDA-recognized standard. When the deficiency cannot be traced to a specific document and relates to a scientific or regulatory issue pertinent to the determination, you should cite the specific scientific issue and the information to support your position.

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Part 4 is to tell the applicant what we need. You should be succinct about what you need. Too much background or too many words makes it hard for the reader to spot the writer's point. You should be specific and complete. No one can submit an "et cetera". You should use a professional tone. We recommend you use direct phrases to communicate deficiencies, such as "Please provide…", "Please justify….", "Please clarify".

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In contrast, please avoid words that suggest an absolute requirement, such as “shall”, “must” or “require”, unless you provide a clear reference to the law or a regulation. “Must” has specific legal implications and should not be used unless directly linked to either the statute or regulations. A special control for a device is an example of a specific requirement. We also recommend against using indirect questions, such as: “Why did you…” or “What if you….”. Remember, when appropriate, suggest alternative ways of addressing the issue.

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To bring it all together, let’s recap all four parts of the four-part harmony structure. Four-part harmony recommends that all deficiencies: one, identify what was provided; two, explain what is deficient in what they provided; three, explain why we need additional information; and four, identify ~~w~~hat the applicant should provide.

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Four-part harmony should be applied to writing both major and minor deficiencies. Let’s review what these terms mean.

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Let’s start with the definitions. Major deficiencies are those based on the least burdensome principles that, if not resolved, will lead to a Not Substantially Equivalent decision for a 510(k) submission. Minor deficiencies are requests that can be resolved in a straightforward manner, but still need to be addressed to meet regulatory requirements. Additional considerations may also be included. These are suggestions, recommendations, or requests that are not expected to preclude a favorable decision on the marketing application.

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Major deficiencies are time-or-resource-intense requests, for example, a request for new testing or data analysis.

Major deficiencies should only be included if their resolution is necessary to reach a final decision regarding the marketing authorization recommendation. They should be written in four-part harmony.

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Minor deficiencies are issues that can be resolved in a straightforward manner, for example, by changing the label statements. They still need to be addressed to meet regulatory requirements or to prevent potential misbranding or adulteration. Minor deficiencies should also be written in four-part harmony.

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To distinguish additional considerations from the minor and major deficiencies, ask a question: “Is it needed for the decision?” If the answer is “no”, then it is an additional consideration. Because additional considerations are not expected to preclude a favorable decision, they do not require an applicant’s response. Additional considerations do not have to be written in four-part harmony, but this is still the best practice.

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Here are some additional tips for good deficiency writing. Be as detailed as possible about the submission - for example, indicate the specific location you reference, such as “on page x, section y of

the submission". If the deficiency is about a very specific item, make sure you provide enough information to put the request in proper context. Deficiency categories should be ordered by what you believe are the most significant. This is related to the time or resources necessary for the applicant to address the deficiency.

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Let's summarize what we have covered in this module. Clear communication of deficiencies is a key to efficiently completing the third-party review and reaching a final recommendation. Deficiencies should be least burdensome and written in four-part harmony. FDA separates deficiencies into major, minor, and additional considerations. These are prioritized in order of significance.

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Let's conclude with your call to action. First, apply the principles of efficient deficiency writing described in this presentation. And, second, view the companion CDRH Learn module containing specific examples of deficiency letters to test your knowledge.

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Thank you for viewing. I hope that the principles described today will be your way of writing deficiencies now.

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