in focus

Medical devices

What to include in non-clinical bench performance testing

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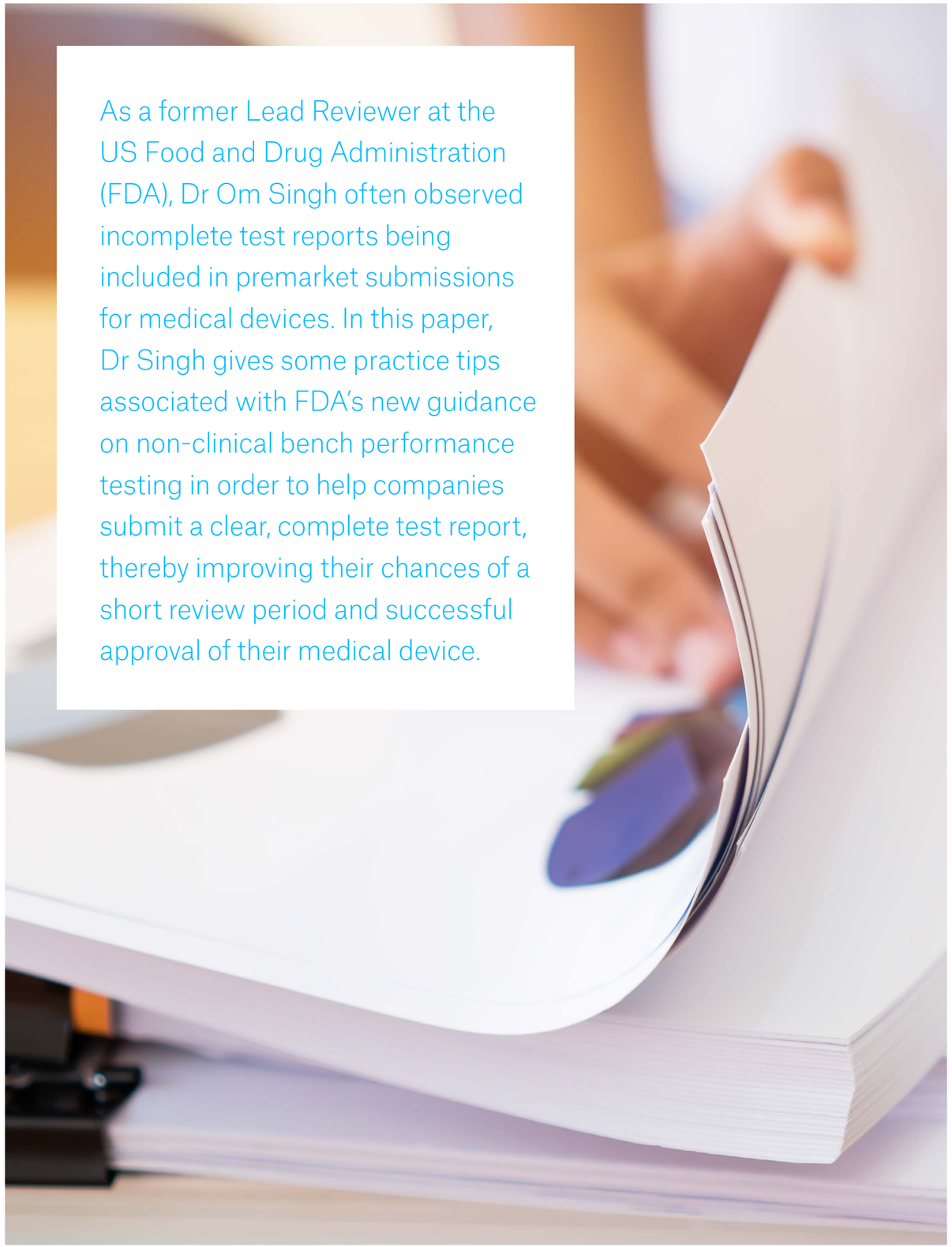


As a former Lead Reviewer at the US Food and Drug Administration (FDA), Dr Om Singh often observed incomplete test reports being included in premarket submissions for medical devices. In this paper, Dr Singh gives some practice tips associated with FDA's new guidance on non-clinical bench performance testing in order to help companies submit a clear, complete test report, thereby improving their chances of a short review period and successful approval of their medical device.

In the United States, the FDA is responsible for reviewing the safety and efficacy of medical devices. Based on the complexity and intended use, medical devices are categorized into three different classes – Class I, Class II, and Class III. If not exempted, most Class II and Class III medical devices are subject to a rigorous review for safety and effectiveness under a different application submission process, which largely includes premarket notification (510(k)), premarket approval (PMA) application, and *De Novo* requests. Each submission requires appropriate and complete testing to be presented in a report so that the Agency can evaluate the safety and efficacy of the device.

However, applicants are often confronted with FDA identifying major deficiencies in the test report due to incomplete information.

To help applicants reduce the risk of rejection or receiving a notice of deficiencies, FDA published a new guidance document in April 2019.

The new guidance clarifies the contents and format required for non-clinical bench performance testing in premarket submissions, and explains the depth of information required[1].

In the following three sections we outline practice tips associated with FDA's new guidance.

It is in the best interest of the applicant to help FDA reviewers by providing a complete, clear and concise submission so that they do not have to tease out review-related information.

[1] Recommended Contents and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions. https://www.fda.gov/media/113230/download

Practice tips – non-clinical bench performance testing

1 Major points from guidance:

FDA's new guidance explains the type of information to include in a variety of submissions, including:

1. Non-clinical bench performance testing packages for premarket approval (PMA) applications
2. Humanitarian device exemption (HDE) applications
3. Premarket notification (510(k)) submissions
4. Investigational device exemption (IDE) applications
5. *De Novo* requests

The FDA recommends that all premarket submissions include 'test report summaries' and 'complete test reports'.

The test summaries embedded in the submission should discuss how the performance test results support substantial equivalence for the 510(k), and a reasonable assurance of safety and effectiveness for the PMA.

2 What is required in the test report?

FDA requires that test reports are provided in three different sections:

i) Test report summaries

ii) A complete test report

iii) Test protocols

i) Test report summaries

The test summaries should be included in the body of the text, in the executive summary document of an actual submission, or as a distinct document. The guidance states that the test summaries should 'briefly describe and summarize the testing performed to support the submission.' Essential elements of testing such as the name and objective of the test, as well as a brief description of the test methods (including sample size, device type and consensus standard(s), criteria for acceptance, summary of results, and brief discussion of the results) should be provided.

Notably, the summary of results must specify the quantitative and qualitative data assessment, including statistical information for data analysis in light of the assessment criteria. The test summary must also provide a reasonable justification if the assessment criteria were not met due to protocol deviations, along with a potential resolution for concerning results. A brief discussion of the results and conclusion is recommended to interpret how the test results would support the overall submission.

ii) Complete test report

A complete test report is required, which can be marked with the appropriate appendix number in the submission. The FDA recommends high standards for complete test reports so that the safety and effectiveness of the device can be evaluated efficiently. Per the guidance document, 'A complete test report means the entirety of the testing documentation submitted for a study.'

In addition to the elements recommended for test summaries, the complete test report should contain a description of methods, including protocols, test parameters, conditions, assessment criteria, and sample size. It should also include scientific rationales for selecting one particular device model to represent a family of devices. The complete test report must specify whether the sample type is the entire device, a part or component of the device, or the device's composition material or packaging, as well as the number of devices used in the testing, i.e.sample size.

In the complete test report, FDA recommends that the submitter provide a data analysis plan for quantitative and/or qualitative assessments of the test device. The interpretation of results should reveal whether the pre-specified acceptance criteria were met. In the case of a recognized protocol deviation, the submitter must discuss how the study results and conclusions were impacted by the deviation and if the data integrity was compromised. It is essential that the submitter provides a scientific rationale if the acceptance criteria were not met. Scanned copies of test reports are acceptable as long as they are legible for evaluation.

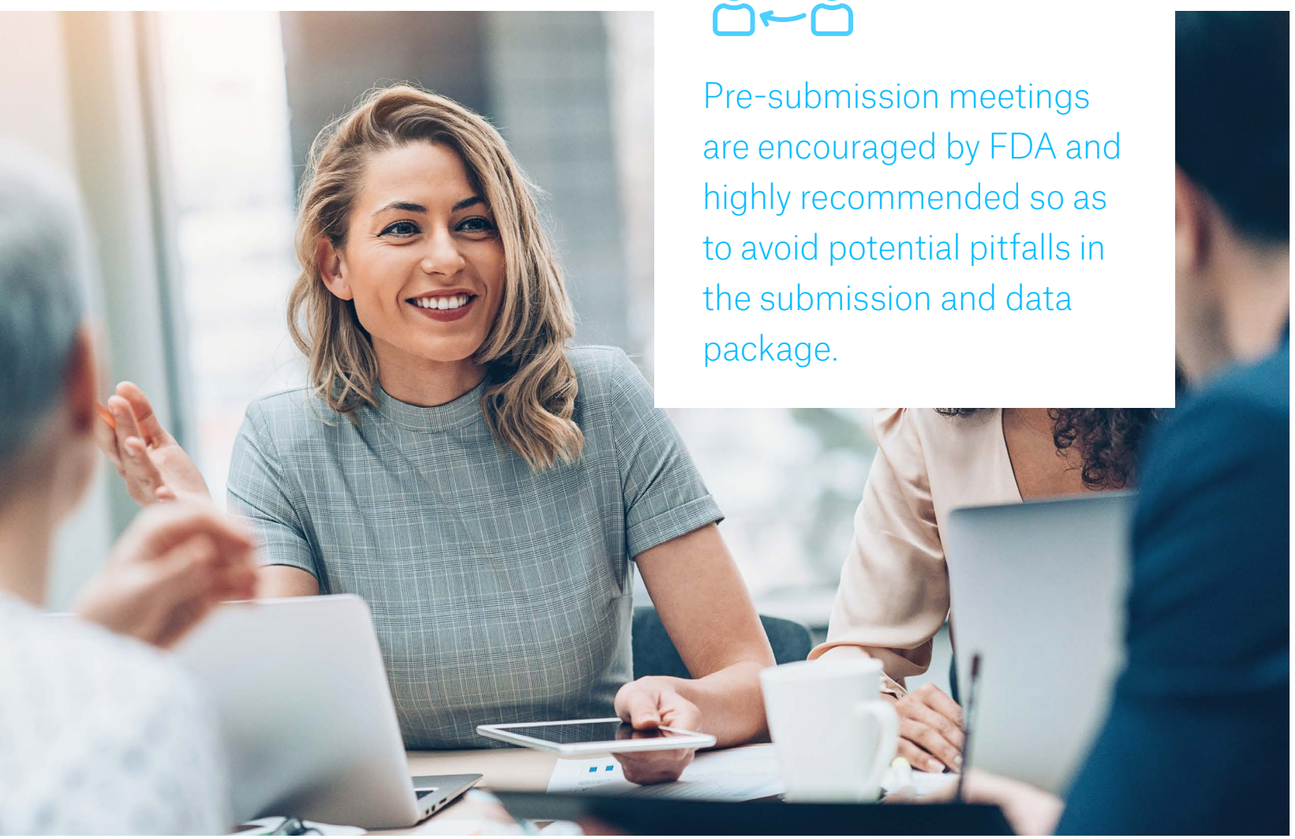
iii) Test protocols

The protocol should be provided in the test report, including the test objective, a description of test methodology, acceptance criteria, and the data analysis plan. However, if these elements are included in the test report, a separate test protocol document is not necessary.

3 How does following content and formatting recommendations help submitters?

It is in the best interest of the applicant to help FDA reviewers by providing a complete, clear and concise submission so that they do not have to tease out review-related information from descriptive test reports. If reviewers have a difficult time understanding the test methodology, conditions, and so on, this has the potential to result in a deficiency for the submitter. By providing a clear and complete test report, applicants increase their chances of a short review period and successful approval.

It is important to note that in addition to the guidance explained above, FDA does have a mechanism for applicants to request and obtain feedback in pre-submission meetings[2]. However, these meetings are limited for FDA to review the test protocols and not the test results or the interpretation of the test results.



Pre-submission meetings are encouraged by FDA and highly recommended so as to avoid potential pitfalls in the submission and data package.

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For almost 30 years, TSG Consulting has provided companies around the world with regulatory guidance and scientific expertise.

Our experts can assist in the test-report process by:

- Working with clients to develop strategies for device-specific performance testing for safety and effectiveness
- Assisting in the preparation of test protocols and evaluating the test reports prior to FDA's review
- Developing test report summaries and interpreting value added data points
- Helping fill the gaps of test reports to meet the required standards of data generation for a device's safety and effectiveness
- Representing and supporting clients throughout the submission process with clear and complete responses to FDA deficiencies

Interested in learning more?

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About the author

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Dr Singh has substantial experience working with companies looking to commercialize medical devices and antimicrobial products such as sterilants, high-level disinfectants, and antiseptics. His previous experience working at the US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) allows him to better advise companies of anticipated regulatory hurdles when seeking approval and registration for their human health products.

[2] Singh OV (2019) Importance of pre-submission meeting with FDA prior to 510(k) submission. TSG Consulting. Washington, DC, USA.

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