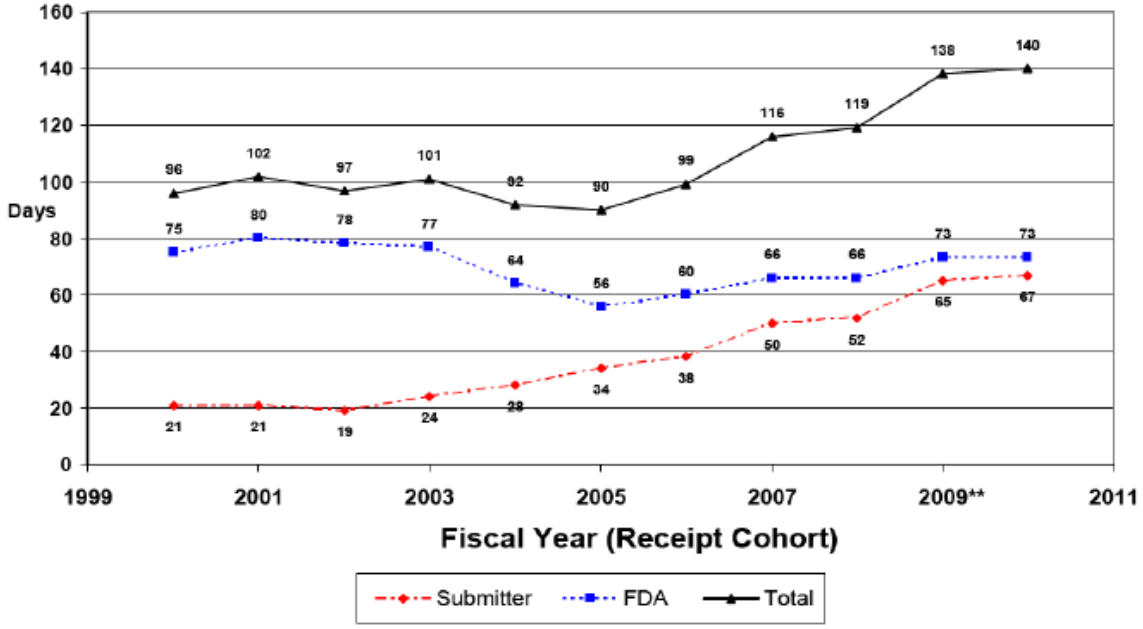
Tips for Preparing 510(k) Submissions

Review Times Increasing

Perhaps you are aware that review times have increased for 510(k) submissions. The below chart has been extracted from the FDA's recently published "Analysis of Premarket Review Times under the 510(k) Program". As can be seen from the chart below there has been a significant increase in review time since 2006. The evidence from this report is that the increase in average review times is due to poor quality of the submissions prepared by the manufacturers. In truth the more detailed questions being asked by reviewers suggests the need for a more structured approach to the submission process.

Chart 1: Average Time to 510(k) Decision



*SE and NSE decisions only: Averages may not sum to total due to rounding
** 2009, 2010 some cohort still open as of July 5, 2011 data may change

Reducing Reviewer Questions

The FDA reviewers need to satisfy certain criteria in order to ensure that each submission is complete. Attached to this summary are two checklists that are used by reviewers to evaluate submissions. The first checklist includes the basic sections of the 510(k) submission and the second is the list of documentation required for submissions that contain software. CCS has used these checklists to ensure that all required items for the submission are covered. In addition, these checklists serve as a roadmap to help reviewers complete their review process.

The referenced FDA report of 11/2011 cited the following as the top three quality problems with initial submissions:

(1) Inadequate device descriptions
(2) Inadequate performance testing
(3) Missing or inadequate predicate comparison(s).

The most deficiencies (74%) were cited in the "device description" section (inadequate 52% and discrepancies 22%). This is an area of the 510(k) that was not traditionally scrutinized in detail but is clearly receiving much greater attention with current review practices. The same can be said for "performance testing" with 60% deficiencies (52% deficient and 8% missing).

Realizing these areas are the ones most often cited as deficient is important to ensure that these sections are given increased attention during preparation of the submission. It also follows that the new training for reviewers is placing increased emphasis on these sections.

Responding to Questions

It is our experience today that almost every submission for a device with any level of complexity will receive questions. Several of our recent submissions have received over twenty questions in an Additional Information (AI) letter after the initial submission was reviewed. In order to receive a successful clearance each question needs to be thoroughly addressed.

The AI letter states that a response to questions is requested in thirty days. Usually this is not sufficient time to answer all of the questions received so it is best to ask for an extension. We recommend any extension should request the maximum amount of time of 180 days. Of course the response can be submitted as soon as it is ready, although the 180 day request provides additional time if necessary.

If the answer to the question is already in the submission it is best to simply provide the answer again. If you feel the question is inappropriate it is best to try to answer the question as best you can. Realize that if your answer is not accepted you can request a conference call with a supervisor or the branch chief to discuss further.

Simplify the Submission

It is useful to keep the perspective of the reviewer in mind as you prepare your submission. Realize that the reviewer has many other submissions to review so the easier you can make their job the better. Simplifying the review process includes following the attached checklists and making the submission as well as the attachments easy to read by providing summaries for large documents or complex discussions. Pictures and graphs make the submission easier to read and allow the reviewer to more quickly grasp complex concepts and understand the device. It is also very important to be consistent in the use of terminology throughout the submission. This will not only facilitate the reviewer's ease of understanding the device, but also prevent questions related to the misalignment between intended use statements and device descriptions in supporting documentation.

Using checklists is not only helpful in addressing the structure of the submission but also in demonstrating compliance to performance standards. Checklists that show coverage of guidance or standard test requirements facilitate a more efficient review.

Summary

The 510(k) review process has become more complex in the last five years and it likely to become more complex in the future. Following checklists to ensure the completeness of the submission and performance testing can simplify the submission review (be careful not to blindly follow the checklist without providing the necessary content for each element of the checklist). It is also important to keep in mind the reviewer as you prepare the submission and include pictures, diagrams, graphs and summary information to make the submission easier to read.

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References:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Food and Drug Administration, CDRH, May 11, 2005
- Format for Traditional and Abbreviated 510(k)s, Food and Drug Administration, Center for Devices and Radiological Health, August 12, 2005
- Analysis of Premarket Review Times under the 510(k) Program, FDA, CDRH, 11/2011.
- Certified Compliance Solutions 510k Format Checklist

CCS provides additional services in the areas of:

- Medical Device Validation and Verification
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