Hogan Lovells

CDRH's "Critical to Quality" PMA Pilot Program Opens to Applicants Today

September 29, 2017

The Food and Drug Administration (FDA or the Agency) Center for Devices and Radiological Health (CDRH or the Center) recently announced that it will be leading a voluntary Premarket Approval Application (PMA) "Critical to Quality" pilot program (the "voluntary PMA pilot program"),[1] which will engage nine PMA applicants in identifying and defining device characteristics that reflect quality in device design and manufacturing. The announcement of this program is aligned with CDRH's 2016–2017 strategic priority to "Promote a Culture of Quality and Organizational Excellence."[2]

A key benefit to firms interested in this voluntary PMA pilot program is that FDA will forego the standard PMA preapproval inspection and will, instead, perform a postmarket inspection focusing on the applicant's implementation of the "critical to quality" (CtQ) controls identified in the applicant's PMA. This may potentially signal a future where FDA no longer conducts PMA preapproval inspections for certain qualifying entities, depending on the outcome of this pilot.

The voluntary PMA pilot program will run from September 29, 2017, to December 31, 2018, or until a total of nine PMA applicants have been enrolled. Firms participating in the voluntary PMA pilot program will be expected to have early discussions with FDA regarding device design and manufacturing process quality information to help FDA review the PMA manufacturing section and post-approval inspections.

Participation criteria

FDA indicated that the first nine applicants that meet the participation criteria will be accepted into the voluntary pilot program. In order to participate in the pilot program, the firm must:

- Submit a request for a pre-PMA q-submission meeting (at least 75–90 days in advance of submitting the PMA), that includes (1) the recommended information identified in the FDA

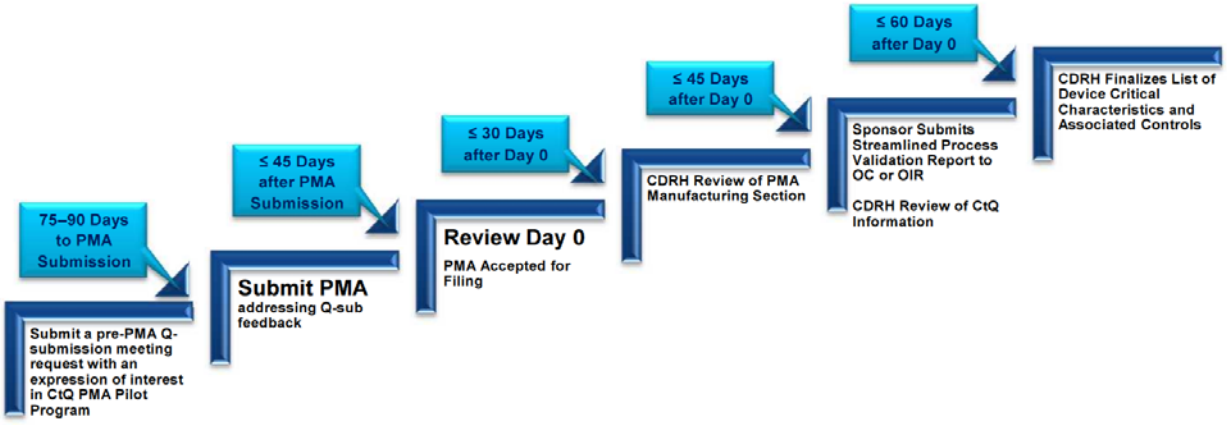
[1] See https://www.federalregister.gov/documents/2017/09/12/2017-19258/center-for-devices-and-radiological-health-premarket-approval-application-critical-to-quality-pilot

[2] See https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM481588.pdf

guidance on the pre-submission program,[3] (2) a list of PMA-related facilities responsible for the manufacturing and processing of the device, (3) a draft list of the device's characteristics that are a subject of the PMA application (if available), and (4) a statement of interest in participating in the program;

- Submit an original PMA, with a manufacturing section that includes a proposed list of device critical characteristics[4] and the associated controls for the device;
- Have its PMA application accepted and filed for review by FDA;
- Have had an FDA inspection of all PMA-related facilities within the last five years; none of which were classified as Official Action Indicated or were subject to a judicial action;
- Have no Quality System Deficiencies identified in FDA's review of the PMA manufacturing section; and
- Submit a streamlined process validation report to the Office of Compliance (OC) or Office of In Vitro Diagnostic and Radiological Health (OIR), as appropriate, within 45 days after the PMA is accepted for filing.[5]

PMA applicants for combination products, products regulated by the Center for Biologics Evaluation and Research, and companion diagnostic In Vitro Diagnostic devices that require coordination with the Center for Drug Evaluation and Research are not eligible for this voluntary pilot program.



The PMA review is expected to otherwise continue as usual. Following approval of the PMA, FDA will conduct the postmarket inspection based in part on the PMA CtQ information developed jointly by FDA and the PMA applicant.

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[3] See https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf

[4] Critical characteristics are based on risk to the patient or user, including whether failure in meeting the characteristic can have a reasonable likelihood or a remote likelihood of causing a death or serious injury.

[5] The filing of a PMA means that FDA has made a threshold determination that the application is sufficiently complete to begin an in-depth review. FDA will notify the applicant whether the application has been filed within 45 days of submission. The 180-day period for review of a PMA starts on the date of filing.

For established companies with a positive inspection history, participation in the pilot program may offer an impressive benefit of avoiding a pre-PMA inspection, which is also likely to result in faster approval. To be successful, an applicant will need to submit a complete PMA manufacturing section with the additional information on device critical characteristics and associated controls to avoid any quality system regulation deficiencies that could knock them out of the program. Development of the proposed list of device critical characteristics and associated controls should be well defined in the company's risk management documents, which should make them relatively easy to generate. That said, the program contemplates that arriving at a final set of CtQ characteristics and controls that will serve as an input to the post approval inspection will require close interaction with the Agency, which may well eat up some of the review time that was previously allocated to pre-PMA inspections. Thus, while the program appears to offer significant advantages to industry that may well expedite the approval process, like all new regulatory processes, the devil will be in the details.

Contacts

Jodi Scott
Partner, Denver
Tel +1 303 454 2463
jodi.scott@hoganlovells.com

Danielle C. Humphrey
Partner, Washington, D.C.
Tel +1 202 637 8853
danielle.humphrey@hoganlovells.com

Tammi Tram Huynh
Associate, San Francisco
Tel +1 415 374 2461
tammi.huynh@hoganlovells.com