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08 Feb 2024 | **Interviews**

The Practicalities Of Working With The FDA's eSTAR Submission Form

by Hannah Daniel

The FDA's eSTAR PDF is supposed to standardize premarket submissions, but is it really easier for regulatory specialists?

The US Food and Drug Administration's electronic Submission Template and Resource (eSTAR) form was created to streamline premarket submissions, but there are still a few hiccups.

Medtech Insight spoke to a regulatory affairs specialist at a large musculoskeletal solutions company, whose company requested she remain anonymous about the pros and cons of the eSTAR form. She has expertise in 510(k) applications and works in-house with her team to prepare submissions.

Her company waited till the last moment to switch to using eSTAR forms, submitting its first eSTAR application in September, she said. Even now, the regulatory team still uses the company systems and processes to write up all of the submission documentation, and then inputs the information into the form through various attachments.

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A SCREENSHOT FROM THE ESTAR FORM CYBERSECURITY SECTION. *FDA*

There are sections for uploading attachments and filling out text boxes, but the source said that oftentimes her team will use the text boxes to refer to attachments instead of typing out the information again.

This allows team members to work with familiar systems and use the form more as a checklist to make sure all the necessary information is included in the submission.

This was one of the main reasons the FDA introduced this form, as it is supposed to cut down—and theoretically eliminate— refusal to accept (RTA) decisions based on missing information. (Also see "*Cybersecurity Expert Says eSTAR Requirement Will Push FDA, Industry In Positive Direction*" - Medtech Insight, 16 Aug, 2023.)

There are a few downsides to uploading everything as attachments, the source said, because the form doesn't allow you to change the order of attachments after they're uploaded. If one document covers multiple sections of the form, it can be tricky matching them up.

Another source who works as a regulatory affairs specialist at a global corporation specializing in heart valves told *Medtech Insight* that only one person being able to work on the form at a time significantly decreased productivity. Team members were able to work together on one document before the team began using the eStar form, but now their once-efficient workflow has become more segmented as the form is passed from person to person.

It is unclear if the FDA expects companies to completely switch to using its eSTAR system for the submission from beginning to end, or if this process of creating submissions using established company processes and then uploading most of the information as attachments is also an

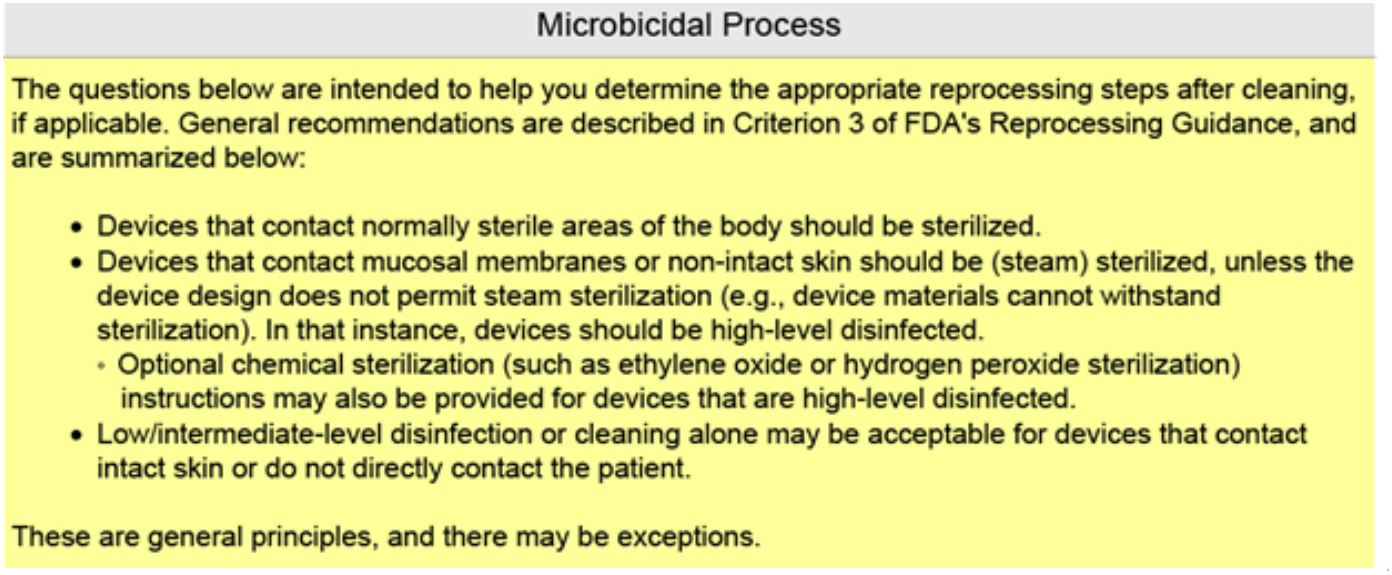
acceptable option, but the form's design favors filling it out as you go.

The form begins as a few pages and populates the sections as specific choices are made. However, the time it takes the sections to load can be frustrating, the source said. This lag time usually doesn't exist for submissions done with in-house processes.

'Comprehensive And Instructive'

The auto-population feature might cause submitters to miss sections if some parts of the form aren't filled out correctly, but the comprehensive and instructive nature of the form can be helpful for newer submitters and is meant to serve as a checklist for submitters. Additionally, the fact the form starts as a few pages and then grows in response to user choices can make it less daunting for submitters.

Certain sections of the form make reference to different FDA standards and guidance documents, making it easier for submitters to make use of the FDA resources necessary for that section.



Microbicidal Process

The questions below are intended to help you determine the appropriate reprocessing steps after cleaning, if applicable. General recommendations are described in Criterion 3 of FDA's Reprocessing Guidance, and are summarized below:

- Devices that contact normally sterile areas of the body should be sterilized.
- Devices that contact mucosal membranes or non-intact skin should be (steam) sterilized, unless the device design does not permit steam sterilization (e.g., device materials cannot withstand sterilization). In that instance, devices should be high-level disinfected.
  - Optional chemical sterilization (such as ethylene oxide or hydrogen peroxide sterilization) instructions may also be provided for devices that are high-level disinfected.
- Low/intermediate-level disinfection or cleaning alone may be acceptable for devices that contact intact skin or do not directly contact the patient.

These are general principles, and there may be exceptions.

A SECTION OF THE ESTAR FORM ON THE MICOBICIDAL PROCESS, REFERRING TO THE FDA'S REPROCESSING GUIDANCE.

There are also helpful data-input features that make the repetitive task of writing in the company name, address and other identification details automatic.

While some of these changes seem small, they make the submission process much easier for regulatory specialists, who are often the last step in making sure a life-saving product can get to market.

The FDA began requiring eSTAR submissions for 510(k)s on 1 October 2023, and the PDF opened

for use for PMAs on 6 December. The FDA has not announced when, and whether, it will expect all premarket submissions to make use of eStar. (Also see "*eSTAR Now Open For PMA Submissions*" - Medtech Insight, 6 Dec, 2023.)

The previous version (version 4) of the eSTAR form was retired on 4 February. Version 5 includes more comprehensive cybersecurity requirements, such as additional questions about risk management and cybersecurity architecture plans. (Also see "*News We're Watching: V-Champs Winners Named, Recalls for Fresenius Infusion Pumps and GE Vents, FCC Updates Rural Telehealth Rule*" - Medtech Insight, 12 Jan, 2024.)

The eSTAR form replaced the other digital submission standard—the eCopy form, which was introduced in 2020 to replace mailing in CDs. At that time, mailing paper copies of applications was also accepted, but now all 510(k)s must be submitted electronically unless exempted. (Also see "*FDA Launches Pilot eCopy Program To Eliminate Mailing CDs, DVDs, Flash Drives*" - Medtech Insight, 6 Oct, 2020.)