Introduction to Medical Device Development Tools (MDDTs)

Slide 1

Hello, everyone. Thank you for joining us today. My name is CDR Margaret Caulk, and I'm with the Division of Partnerships and Innovation in the Office of Strategic Partnership and Technology Innovation at the Center for Devices and Radiological Health, or CDRH.

Welcome to CDRH Learn, FDA's catalog of multi-media educational modules about medical devices and radiological products.

In this module, I will provide an introduction to Medical Device Development Tools, or MDDTs —a voluntary program that can streamline the device development process and make regulatory interactions more predictable.

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This module is the first in a series covering MDDTs. In this module, we will focus on an introduction to MDDTs.

Subsequent modules in this series will cover the regulatory use of MDDTs, MDDT categories, and the two phases of the qualification process — the Proposal Phase and the Qualification Phase.

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Before we begin, consider this image. It represents the spark of an idea — the starting point for a potential Medical Device Development Tool. From that single idea, there are multiple pathways forward.

One pathway may focus on tool development and validation. Another may center on data generation and building an evidentiary foundation. And another may involve engagement with FDA to align on the context of use.

These pathways are not always linear. They often involve iteration and refinement. Ultimately, they come together in the MDDT qualification process, where the goal is to demonstrate that the tool is reliable and appropriate for its intended purpose. With that, let's get started with Module 1.

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This progress bar outlines the topics we will cover in this module and will be present on each slide to indicate the topic.

We will start with the basics — what exactly is an MDDT? Then we will discuss the purpose and scope of the MDDT Program, how the qualification process works, and finally, we will spend some time on Context of Use — a central element of every qualified MDDT.

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This module has five learning objectives. By the end of this module, you will be able to: define what constitutes an MDDT; describe the purpose and scope of the MDDT Program; explain how MDDT qualification works; and define Context of Use, or COU.

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Let's start with the basics. An MDDT is a method, material, or measurement used to assess the safety, effectiveness, or performance of a medical device. An MDDT is scientifically substantiated and can be

qualified for use in device evaluation to support regulatory decision-making within a specified context of use. This definition comes directly from FDA's 2023 guidance document, "Qualification of Medical Device Development Tools," which is linked on this slide and in the resources slide at the end of this module.

It is worth noting what sets a qualified MDDT apart from other tools used in device development. Many tools can support the device development process, but a qualified MDDT also has regulatory utility — meaning the tool can be used in regulatory evaluation, such as when assessing premarket device submissions. That regulatory utility is what distinguishes a qualified MDDT from other development tools.

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This slide highlights four key characteristics of a qualified MDDT. Every MDDT is qualified within a specified Context of Use, or COU, which defines how the tool is to be used in the regulatory evaluation of medical devices.

A qualified MDDT is scientifically substantiated — meaning the evidence provided supports the tool's use within that context. It is qualified for use in device evaluation, and it supports regulatory decision-making across the total product lifecycle — which includes premarket submissions, such as a 510(k) or De Novo request, as well as post-market studies and surveillance activities depending upon the qualified COU for the MDDT.

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The voluntary MDDT Program was established by FDA to address regulatory challenges in both device development and regulatory evaluation. Prior to the development of the MDDT qualification process, FDA evaluated tools on a case-by-case basis for each medical device submission. Through the MDDT Program, publicly qualified tools can now be used by medical device manufacturers across multiple device types and submissions for the development and evaluation of medical devices.

Historically, the program was created to address four goals.

The first is to advance innovation by focusing on the science needed to evaluate novel technologies. As medical devices become increasingly complex, having scientifically substantiated tools available to support their evaluation is an important part of keeping pace with that innovation.

The second is to increase predictability for medical device manufacturers. When a tool is qualified, FDA has made clear that it accepts assessments from that MDDT in support of demonstrating the safety, effectiveness, or performance of a medical device, when used within the qualified context of use. That clarity can help reduce uncertainty during the device development and review process.

The third is to improve efficiency and transparency by facilitating the use of qualified tools across multiple device submissions and manufacturers. Rather than evaluating a tool's suitability on a case-by-case basis for each submission, a qualified MDDT can be relied upon across multiple device submissions and manufacturers.

And the fourth is to encourage collaboration in developing tools and supporting evidence. The program provides a mechanism for multiple stakeholders to pool resources and drive increased use and acceptance of qualified tools.

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Building on those four goals we just discussed, this slide takes a closer look at the purpose of the voluntary MDDT Program today.

First, the MDDT Program is intended to qualify scientifically substantiated tools that can support regulatory decision-making within a specific context of use for medical devices. This connects directly to the innovation and predictability goals we just covered: qualified MDDTs are grounded in science and are evaluated for a defined and specific use within regulatory decision-making, not as general-purpose tools.

Second, the MDDT Program facilitates the use of qualified tools across multiple submissions and manufacturers, without FDA needing to re-evaluate the tool's suitability each time. This is what makes the efficiency and transparency goal tangible; once a tool is qualified, any medical device manufacturer with access to the tool can use it within its qualified context of use in their regulatory submissions.

Third, the MDDT Program brings greater predictability, consistency, and efficiency to device development and review. By establishing a clear pathway for tool qualification, the program is intended to reduce uncertainty around what evidence is needed and how tools will be assessed — reinforcing the collaborative and predictable framework the program is designed to support.

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Let's take a moment to discuss what falls within and outside the scope of the MDDT Program. A tool is within scope if it is used to assess the safety, effectiveness, or performance of a medical device; has a defined Context of Use; and has a clear regulatory utility. A tool falls outside the scope of the program if it is used only to assess drugs or biologics, does not aid in regulatory evaluation or decision-making, or is intended for confidential or non-public use. Keeping these boundaries in mind will help determine whether MDDT qualification may be appropriate for a given tool.

While there are no requirements regarding how developers should distribute their MDDTs or what level of access they must provide to their intellectual property, FDA does intend to make public certain high level information about the existence of the tool and its utility in the Summary of Evidence and Basis for Qualification (SEBQ) and encourages MDDT developers to make their qualified MDDTs publicly available so that the MDDT can be used by any medical device manufacturer for the qualified COU.

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What does it mean for an MDDT to be qualified?

According to FDA's 2023 guidance on the Qualification of Medical Device Development Tools, qualification reflects FDA's expectation that, quote, "within a specified context of use, the results of an assessment that uses an MDDT can be relied upon in device evaluation and to support regulatory decision-making."

Once qualified, the tool can be used by any medical device manufacturer in multiple device development programs and regulatory submissions for that context of use, without FDA needing to re-evaluate the tool's suitability each time. You can learn more by visiting FDA's MDDT webpage, linked in the resources slide at the end of this module.

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Now let's discuss how MDDT qualification works. The voluntary MDDT qualification process consists of two phases: the Proposal Phase and the Qualification Phase.

The first phase is the Proposal Phase. The goal of this phase is an initial assessment to determine whether the tool is suitable for qualification through the MDDT program. During this phase, the tool developer submits a Proposal Package that describes the tool, defines the proposed Context of Use, outlines the performance criteria, and provides a plan for collecting the evidence needed to demonstrate that the tool reliably and accurately meets its intended purpose.

FDA reviews the Proposal Package and notifies the submitter in writing of its decision — typically within approximately 90 days of receipt.

The second phase is the Qualification Phase. The goal of this phase is to determine whether, for the proposed Context of Use, the tool is qualified based on the evidence provided. FDA evaluates the strength of the evidence submitted in the Qualification Package against the performance criteria and qualification plan established in the accepted proposal. If the evidence supports the proposed Context of Use, FDA qualifies the tool.

It is worth noting that these two phases are sequential — a tool developer would first submit a proposal, and if that proposal is accepted, they would then proceed to submit a Qualification Package. Later modules in this series will cover each of these phases in greater detail.

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Every MDDT is qualified for a specific Context of Use, or COU. The COU is a statement that fully and clearly describes the way the MDDT is to be used and the device development-related purpose of that use. It describes what the tool measures or assesses, including its inputs and outputs. It describes how the tool is used in medical device development and how it is used to assess a medical device. It identifies which phase of device development the tool can be applied in. And it describes the limitations of the tool.

Taken together, these elements define the boundaries within which FDA has determined the tool can be relied upon.

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To illustrate what a COU may look like in practice, let's walk through a fictitious example called CardioSim-Stress. Please note that this is a hypothetical, non-clinical assessment model created for educational purposes only — it does not represent an actual qualified MDDT. The COU for this tool reads as follows:

CardioSim-Stress provides a quantitative analysis of the maximum principal stress and cumulative fatigue damage on a virtual coronary stent model for de novo coronary lesions when subjected to physiological cardiac cycle loading conditions. The output is a predictive report detailing the structural integrity over a simulated 10-year implantation period. CardioSim-Stress is intended to supplement physical bench testing and short-term implantation studies during design verification and may reduce test duration in long-term implantation studies.

CardioSim-Stress is not a standalone replacement for physical fatigue testing or other nonclinical studies. It is validated only for coronary stents made of L605 cobalt-chromium alloy with strut thicknesses between 80µm - 120µm. CardioSim-Stress is based on healthy adult coronary artery anatomy and does not account for patient-specific anatomical variations or severe disease states.

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Now that we have seen an example of what a complete COU statement looks like, let's break down the key components that make up a well-defined COU. A well-defined COU addresses four areas.

The first is WHAT the tool measures — specifically, its inputs and outputs. A clearly defined COU describes what information goes into the tool and what the tool produces as a result. This precision is important because it establishes the boundaries of what the tool is actually measuring or assessing.

The second is HOW and by WHOM the tool is used. This includes the phase of device development in which the tool is applied, who the intended users of the tool are, and the study type and population the

tool is designed for. Together, these elements describe the conditions under which the tool is intended to operate.

The third is the regulatory role the tool plays. MDDTs can be used in a nonclinical or clinical, pre- or post-market context, and the COU tells the tool user where it can be applied. It is important for the COU to describe what the tool supports or supplements in a regulatory submission. Clearly articulating the regulatory role helps establish how the tool's output connects to regulatory decision-making.

And the fourth is the limitations and constraints of the tool. These could include, but are not limited to, intended population and exclusions, the conditions and environment of use, and the input parameter boundaries within which the tool has and has not been evaluated. A well-defined COU is transparent about where the tool's applicability ends — describing not just what the tool can do, but what it cannot.

In the next few slides, we will walk through each of these four areas using the CardioSim-Stress example to illustrate how a complete COU addresses each component in practice.

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We will start with the first consideration — WHAT the tool measures.

A well-defined COU clearly describes the outputs of the tool. For CardioSim-Stress, the output is two-fold.

First, the tool calculates a quantitative analysis of the maximum principal stress and cumulative fatigue damage on a virtual coronary stent model when subjected to simulated physiological cardiac cycle loading conditions. Using that analysis, the tool generates a predictive report detailing the stent's structural integrity over a simulated 10-year implantation period. These descriptions establish a clear and measurable picture of what this tool does, which is the foundation of a well-defined COU.

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Let's look at the second and third COU content considerations — HOW and by WHOM the tool is used, and the regulatory role it plays.

For HOW and by WHOM, the COU states that CardioSim-Stress is intended to supplement physical bench testing and short-term implantation studies during the design verification phase. This tells us the phase of device development in which the tool is applied — design verification — and how it is intended to be used in relation to other testing activities. It is not a standalone tool, but one that operates alongside existing methods.

For the regulatory role, we again look at the COU language specifying that the tool supplements physical bench testing and short-term implantation studies and also that the tool may reduce test duration in long-term implantation studies. It is worth pausing on that second point. Long-term implantation studies are among the most time- and resource-intensive activities in the device development process.

For a coronary stent, these studies may span years and require significant investment before a manufacturer can move forward with a regulatory submission. A tool that may reduce that duration — while still providing scientifically substantiated evidence to support regulatory decision-making — represents a meaningful potential benefit for device manufacturers and, ultimately, for patients who may benefit from timely access to new devices.

This is a concrete illustration of how the MDDT Program's goals of advancing innovation and improving efficiency translate into practice.

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The final COU content consideration is limitations and constraints. The COU clearly states that the tool is not intended to replace fatigue testing or other nonclinical studies. This directly addresses the boundaries of the tool's regulatory role. The COU then specifies the input parameter boundaries — the tool has been evaluated only for stents made from L605 cobalt-chromium alloy with strut thicknesses between 80 and 120 micrometers. Use of the tool outside of these parameters falls outside the qualified context of use.

The COU also describes the conditions and environment of use — the model is based on a standardized, healthy adult coronary artery anatomy. As a result, it does not account for patient-specific anatomical variations or severe disease states. These are explicit statements about where the tool's applicability ends.

Taken together, the limitations and constraints section of a COU is not a weakness — it is a strength. A COU that clearly defines what a tool does not do is more reliable and more useful to both FDA and device manufacturers than one that overstates the tool's applicability. This transparency is a hallmark of a well-defined COU, and it is what allows FDA to rely upon the tool with confidence within its qualified context of use.

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This slide brings together the key principles of a well-defined COU, using the CardioSim-Stress example to illustrate each one.

A strong COU has a clear definition of outputs — here, a predictive report of stent structural integrity over a simulated 10-year implantation period. It identifies the phase of device development in which the tool is applied — in this case, design verification. It defines the device scope — L605 cobalt-chromium alloy coronary stents with strut thicknesses of 80 to 120 micrometers. It articulates a defined regulatory purpose — supplementing bench testing and short-term implantation studies, with the potential to reduce long-term implantation test duration and sample size. And it states explicit limitations — the tool does not replace physical fatigue testing or other nonclinical studies, and is not applicable to patient-specific anatomical variations or severe disease states.

A COU that is specific, transparent, and grounded in evidence is one that FDA can rely upon — and one that provides device manufacturers with a clear and predictable framework for using the tool in their regulatory submissions. With that, let's move to our module summary.

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Let's conclude Module 1 with a brief summary of what we covered.

An MDDT is a method, material, or measurement used to assess the safety, effectiveness, or performance of a medical device. An MDDT is scientifically substantiated and can be qualified for use in device evaluation to support regulatory decision-making within a specified context of use.

The purpose of the MDDT Program is to qualify tools that can be used in the development and evaluation of medical devices within a specified context of use. The scope of the program covers tools that assess the safety, effectiveness, or performance of a medical device, have a defined Context of Use, and have clear regulatory utility.

MDDT qualification occurs through a voluntary two-phase process — the Proposal Phase and the Qualification Phase — and later modules in this series will cover each of these phases in greater detail.

And finally, the Context of Use describes what the tool measures, how and when the tool is to be used in regulatory evaluation, and the limitations of the tool. As we saw through the CardioSim-Stress example, a well-defined COU is specific, transparent, and grounded in evidence — and it is what allows FDA to rely upon a qualified tool with confidence.

Thank you for completing Module 1: Introduction to Medical Device Development Tools. Please continue to the next module in this series to learn more about the MDDT qualification process, or visit FDA's MDDT webpage for additional information and resources.

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FDA offers a variety of educational resources that may be helpful as you continue learning about medical device regulation and the MDDT Program.

CDRH Learn provides a large collection of multimedia educational materials, including videos, webinars, presentations, and interactive learning modules covering a wide range of regulatory topics.
Device Advice contains comprehensive text-based information spanning the medical device total product life cycle.

You may also contact the Division of Industry and Consumer Education, or DICE, for assistance with questions related to medical device regulation and FDA programs.

These resources can provide additional guidance as you explore opportunities to develop or use qualified MDDTs.

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Here are the resources I mentioned earlier in the presentation, along with the full URL that you can access after the presentation.

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We are excited for your interest in MDDTs and are here to help navigate you through the process.

So what are your next steps? We encourage you to visit the Medical Device Development Tools website to learn more about the program and qualification process.

We also encourage you to review the existing qualified MDDTs to see what's already been qualified – they can serve as great examples for your own MDDT submission, and you may even find something that fits your needs.

Please check out the other modules in this series that dig deeper into the four categories of MDDTs, the role of MDDTs in the regulatory process, and how to put together a submission.

Lastly, if you have questions about qualification, or next steps, please don't hesitate to contact the MDDT Program at the email address shown here. We'd be happy to hear from you!
Thank you for your attention to this presentation.