Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:

Draft Guidance on Computer Software Assurance for Production and Quality System Software

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Computer Software Assurance for Production and Quality System Software

Draft Guidance

Francisco Vicenty
Program Manager, Case for Quality
Compliance and Quality Staff
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration

Draft Guidance

- **Computer Software Assurance for Production and Quality System Software**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-system-software

Learning Objectives

- Identify and describe scope and purpose of draft guidance
- Describe computer software assurance (CSA) as a risk-based approach to establish confidence in automation used for medical device production or quality systems
- Describe risk-based assurance activities that may be applied to establish CSA

Background

- FDA recognizes advances in manufacturing technologies have the potential to allow manufacturers to:
  - reduce sources of error
  - optimize resources, and
  - reduce patient risk

Background

- FDA recognizes these technologies have the potential to provide significant benefits for enhancing medical device quality, availability, and safety

- Medical device manufacturers have expressed a desire for greater clarity regarding software validation for computers and automated data processing systems used as part of production or quality system

Draft Guidance
Purpose and Scope

Purpose of Draft Guidance

- Provide recommendations on computer software assurance (CSA) for computers and automated data processing systems used as part of medical device production or the quality system

- Describe CSA as a risk-based approach to establish confidence in automation used for production or quality systems

- Describe various methods and testing activities that may be applied to establish CSA and provide objective evidence to fulfill regulatory requirements

Scope of Draft Guidance

- Computers or automated data processing systems used as part of production or the quality system where 21 CFR 820.70(i) applies
- Includes, but not limited to:
  - Design
  - Development
  - Manufacturing
  - Quality System

Not in Scope:

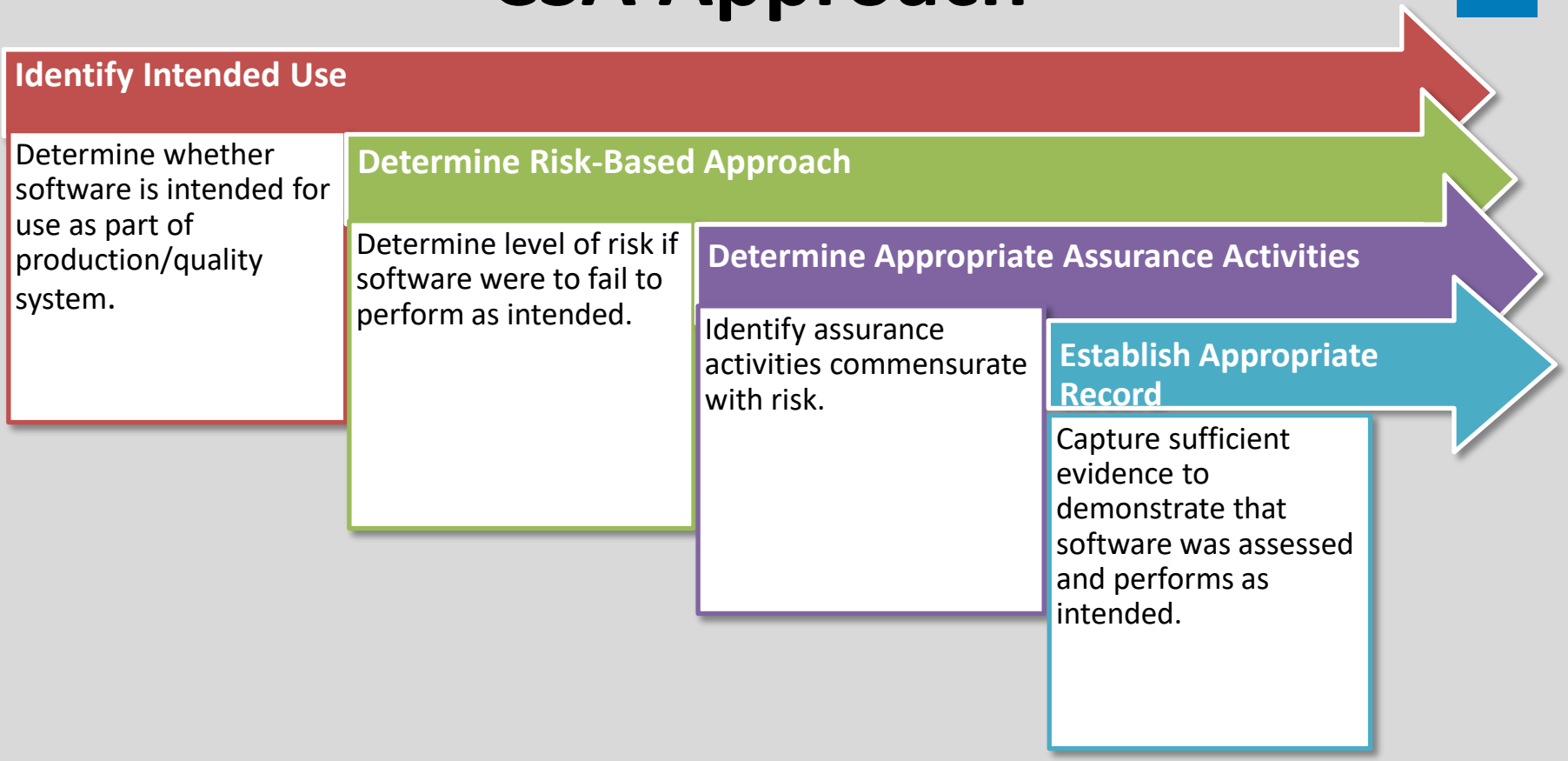
- Software as a Medical Device (SaMD)
- Software in a Medical Device (SiMD)

Computer Software Assurance (CSA)

What is CSA?

- Risk-based approach for establishing and maintaining confidence that software is fit for its intended use
- Establishes and maintains that software used in production or quality system is in a state of control throughout its lifecycle (“validated state”)
- Effort and record should be “right-sized” to the risk

CSA Approach



Intended Use

Identify Intended Use

Determine whether software is intended for use as part of production/quality system (QS).

Is it:

- Used **directly** as part of production/QS?
- Used to **support** production/QS?
- **Not used** as part of production/QS?

21 CFR 820.70(i) Applies

- Software intended to be used **directly** as part of production or QS
  - Production processes, inspection, testing, or collection and processing of production data
  - Quality system processes, collecting or processing quality system data, or maintaining a quality record established under the Quality System regulation

- Software intended to be used to **support** production or QS
  - Development tools that test or monitor software systems, or automate testing activities
  - General record-keeping that is not part of the quality record

Lower Risk

Risk-Based Approach

Determine Risk-Based Approach

Determine level of risk if software were to fail to perform as intended:

- **High Process Risk**
- **Not High Process Risk**

*FDA is primarily concerned with review and assurance for software that is **high process risk** because a failure also poses a **medical device risk.***

High Process Risk

- Failure to perform as intended may result in a quality problem that foreseeably compromises safety (that is, increased **medical device risk**)
- *Example:*

  Software that maintains process parameters that affect physical properties that are essential to device safety or quality

Not High Process Risk

- Failure to perform as intended either:
  - would not result in a quality problem OR
  - may result in a quality problem that does not foreseeably lead to compromised safety
- *Example:*

  Software that collects and records data for monitoring and review purposes that don't directly impact production/process performance

Assurance Activities

Determine Appropriate Assurance Activities

Identify assurance activities commensurate with risk.

- **High Process Risk** → level of assurance commensurate with **medical device risk**
- **Not High Process Risk** → level of assurance commensurate with **process risk**

Leverage

- Activities, people, and established processes that provide control in production
- Purchasing controls
- Process controls
- Data collected by the software for monitoring or detecting issues/anomalies
- Computer system validation tools
- Iterative/continuous testing throughout the software lifecycle

Testing methods

- **Unscripted Testing**
  - Ad-hoc testing
  - Error-guessing
  - Exploratory testing
- **Scripted testing**
  - Limited scripted testing
  - Robust scripted testing

Records

Establish the Appropriate Record

Capture sufficient evidence to demonstrate that software was assessed and performs as intended.

Record should include:

- intended use of software feature, function, or operation;
- determination of risk of software feature, function, or operation;
- documentation of assurance activities conducted, including:
    - description of testing conducted based on assurance activity;
    - issues found (examples: deviations, failures) and disposition;
    - conclusion statement declaring acceptability of results;
    - date of testing/assessment and name of person who conducted testing/assessment;
    - established review and approval when appropriate (examples: when necessary, a signature and date of an individual with signatory authority)

Electronic Records Requirements

Electronic Records Requirements

- FDA's Guidance, "Guidance for Industry, Part 11, Electronic Records; Electronic Signatures – Scope and Application," describes narrow interpretation of scope of 21 CFR Part 11
- Agency intends to exercise enforcement discretion regarding specific Part 11 requirements for validation of computerized systems*
- We invite comments or questions regarding the application of Part 11 requirements to systems in scope of 21 CFR 820.70(i)

*21 CFR 11.10(a) and corresponding requirements in 21 CFR 11.30.

Summary

- Computer software assurance (CSA) is a risk-based approach to establish confidence in the automation used for production or quality systems

- The CSA approach features four steps:
  1. Identify intended use
  2. Determine risk-based approach
  3. Determine appropriate assurance activities
  4. Establish appropriate record

- We invite you to provide comments and ask questions about this draft guidance

Providing Comment on Draft Guidances

A Note about Draft Guidances

- You may comment on any guidance at any time
  - see 21 CFR 10.115(g)(5)
- Please submit comments on draft guidance before closure date
  - to ensure that FDA considers your comment on a draft guidance before we work on final guidance

Submit Comments to Dockets by: November 14, 2022

- **Draft Guidance: Computer Software Assurance for Production and Quality System Software**
  - Docket: FDA-2022-D-0795

    (www.regulations.gov/docket/FDA-2022-D-0795)
  - Draft Guidance

Resources

Slide Number	Cited Resource	URL
3	CSA Draft Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-system-software
18	Part 11, Electronic Records; Electronic Signatures – Scope and Application	www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application
22	Comment Docket	www.regulations.gov/docket/FDA-2022-D-0795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Additional Panelists

Ian Ostermiller
Policy Advisor
Office of Policy

Mary Wen
Regulatory Policy Analyst
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration

Let's Take Your Questions

- **To Ask a Question:**
  1. Raise your hand in Zoom 

  2. Moderator will announce your name and invite you to ask your question
  3. Unmute yourself when prompted in Zoom to ask your question

- **When Asking a Question:**
  - Ask one question only
  - Keep question short
  - No questions about specific submissions

- **After Question is Answered:**
  - Mute yourself and lower your hand
  - If you have more questions - raise your hand again

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**
  - www.fda.gov/Training/CDRHLearn
- **Additional questions about today's webinar**
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
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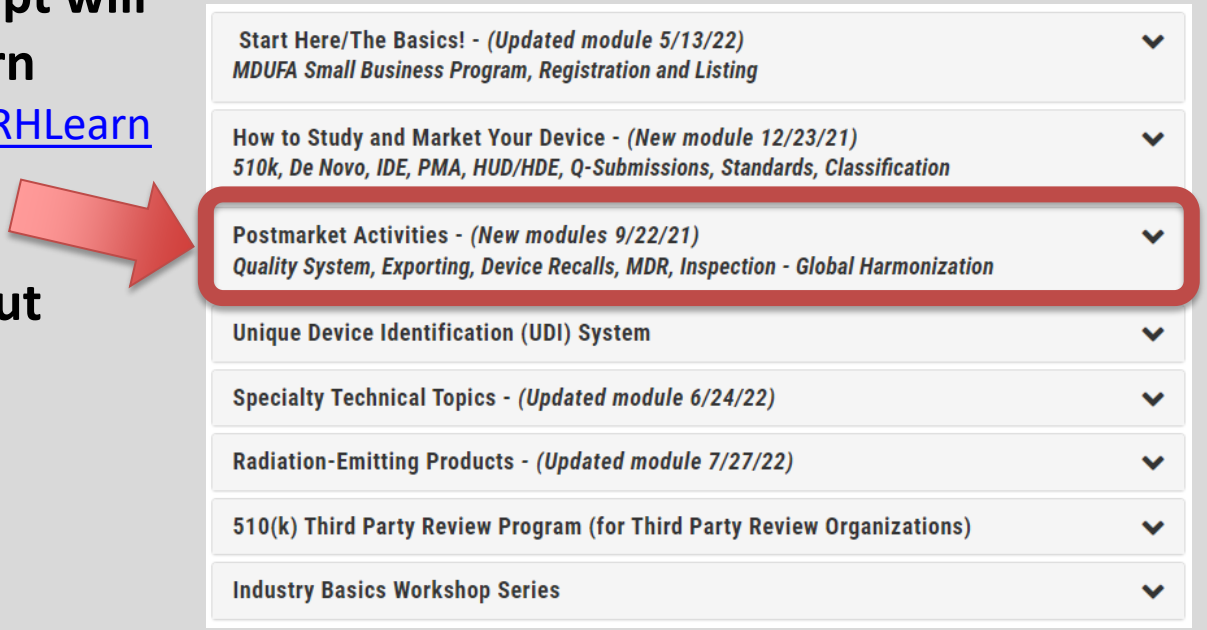


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