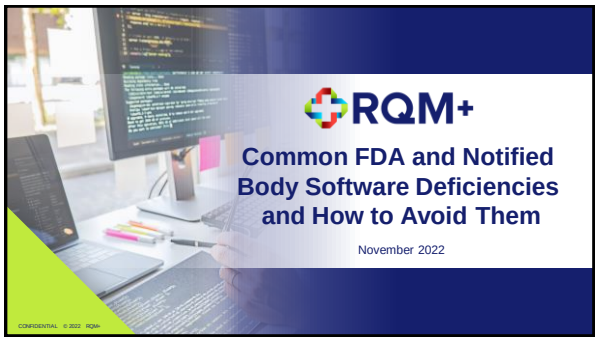

1

Who We Are

RQM+ is the leading MedTech service provider with the world's largest global team of regularly and quality experts. We provide comprehensive regulatory, quality, clinical, and laboratory services, supporting market access throughout the entire product lifecycle for medical devices and diagnostics.

Learn more about us at **RQMplus.com**.

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RQM+ Services

Regulatory Affairs

- Worldwide regulatory strategies
- FDA 510(k), PMA, De Novo, IDE, EUA, Breakthrough, and Pre-Subs
- CE marking strategy, technical documentation and sustaining support
- EU MDR/IVDR – complete transition solution
- RA leadership/support to new product development teams
- Strategic direction on labeling, regulations and standards
- Acquisition due diligence & integration

Design Quality Engineering

- Design control assurance to new product development teams
- Safety risk management, including implementation of EU MDR/IVDR
- DHF and technical documentation gap analysis and remediation – proactive or reactive

Clinical Regulatory Affairs

- EU MDR CERs (includes CEP, literature searches, SAP and SotA)
- IVDR PERs (includes PEP, literature searches, SotA, CP, SV and AP)
- Clinical-regulatory strategy
- Clinical/performance evidence matrix development
- Clinical regulatory affairs training
- Ongoing maintenance and updates of CERs/PERs, and other MDR/IVDR documentation.
- MDR SSCP and IVDR SSP

Post-Market Surveillance

- Worldwide PMS including EU MDR/IVDR
- Strategy and integration of PMS, CER/PER, and risk management
- PMS procedures, plans and reports
- Periodic Safety Update Reports (PSUR)
- PMCF & PMPF plans, reports and user surveys (PMCF)
- Complete managed outsourcing service

Quality Systems

- Quality system development: ISO 13485, QSR, EU MDR, MDSAP
- Quality system improvements and remediation
- Internal audits
- Supplier quality and audits
- Economic operator audits
- FDA inspection readiness and support
- EU MDR/IVDR mock NB audits
- Acquisition integration

Regulatory Compliance

- Complete strategic remediation solution – leadership, project management and scalable team for execution
- Regulatory agency audit findings – strategy and response
- Corrective action and remediation planning and leadership
- Recall strategy and execution
- 483s, warning letters, consent decrees and NB non-conformity reports

Manufacturing Quality Engineering

- Quality assurance of manufactured product
- Process improvements and validation/qualification
- Computer systems validation
- Packaging validation
- Sterilization validation
- Manufacturing site transfer
- Strategy and implementation of EU MDR/IVDR requirements

Laboratory Services

- Extractables and leachables (E&L) testing
- Product deformulation
- Investigative polymer analysis & quality control
- Biological consulting
  - *Product development strategy*
  - *Biological evaluations (in-vitro and in-vivo testing)*
  - *Risk assessments*

3

Slides, Recording, and the Knowledge Center

- Slides and Recording will be sent via email
- Knowledge Center at **RQMplus.com**
  - Explore our resources, including *RQM+ Live!* (pictured), webinars, whitepapers, technical briefs, interactive tools, video FAQ, helpful links, glossary, and the *Device Advice* podcast.

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Senior Principal

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Agenda

01 Introduction: Why Does Software Get So Much Scrutiny?

02 Pre-Market Findings Related to Software from the U.S. and EU

03 Clinical Deficiencies

04 Post-Market Pitfalls

05 What's Next for Software?

Disclaimer: The specific findings listed in this presentation have been modified and may represent merged statements from multiple findings. Care has been taken to preserve the intent of the original feedback.

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Objectives

- ✓ Review findings from the U.S. Food and Drug Administration (FDA) and notified bodies (NBs) that are uniquely related to software in a medical device (SiMD) or software as a medical device (SaMD).
- ✓ Identify solutions to avoid these findings in your pre-market submissions, PMS/PMCF reports and QMS inspections.

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Why does software get so much scrutiny?

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Software Can and Does Lead to Recalls

A Few Examples

- Sporadic software errors during interventional workflows may also result.
- Power outages cause reporting software to shut down.
- Potential for patient data to be sent to the wrong patient record.
- ... system may delay or omit reporting of clinically significant results, including organisms and drug sensitivities.
- This caused multiple patient records to be printed on the same page. All affected clients were notified of the issue ...
- In rare circumstances ... an inverted image of the frame is generated by the software.
- ... the operator will receive a false hard limit exceeded error, preventing him or her from programming the infusion.
- Under certain conditions, the system may not perform as intended, causing the release of results to the laboratory information system that should have been held for manual review ...

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Software Can and Does Lead to Recalls

A Few Examples

- Software does not display appropriate allergy interaction warning.
- Demographic data, most notably allergy and precaution data, can be overwritten with incomplete data or blanks by the interface …
- Software anomaly may result in incorrect values and interpretations.
- Under certain conditions, a marble pattern infrequently appears on the monitor.
- … an issue on the affected products listed below where the "Patient Orientation" button may inadvertently be clicked when intending to click on the "Save RX" button.

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Software Considerations

- Each jurisdiction has its own classification schemes, and sometimes, a region has multiple risk classifications that are not exactly aligned:
  - FDA Class 1, 2 or 3
  - Major/moderate/low level of concern based on guidance
  - Class A, B, C per IEC 62304
  - EU Class I, IIa, IIb, III
- Sometimes, the software is classified on its own, and sometimes, it takes on the classification of the device.
- Failures can lead to patient harm, disrupted operations and expensive business-disrupting recalls.

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Pre-Market Findings

Start by getting your device on the market – navigate and avoid AIs, deficiencies and delays in getting your software device to market.

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Deficiency: Understanding the Device

NB

- ... the complexity and interconnectivity of software can make delineation of a software device difficult to define. Therefore, a clear explanation of the function and scope of the device is required, **including a clear definition of interfaces, connectivity, interoperability and data flows with other software/hardware devices and products** (both medical and nonmedical), and description of any reliance on external data or software modules (such as third-party libraries/routines) considered outside the boundary of the device ...
- Intended use is not consistent/not clear.
- Software release/version covered is not clear.

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Deficiency: Understanding the Device

FDA

- However, you have not provided the software programming language and hardware platform in the software description section. **A clear and accurate description of your software, including all functionality, is needed to allow the understanding the role of your software and to assess your software implementation and testing.**
- Your IFU indicates that this device can be an adjunct for diagnosis. ... **it is not clear yet that the performance of the device would support such use**; however, please **modify the IFU to accurately define the role of this device** for a user unfamiliar with the diagnosis ...

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Deficiency: Understanding the Device

FDA

- In various parts of your submission, you mention numerical algorithms that were implemented to process and evaluate the data. However, few details were provided regarding how these algorithms process the acquired data and assess its quality. **Please provide a detailed explanation of the algorithms used and their mathematical/physical basis.** This information is needed to elucidate the fundamental working mechanisms of your device.
- Please **fully describe the algorithm**, including its inputs, as well as any associated calculations. Please provide the appropriate software documentation as well.

Algorithms are an FDA hot button.

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Deficiency: Understanding the Device

NB

- From clinical and technical documentation, apparently, the <device> has evolved ... please provide a summary of history – including **when they were initially placed into the market**, when they were initially placed into the EU market (or CE marked), the major design changes (in both hardware and software) and intended use changes (such as changes in indications, intended users, etc.)**, global and EU sales up to date**.
- Please have these presented for each of the <devices>.

Pro Tip: The requirement for device history is unique to the EU MDR and EU IVDR. Be sure to add this to your technical documentation when applying for a CE mark.

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Lessons Learned: Describing Your Device

1. Both the FDA and NB need a clear description of your device in order to complete the review; get this wrong, and the rest of the review will be painful.
2. The FDA will often provide advice on how to correct the deficiency "update the IFU," while the NB will not "consult" and, therefore, leaves you figuring out how to best address the deficiencies.

Pro Tip: Have someone else read the device description and describe what it does to you. If you agree, then you probably have a good description.

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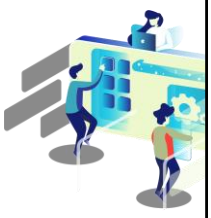
Deficiency: Change Control



NB

- Please clarify procedures for users of the device to request/receive/install new releases of the software, including how major upgrades, system patches and bug fixes are communicated and distributed. Where appropriate, please indicate where this information is provided in the submitted technical file.
- The SW configuration management plan is missing or incomplete.

FDA

- We recommend that you develop software update plans to cover mobile app updates, algorithm updates and web app updates that may impact the performance of the device. The software update plan should include details on the types of updates that may be made (adding or changing functionality, addressing software anomalies, cybersecurity updates, user interface changes, updates to maintain compatibility with OS changes, software deprecation/obsolescence planning for app or mobile device) and the types of validation necessary to ensure the safe and effective functioning of each software application.

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Deficiency: Change Control

FDA

- (PCCP) A proposed "Predetermined Change Control Plan (PCCP)" was provided ... However, the provided plan does not include adequate detail regarding your planned modifications, and it is not clear that a specific set of pre-specified changes has been identified. SaMD Pre-Specifications (SPS) provided in a change control plan should be specific, verifiable and presented at a level of detail that permits understanding of the specific modifications that will be made ... there should be a specific rationale available for each proposed change ...

A unique FDA option for de novo devices (and limited 510k products) to submit a PCCP is an evolving program and a challenging regulatory submission.

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Lessons Learned: Change Control

1. Change control/configuration management should follow a clear and well defined process
2. If you are considering a PCCP, FDA highly recommends submitting a Pre-Submission to discuss it beforehand.

Pro Tip: Reference IEC62034, Developing Software Precertification Program (fda.gov) and Proposed Regulatory Framework for Modifications to AI/ML Based SaMD for some key considerations for your software configuration model.

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Deficiency: Assessing Risk

NB

- Cybersecurity: Application of 14971 was not done.
- Please indicate where to find the evaluation of the acceptability of the residual risk and communication of known adverse effects in IFU.

FDA

- A risk analysis should include an identification of all potential risks to the health of the user (by harm, severity, probability and risk level) **before mitigations** and assessment of residual risk by implementing the mitigations. The risk analysis you provided may contain the necessary information, but it is not provided in a clear, comprehensive way so that we can readily assess that all of the health risks have been considered and sufficiently mitigated.

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Deficiency: Assessing Risk

FDA

- Wireless Quality of Service (QoS) should be carefully considered in conjunction with the intended use of the wireless medical device. As per the Radio Frequency Wireless Technology in Medical Devices, the following should be assessed: acceptable latency, acceptable level of probability for loss of information within the network, accessibility and signal priorities of the network. **FDA recommends use of a risk management approach to deployment, security and maintenance of the network's QoS.** Depending on the intended use of the device, additional failure modes may need to be considered. **Once failure modes and associated risks are identified, we recommend a justification of acceptable risk or testing or other measures to demonstrate appropriate risk mitigation.**

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Deficiency: Assessing Risk

FDA

- Accordingly, your "Low (or Moderate)" software Level of Concern (LOC) designation appears to underestimate the level of risk of your device prior to mitigations of hazards.
- Per Draft Guidance for Industry and Food and Drug Administration Staff: Content of Premarket Submissions for Device Software Functions (November 4, 2021), you stated the subject device Documentation Level is "Basic Document Level" in Section 16 of VOL 001. The guidance you referred to is a draft version, which is not for implementation yet based on "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," and include supporting rationale for the software device LOC.

The FDA creates new risk classifications for software through guidance that determines the amount of information needed for the submission. Even though there is new draft guidance that has two levels instead of three, the FDA is still looking for a Level of Concern based on the older guidance.

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Lessons Learned: Assessing Risk

1. Risk assessments need to account for the risks prior to mitigations for the U.S. and EU.
2. The FDA's Level of Concern is an independent risk assessment regardless of risk class per IEC 62304 or device classification.

Pro Tip: Make sure your risk assessment activities include cross-functional team members to account for the range of hazards and potential harms. Reference the reasons for recalls if you need ideas of what can go wrong.

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Deficiency: Documentation Gaps

NB

- Technical documentation shall be presented in a **clear, organized, readily searchable** and unambiguous manner:
  - Device name/model/versions are not clear.
  - Software release/version covered is not clear.
  - Technical file structure is not clear.
- **Missing software design specifications** and/or architectures.
- SW development plan missing or inadequate.
- **Missing trace matrix.**
- Missing unit test results and code review.
- MDR Annex II states that "The technical documentation ... shall be presented in a clear, organised, readily searchable and unambiguous manner" ...
  - There are currently a number of areas within the technical file that do not satisfy this overarching requirement of the MDR. These include the following:
    - References to device name/model – clarity and consistency: Within the submitted technical file, the device under conformity assessment is referred to in a number of ways. **A range of device names, version numbers and model identifiers are used,** some of which are clearly alternate model names for the same device, although this is not always made clear. Examples are as follows (nb. this is not an exhaustive list): ...

25

Deficiency: Documentation Gaps

FDA

- Your architecture diagram shows a variety of system components that we do not completely understand the use of, context for or source of. For example, it is not clear why you have private subnets that include ... and you do not describe the structure or content of those subnets or databases. Please provide more details about these databases, including whether or not you are using off-the-shelf (OTS) software ...
- You have not provided a description of OTS software components.

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Deficiency: Documentation Gaps

FDA

- The SDS should include the information of an implementation plan for the software requirements in terms of intended use, functionality, safety and effectiveness. We are unable to assess your proposed device's safety and effectiveness without an adequate SDS.
- A traceability analysis links together your product design requirements, design specifications and testing requirements. It also provides a means of tying together identified hazards with the implementations and testing of the mitigations. This information is necessary to determine if all requirements have been implemented and tested. Please revise your traceability document to indicate the traceability between software requirements, software design specifications, identified hazards, mitigations, and verification and validation testing.

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Lessons Learned: Documentation Gaps

1. FDA and NB review time is limited; it is worthwhile to make the review process as easy as possible for the reviewer. Make it easy to find the required elements.
2. A trace matrix is critical to facilitate the review process.

Pro Tip: Review guidance and provide a roadmap to each of the software document requirements. It is common to get these findings and then have the team say, "But it was submitted!"

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Deficiency: Testing

NB

- Missing **unit test** results and code review.
- It is not clear how the **software is fully verified and validated.**
- Please demonstrate how you **trace and document all regression testing** done related to each iteration of each version.
- Incomplete details on the release, including anomaly list.
- Software revision: **The software release/version covered by this technical file is not clear.** Appendix X, which was submitted as part of the application for a conformity assessment of the device against the MDR, references version XX of the software. However, in many instances within the submitted technical file, the documents submitted and the statements/references made relate to earlier or later versions of the software ... By way of an example of this inconsistency, the CER refers to the following design verification and validation reports – **showing separate verification and validation reports** for versions xx.x, xx.x, xx.x.

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Deficiency: Testing

FDA

- You conducted unit testing on your software components. **However, it is unclear how the off-the-shelf (OTS) components are accounted for in the unit testing.** The FDA needs to know that the information surrounding the OTS components is adequate per our final guidance, Off-the-Shelf Software Use in Medical Devices (2019). Please provide the information on your OTS components per the aforementioned guidance document. In addition, please provide a valid scientific rationale for how your current documentation covers these components.

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Lessons Learned: Testing

1. Regression testing and rationale for what is included/excluded is a common sticking point on submissions.
2. Surprisingly, perhaps, is that when testing is submitted, we don't see a lot of findings related to the test itself in contrast with physical medical device submissions. This may change as regulatory authorities get more experience with software.

Pro Tips

- **For each of your performance tests, define what version of the device and software were tested and explain what regression testing was completed and why those tests were selected.**
- **Include the rationale for regression testing decisions.**

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Deficiency: Cybersecurity

NB

- Reference documents related to GSPR 17 are provided, however cybersecurity-related EU regulation is not mentioned. (EU Cybersecurity Act Regulation (EU) 2019/881)
- It is not clear how MDCG 2019-16 (cybersecurity) requirements have been implemented.

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Deficiency: Cybersecurity

FDA

- Based on the information provided, it does not appear you have provided adequate information on the confidentiality controls for the device. In Section 5 of the guidance document titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", FDA recommends that **manufacturers ensure capability of secure data transfer to and from the device** and, when appropriate, **use methods for encryption**. Inadequate confidentiality controls can lead to the exposure of authentication protocol keys, passwords and information or commands transmitted to or from the device whose plaintext form could expose commands or information which could be used to impact device safety and effectiveness. Please provide a description of the confidentiality controls implemented for securing data transfer to and from the device. For encryption algorithms, please provide a detailed justification for how the algorithm(s) used provide sufficient security based on the risk of the asset.

33

Deficiency: Cybersecurity

FDA

- Based on the information provided, it does not appear you have provided adequate information on the authentication controls for the device. In Section 5 of the guidance document titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", FDA has recommended that manufacturers address the following related to authentication:
  - Strengthen password protection by avoiding "hardcoded" passwords or common words.
  - Limit access to devices through the authentication of users.
  - Employ a layered authorization model by differentiating privileges based on the user role.
- We acknowledge that you have provided some information to demonstrate how you have traced your cybersecurity risks to your cybersecurity controls. However, your submission does not provide adequate traceability for cybersecurity.

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Lessons Learned: Cybersecurity

1. Regardless of device classification, cybersecurity will be examined, and we are seeing more questions on devices that are not connected (to a healthcare network) that used to be reserved for either wireless or physically connected devices.
2. Include cybersecurity in your change management because there are always new threats.

Pro Tip: Follow the guidance documents for both the U.S. and EU during design and development. It is tough to create the necessary documentation after the software is implemented. Tap into your internal IT department for support; as iti is possible that they have already handled cybersecurity threats for your business.

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Clinical Deficiencies

These are the most expensive and time-consuming deficiencies.

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Deficiency: Clinical Safety and Efficacy

NB

- Claims on **clinical benefit** are not included.
- Claims on **clinical safety** are not included.
- **There is not sufficient clinical evidence** to support the clinical performance and safety of the device for the claimed intended use and indications.
- The CER does not appear to discuss **how the module has been trained** in terms of the datasets used or the methods adopted.
- In addition to the **very low number of patients,** which does not allow formal conclusions to be drawn, it should be noted that the provided **demonstration of equivalence** did not allow, at this stage, to formally demonstrate equivalence.
- **Based on state of the art,** the manufacturer did not describe the parameters used to determine the acceptability of the **benefit-risk ratio** for the intended purpose of the device.
- Generally speaking, there is **insufficient detail and consistency across the technical file** in relation to the scope, function, intended purpose and clinical benefit of the device.

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Deficiency: Clinical Safety and Efficacy

FDA

- The study did not track how much time participants spent logged into the software.
- Device is based on a machine learning-trained algorithm; it is important to demonstrate that the device is robust to the different patterns in patient signals.
- While there could be benefits for your device if it can be demonstrated to improve diagnosis in some groups of patients or clinical scenarios, your study does not address FDA concerns with respect to real-world performance (concerns that your panels were not representative of real-world providers).
- Not testing the device on current care patterns and patients affected by COVID-19 may provide device performance estimates not generalizable to current patients, presenting a risk of incorrect patient management based on nonrepresentative performance data. Please provide clinical performance testing from patients representing current care patterns or a scientific rationale of why the results provided are representative of the intended use population.
- Lacking critical subgroup analysis.

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Lessons Learned: Clinical

1. SaMD is not exempt from all the clinical requirements that are required for physical medical devices, and the findings are similar across product categories.
2. Getting the indications correct is critical to have supporting data for each of the intended uses.

Pro Tip: We are seeing an increase in requests to make sure that there are quantitative benefits and risks.

Download the white paper, "Benefit-Risk Determination: A Quantitative Approach" (rqmplus.com)

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Lessons Learned: Clinical

3. If your study doesn't capture critical information during the clinical study, it can be hard to go back and get that information when deficiencies are identified.
4. The FDA is putting increased emphasis on subgroup analysis covering items such as ethnicity, diagnosis, age, race, etc.

Pro Tip: Providing your study protocol and Statistical Analysis Plan (SAP) to the FDA via a pre-submission meeting can avoid costly misses in the protocol.

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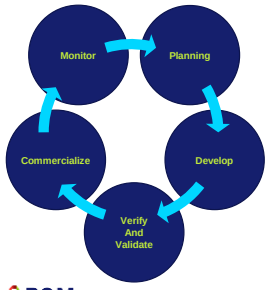

Post-Market Considerations

The product-related issues do not end once the product is cleared, approved or CE marked.

- Bug fixes and New features
- Post-Market Surveillance / Post-Market Clinical Follow-up
- Quality Management System Inspections

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Bug Fixes: U.S. Focus

The Problem

- Software can have bugs that are known at the time of release or discovered after the launch.
- A conservative reading of the FDA guidance on enhancements versus recall can classify some of these fixes as recalls.

"FDA generally considers devices that fail to meet represented specifications or that fail to perform as represented to be of a quality below that which they purport or are represented to possess, rendering them adulterated under section 501(c) of the FD&C Act [21 U.S.C. 351(c)]. Changes intended to resolve a failure to meet specifications or failure of the device to perform as represented would generally constitute recalls."

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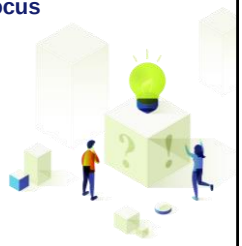
Addressing Bug Fixes: U.S. Focus

The Solution

- Start with a risk assessment of the proposed bug fixes or changes.
- Use the risk assessment to determine if this is a bug fix or something more.
- If the risk assessment reveals a potential issue, proceed to get additional clinical assessment via a Health Hazard Evaluation (HHE) or Health Risk Assessment (HRA) to assess the severity of the situation.
- Document if a new 510k is required (clue: probably not).
- Commission a recall committee to make the final decision if a recall (correction) is warranted, and determine if it is necessary to report to regulatory authorities.



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Bug Fixes: EU Focus

The Problem

- Gathering PMS data and PMCF data will at times reveal unknown failure modes, new risks, trends or off-label use.

"Manufacturers shall report, by means of the electronic system referred to in Article 92, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information."

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Addressing PMS/PMCF Observations: EU Focus

The Solution

- Start with a risk assessment of the situation.
- Determine if an update to the Clinical Evaluation Report (CER)/Performance Evaluation Report (PER) is required.
- Determine if a Field Safety Notice (FSN) is required.
- Determine the impact on your CE marking.
- Check MDR/IVDR for requirements.
- Check NB contract for specific change notifications.
- Implement required device/software changes.
- Check labeling and update as needed (including unique device identification).

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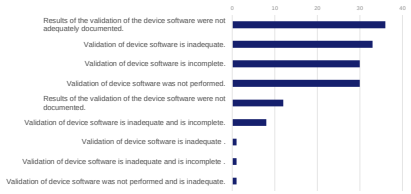
FDA Inspection Findings – Software Validation

Software Inspection Validation Related Findings



Note:
This is only device software; it excludes QMS and production software findings.

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Inspection Results – Device Master Record

- The device master record does not include or refer to the location of device software specifications.

Pro Tip: Make updating your Design History File (DHF), Device Master Record (DMR) and technical documentation part of your change control process to avoid the need for cumbersome reactive updates in preparation for, during or after an inspection!

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Upcoming Developments

EU
- AI regulation pending that impacts all AI devices, not just medical devices
- Specialized NBs to handle the unique needs of software medical devices

U.S.
- More and more de novo devices to leverage as predicates with PCCP built in as a special control
- New Software Guidances on FDA's 2023 priority list:
  1) Guidance for Content of Premarket Submissions for Device Software Functions
  2) Marketing Submission Recommendations for A Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

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Key Messages

- Plan on implementing IEC 62304 requirements as the baseline for all activities related to software development and documentation.
- Even though you can update software on a shorter timeline than a physical device, it doesn't mean you can use shortcuts for design control steps.
- You can reduce questions by following current guidance and being in accordance with the regulatory bodies' requirements.
- Keep up to date on regulations as changes are coming.
- Disclaimer: We focused on software-related findings, but these devices are subject to other findings (e.g., labeling).

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Thank You

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- Slides and recording this week
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