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WEBINAR - Q&A

The ABCs of Medical Device Software Compliance under EU Regulations 2017/745 & 2017/746

April Komplin's Presentation

Q: What should be included in the risk management file?

A: It is your risk management plan and your risk assessments, whether you have 1, 2, 5 or even more than that, you can move on to your benefit risk analysis, and finally your risk management report. And those items together will comprise your risk management file.
Ensure the requirements of ISO 14971 are incorporated into your programs and documentation. This standard will be cited many times in your GSPR analysis, which is of course a technical file requirement for both the MDR and the IVDR.

Q: How does the IEC 62304 safety classification relate to the FDA level of concern?

A: Well, they are both risk-based, they're both three levels, but both ask different questions to arrive at the classification. So, manufacturers who are attempting global clearance should refer to both separately.

Q: What if I cannot find a notified body to support my device?

A: We recommend that manufacturers reach out to multiple notified bodies if they haven't already. Some are months out from the ability to take on new clients.

Q: How do I know if my medical device software requires notified body involvement?

A: Review all of the regulations, and simply put, notified body involvement is required for devices higher than class 1 in the MDR and higher than class A of the IVDR.

Q: How does Brexit impact the ability to market my device in the UK?

A: The UK will accept a CE mark until June 30th, 2023. During this transition time, manufacturers will begin to transition to UKCA, so the UK conformity assessment will be in effect.

Q: What IEC 62304 documentation will I submit to my notified body?

A: IEC 62304 is very program oriented, so be ready to show your procedures during your onsite MDR or IVDR audit. In the technical file submission, consider the following: the summary information into your dossier, which would include interoperability, security controls, reference to design and items such as that. Also consider writing a formal 62304 report. You also may submit your test plans, your maintenance plans, and your validation reports and your software requirements specifications as required by your notified body.

Q: What IEC 62304 documentation will I submit to my notified body?

A: Procedures are not typically included in a technical file submission. These will be needed for the first part of your conformity assessment, and your onsite MDR or IVDR audit.

Q: Do I need to write a procedure specifically for IEC 62304?

A: No. The requirements of IEC 62304 should be blended into your other quality procedures, which includes but is not limited to, software design and development, risk management, change control, control of nonconformities, CAPA, post-market surveillance and vigilance reporting.

IEC 62304 is program oriented, so be ready to show your procedures during your onsite audit.

Note: It's recommended to cite your reference standards and regulations at the end of your procedures.

Q: What documentation is required to be maintained in accordance with IEC 62304?

A: Just remember that there are more requirements for safety classes B and C than they are for A. Below is a list; note that all procedures are also required by ISO 1345/MDR/IVDR.

Procedures listed here:

- Software design and development procedure
- Software requirements specification
- Software development plan
- Software maintenance plan
- Software test plan
- Change control procedure
- Control of nonconformities procedure
- CAPA procedure
- Post-market surveillance procedure
- Vigilance reporting procedure
- Gap analysis and documentation of follow-up activities
- Legacy software planning

Helping You With **Regulatory Operations**

Celegence's expert medical device team can provide you with flexible and specific services based on your particular therapeutic area, classification of the device, and notified body requirements to be compliant with all the EU MDR requirements.

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