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Developing Medical Devices using Artificial Intelligence

Engineering processes for AI must comply with generic as well as industry-specific regulations when it comes to medical devices

Deloitte believes that the only way to ensure the safety and security of AI-based medical devices and applications is to establish the right, compliant process framework and pair it with sound quality assurance for the data and the model itself. The first step when you start to work with AI is to adapt and extend the engineering process framework, which must be defined and maintained as a certified quality management system. In this article, we will provide some examples of changes to existing procedures as well as new procedures that are necessary for either generic AI regulations or industry-specific regulations.

Industry non-specific regulations & best practices

The proposed European law on artificial intelligence (AIA) is designed to ensure that AI is safe and to promote the uptake of trustworthy AI within the EU economy. Unfortunately, the medical device and healthcare software sector is already highly regulated with an existing range of AI-focused regulations. There is a risk that the recent regulations on medical devices and in-vitro diagnostics will overlap with the generic provisions of the proposed AIA and cause duplication as well as confusion. Enterprises should expect to cope with a third class of risk coming from the AI Act in addition to the existing device and software risk classifications. To ensure that the process is as efficient as possible, engineers must include all regulatory requirements in a single engineering lifecycle from the initial vision/portfolio to market observation.

However, in addition to the AIA, there are other regulations that we have to consider as well. We currently see three different generic requirements at this level, as illustrated in the following examples:

AI-specific legislation

- Classifications pursuant to the Artificial Intelligence Act (AIA) and the consquences thereof should be included in the quality management system. It is safe to assume that most medical devices will be classified as "high-risk AI systems" within the meaning of the AIA, and later processes may need to use this classification as one of their inputs. Deloitte has created the Trustworthy AI Framework[1] to help enterprises comply with the AIA itself.

  Depending on the type of AI system, certain characteristics (race, sex, age, ...) may act as decision points. It is important to ensure – especially with continuous learning – that this does not lead to discrimination. Developers can manage these risks as part of the standard risk management process (ISO 14971), even if they are not technically related to patient risk.

GDPR

- If patients are subject to a decision based solely on automated processing, manufacturers should conduct a critical review with respect to Art. 22 of GDPR. Device manufacturers are advised to seek legal advice and provide detailed information about their standpoint in the product documents.

- If the AI is processing personal (health) data, manufacturers must ensure they have defined and implemented a process for deleting such data from the system.

Data Monetization

- Depending on the business case, the processed data (used either for training the model or to operate the device) may have a certain monetary value. Manufacturers should seek advice on how to handle this. Based on our strong footprint in the automotive industry, Deloitte has a long track record with and solid insight into proven business cases.

New medical device engineering processes specifically for AI

As a manufacturer, you will need to add some new procedures to your quality management system. Most of these procedures are related to the different ways data is used in AI development and must be both established (documented, trained) and maintained (subject to oversight), as evident in the following examples:

Data Sourcing

Even if managing test data is already an established component of most process landscapes, data quality control is much more important when it comes to AI development because it is the main building block of the product. Manufacturers must carefully specify the sources of the data and any related requirements as well as monitoring and documenting the overall quality of a dataset. Instructions for new practices (e.g., the use of nutrition labels in datasets) should be added to the process landscape.

Data Management

At the data level, there should be instructions on how to evaluate data and exclude invalid data. This includes both patient-related criteria (e.g., age, sex, disease) as well as technical criteria (e.g., data types, coding, precision). There should be a controlled and documented process for deriving labels based on the intended purpose of the system. Pre-processing of data should follow a documented process and should be transparent (especially in terms of converting numerical to categorical data).

Legacy Models

Pre-trained models are beneficial for building AI solutions. However, manufacturers should set up a process to document the rationale for using a pre-trained model as well as the associated risk, and to identify and justify any type of risk oversight that might be necessary.

Well known regulations that need to be interpreted to fit to AI engineering

The medical device and health software engineering process is already highly regulated. However, when AI is introduced, manufacturers need to adapt the existing procedures and add some AI-specific features such as the following:

Requirements

It would be beneficial to include dedicated examples of AI functionality in instructional and training documents for requirements engineers. Among other things, this includes self-tests of the AI (especially for continuous learning) as well as methods of tracking changes to the algorithm and visualizing them for the operator.

Interfaces

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Configuration Management

When it comes to continuous learning in particular, manufacturers have to manage versions that vary considerably based on changes to the algorithms in the field. It is important to extend version control to model, data, soup, frameworks etc. Where the technical AI solutions use PAAS/SAAS, manufacturers will have to contend with changes made by the operators of these solutions.

Conclusion

With its Trustworthy AI Framework, expertise in medical device engineering and its own engineering facilities, Deloitte is perfectly positioned to support your engineering teams as well as your quality assurance teams and ensure your staff, processes, tools and products are ready for the future of AI. The use of AI may introduce some new challenges to your process landscape as above examples shows. We are happy to support you with overall concepts as well as with more technical advisory.

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