Regulatory

cara LIFE SCIENCES PLATFORM

Medical Device Submissions

Medical Devices capabilities designed from the ground up for Device companies

The CARA Life Sciences Platform provides an accurate and secure repository for maintaining DHF, DMR & DHR, serving as a central hub for documentation, development and approval. CARA's workflow capabilities accelerate development, shortening the implementation time to support Medical Device submissions and post-approval maintenance.

Benefits

Fast and User Friendly

CARA is a versatile content management solution that offers extensive configurability, enabling organisations to maintain low implementation and maintenance costs while granting them the flexibility to oversee their own configurations. Additionally, users enjoy a swift and intuitive interface complemented by a wide range of personalisation options.

Pre-configured for Medical Devices DIA Reference Model

We offer a pre-configured package based on the DIA Reference model, with fill support for the complexities of Design History Files (DHF), Device Master Records (DMR) and Device History Records (DHR), as well as individual source documents.

Workflows and structure to support the process

Virtual documents can be configured to automatically populate with a pre-set structure, DHF, DMR and DHR templates can be automatically populated and workflow tasks can be allocated to complete your business process.

MEDICAL
DEVICE
SUBMISSIONS

CARA for Medical Devices

Regulators require that all providers, manufacturers and distributors of Medical Devices meet a stringent approval process and abide by rigorous quality standards before and after a Device is distributed. In addition, all associated records in this process must be securely maintained.

Create

Create or import files, records and other information directly in The CARA Life Sciences Platform, ready for submissions and adhering to regulations (e.g. 21CFR 820). Co-author and review selected documents within CARA's secure collaborative environment. Approve documents with CARA's electronic signature capabilities or through integrations with DocuSign and AdobeSign.

Manage

Generis can configure Structures to meet with company-specific requirements. E.g. automatically populate DHF, DMR and DHR templates with placeholder documents required. Set up workflows to manage and trace every step of the design phase and production process and divide tasks for fast, easy completion.

Submit

Submitting documents once the file has been compiled and approved for submission is easy in The CARA Life Sciences Platform. The documents within a Virtual Document can be transferred in a variety of formats, including to a ZIP File or concatenated to either Word or PDF. We have a range of integrations with publishing tools in order to streamline submissions, including planning.

Third parties

The CARA Life Sciences Platform can empower easy collaboration with third parties. The dynamic per-document-per-workflow security means that access can be granted to the repository and only users with workflows can see any documents. This includes being able to have collaborative (simultaneous authoring) using technology from Box, SharePoint or Google Docs.

Track & re-use

With the use of CARA Structures, re-using components or entire sections of submissions multiple times becomes easy, allowing dossiers to be assembled for different regions more quickly, while also allowing tracking of the submission status and where individual components have been used, thus allowing easier updates to multiple regions.

Contact us for a demo or evaluation
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