TechFile Manager

- ✔ **Compliance with CFR 21 part 11 and Annex 11**
- ✔ **Management of user profiles/roles and permissions for processing/consulting the Technical File**
- ✔ **Support of the entire document cycle of Technical File**
- ✔ **Automated management of chapters and sub-chapters in compliance with legislation**
- ✔ **Template management applicable to each paragraph**
- ✔ **No user involvement in electronic Technical File creation processes by indexing chapters and subchapters to allow efficient navigation throughout the Technical File**
- ✔ **Approval workflow by the Manager or one of his collaborators for each paragraph**
- ✔ **Automatic historisation of versions of technical File**
- ✔ **Simultaneous management of more Technical Files even for more companies**
- ✔ **The following file types can be attached to the individual paragraphs: word, pdf, excel**
- ✔ **Tracking management of consolidated versions with the archiving of changes that have occurred in paragraphs that are part of the Technical File**

GRUPPO SASI s.r.l.

TechFile Manager

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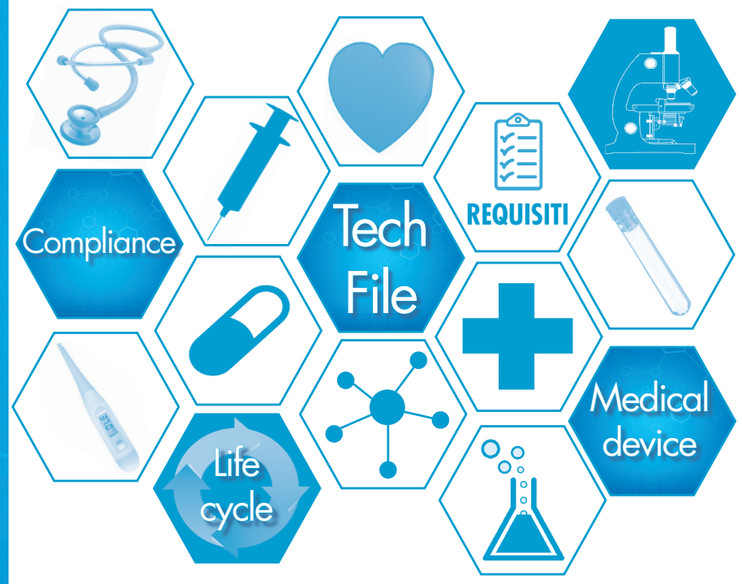
Technical File's management for Medical Devices



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TechFile Manager • Technical File's management for Medical Devices

Introduction to functionality

Gruppo SASI's offer for **the management of the Technical File for Medical Devices** is developed in full compliance with the legislation in force for the European community as illustrated in the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009. and repealing Council Directives 90/385/EEC and 93/42/EEC

The definition for the Technical File is provided in Annex II "TECHNICAL DOCUMENTATION" and in the following subparagraphs, in Annex III "TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE" and in Annex IV "EU DECLARATION OF CONFORMITY".

The organizational model useful to face the amount of documents that will have to be produced and that will become mandatory from May 2021 needs a computer tool comparable to a document management on the eCTD model in use in the pharmaceutical world.

Proposal

The Gruppo SASI's "Techfile Manager" solution for document management aimed at the electronic production of the Technical File has been developed and is based on some important elements such as:

CFR 21 Part 11 and Annex 11 compliance:

The system have the necessary validation capabilities including:

- User profiling: guarantees access and rights to both the various menu functions and documents;
- Versioning: every change made to every single paragraph of every version comes archived with the possibility of consultation and eventual restoration;
- Audit Trail: keeps track, with the possibility of consultation by authorized users, of the main operations carried out on the application.

In addition, the system meets the requirements of the Notified Bodies and is developed according to the guidelines in Gamp5.

Support of the entire Technical File documentary cycle

By inserting the main metadata, which will subsequently be proposed and/or reused by the system in the following editions (Name of Medical Devices, No Version, Holder, No Notified Body), the application develops the entire document structure of which the Technical File is composed by inserting for all paragraphs the correct title, header and footer in the desired representative style, and each document can incorporate predefined templates (E.g. General Safety Requirements).

Creation of the electronic Technical File without user involvement

By calling the appropriate function from the main menu, the publishing is automatically carried out, which creates the package to be sent to the Notified Body, consisting of the folder tree, the relevant paragraphs converted to pdf format with the relocation of hyperlinks, the indexing of chapters and subchapters and, above all, an Index.xml to use to navigate the electronic Technical File.

Life Cycle: Automation for Hyperlink Relocation and Revisions

Starting from the second electronic edition of the Technical File, the application provides a sophisticated management of the "life cycle" that, in addition to automatically relocate all the hyperlinks present in the initial version, through the identification of new or modified paragraphs creates and/or increases, always without the intervention of the user, the No of revision for the aforementioned paragraphs

Tracking management of consolidated editions

Always starting from the second edition of the Technical File, once generated the electronic structure, the application stores in a specific directory the files in pdf format highlighting the changes occurred in the paragraphs that are part of the Technical File.

Conclusions

To finish, we want to underline that the system is developed with the collaboration of specialists working in the Medical Devices field and especially in the implementation and subsequent management of the Technical File.
Therefore, the result is a constantly careful design to meet the most complex application needs entrusting the system with the correct interpretation of the legislation to allow users to focus exclusively on professional content of their role facilitating and streamlining day-to-day activities impacting on the documentary management of the Technical File and making it easier the consultation for Notified Bodies