PSMF Manager

PSMF document management system

- Complies with the rules of CFR 21 part 11 and Annex 11
- Management of user profiles/roles and permissions for processing/consulting the PSMF
- Support of the entire document cycle of PSMF
- Automatically manages chapters, sub-chapters and Annex complies with legislation
- Template management applicable to each section/paragraph
- Automatically manages the document versioning and the transaction Audit Trail
- No user involvement in electronic PSMF creation
- Indexing chapters and subchapters to allow efficient navigation throughout the PSMF
- Automatically creations Logbook (Annex I) based on the changes made
- Automatically archives versions of PSMF
- Simultaneous manages multiple PSMF based on product types and / or companies / branches
- Possibility to upload any type of file to each paragraphs (word, pdf, excel, etc ...)

www.grupposasi.com

GRUPPO SASI s.r.l.

via padre reginaldo giuliani, 10/a - 20125 milano
phone number +39 02 87065690 - e-mail: contatti@grupposasi.com

PSMF Manager

Pharmacovigilance System Master File

PSMF Manager SASI

The prestige of excellence in PSMF management

GRUPPO SASI s.r.l.

PSMF Manager • The integrated and efficient management of PSMF

Introduction

The guidelines for "Good Pharmacovigilance Practices (GVP)" were introduced by Directive 2010/84/EU and made explicit in 16 modules covering the main pharmacovigilance processes.
The section on the indications on the management and maintenance of the PSMF is dealt with in Module II and has entered into force since July 2012 and intended to evolve to become mandatory from 2015 by increasingly using IT media.
With *guideline*, EMA has adapted the regulatory requirements for PSMF to focus on the following topics:

- Collection of key information on medicines
- Better analysis and understanding of data and information
- Regulatory action to protect public health
- Communication with interested parties

Proposal

The Gruppo SASI's solution "**PSMF Manager**" complies with the current standard, has been developed in Web Based mode, so reaching from any location, and also, referring to the quality of the solution, we highlight some important elements such as:

CFR 21 Part 11 and Annex 11 compliance

The system shall have the necessary validation capabilities including:

- user profiling to ensure access and rights to documents
- *versioning* (any change made to a document is monitored and archived)
- *audit trail* (the main operations carried out by users are traced, with the possibility of consultation by the administrator of the system).

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

Support the entire PSMF production cycle

By simply indicating the following metadata:

Unique number assigned by EV System - MAH
MAH of the QPPV - MAH sharing the pharmacovigilance system

the system provides the development of the entire document structure of which the PSMF is composed both for the main contents (listed in the legislation in Chapter II.B.4) and for the Annex. It also provides the production of all documents bearing the title of the paragraph, as well as any *headers* and *footer* in the desired representative style.
Each document can also automatically embed "*templates*" and from the outset, it's been at an advanced stage of the process.

Creation of electronic PSMF without user involvement and historicization of the previous version

Calling the appropriate function from the main menu will automatically generate the PSMF in PDF format with the indexing of chapters and under chapters to allow an efficient navigation throughout the documents. In addition, if a previous version of PSMF was already present, it would be transferred according to agreed specifications and placed in a special *repository* to be consulted at any time.

Automatic management of the Logbook (Annex I)

Downstream of the first electronic version of the PSMF the system provides a sophisticated management of the "*life cycle*" that through the identification of paragraphs inserted ex novo or modified creates and/or automatically updates the paragraph of the *logbook*; also acts on the *header* of documents with the revision of the version and/or modification date.

Conclusions

To finish, we want to underline that the system is developed with the collaboration of specialists working in the field of Pharmacovigilance; therefore the result is a design that is constantly attentive to satisfying the most complex application needs, entrusting the system with the correct interpretation of the technical regulations to allow the user to focus exclusively on the professional contents of his role.
The result is a large-scale applicative computer system, yet easy to insert into the company and easy to use.
This allows the user organisation to achieve its objectives without creating new structures or committing additional resources, having the certainty of being able to assess the investment exclusively on the basis of the economic offer and the guarantee of not having to sustain additional consulting costs.