

Pharmacovigilance System Master File (PSMF)

Managing the PSMF is a complex, ongoing task, involving the updating of sections owned by different parts of the business, and particularly the creation of Annexes from information that comes from various sources. The CARA Life Sciences Platform facilitates the entire process, including the automatic generation of Annexes.

Benefits

Breaking up the PSMF into separately owned sections

The PSMF main body chapters and annexes are separated into sections within CARA, allowing for the flexibility of multiple data owners. Workflows will be generated based on data triggers to the respective owners, and then finally to QPPV for review and approval.

Generating the Annexes

CARA can automate retrieving of data from various systems for automatically generating submission-ready PDF documents for each Annex. The source systems for the data can be CARA (e.g. Safety Data Exchange Agreements), Excel (exports from other systems) or via direct API connection to other systems. The changes within the PSMF sections themselves are recorded in CARA Audit Trails and can automatically generate an Annex documenting the updates.

Quarterly and Annual reviews

Dependent on which section would need to be reviewed quarterly or annually, there will be periodic review workflows managed through CARA, to notify the relevant section owners of the required update. Versioning will be used in CARA to produce the newly updated documents from older versions as well as keep track of previous versions.

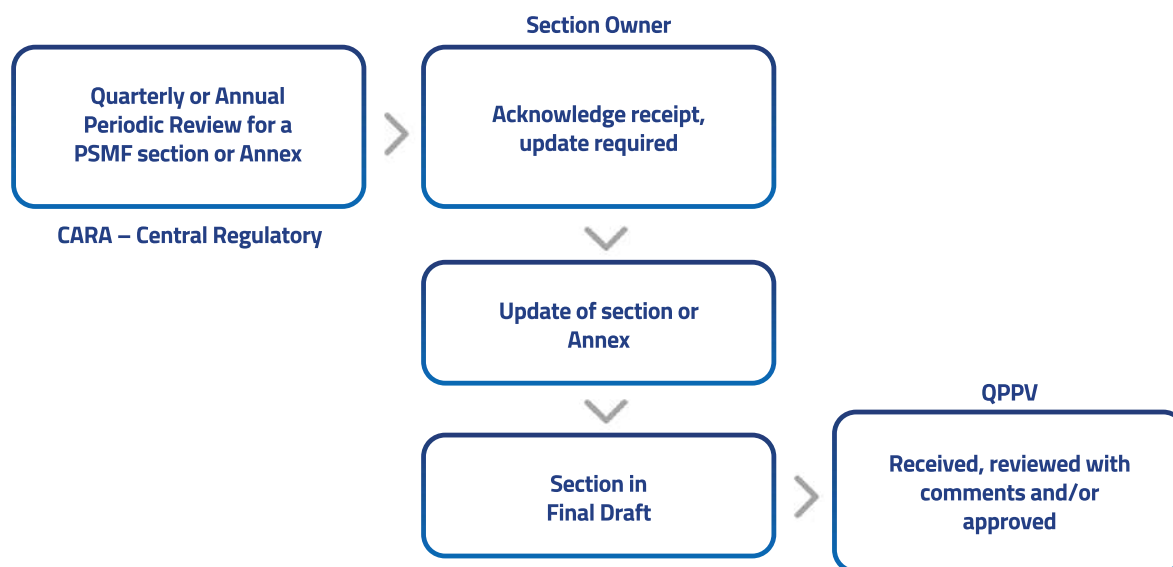
Concatenation

Once all relevant documents are up to date and approved, the different sections are concatenated, assembled, producing one word or PDF document containing all updated sections ready for submission.

Global vs Loca

The sections of the Global PSMF can be used for the Local PSMF or adapted. Through property inheritance, CARA allows an automation for the generation of local sections from global sections. Local PSMFs per country/market are also handled/stored in CARA with the same functionality as the Global PSMF.

PSMF Section Send for Update – Example workflow



Complex PSMF Workflow

- Each section consists of multiple documents that are required to be updated on a periodic basis for each full PSMF submission.
- Traditionally, these involve external systems for sharing content AND some separate system for registering and reporting on submission.
- This can all be done through CARA, with QPPV logging into a simple UI to perform their tasks.
- Define complex workflows in CARA based on process rather than documents.
- Distribute documents to QPPV including reviews for each step and section of the process.
- Defining default sections per country for Local/Global combination.
- Allow Affiliates/QPPV to login to login to a simplified CARA Portal and see/process just their workflows, including visibility of associated documents.
- Allow for automated notifications on each step, including overdue notifications and escalations.
- All actions added to the dashboard so the QPPV have a real time view of the status of each section of the Global/Local PSMF.

Why CARA?

Maximise the user experience

simple to learn, use and is personalised to each individual's requirements.

Access and manage content from one place

a single destination user interface, integrated seamlessly with multiple systems.

Meet corporate and regulatory standards

configure CARA to suit your exact requirements.

Supports the full document lifecycle

from creation to access, search, review, approval and publication.

Automate manual processes

with CARA workflows.

Easily navigate and search content

CARA provides multiple ways to access the information you need.

Securely access content on the go

our mobile app give you the full CARA experience.

Securely share information with external partners

secure third-party access, watermarking and more.

Contact us for a demo or evaluation
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