PSMF TRACKER

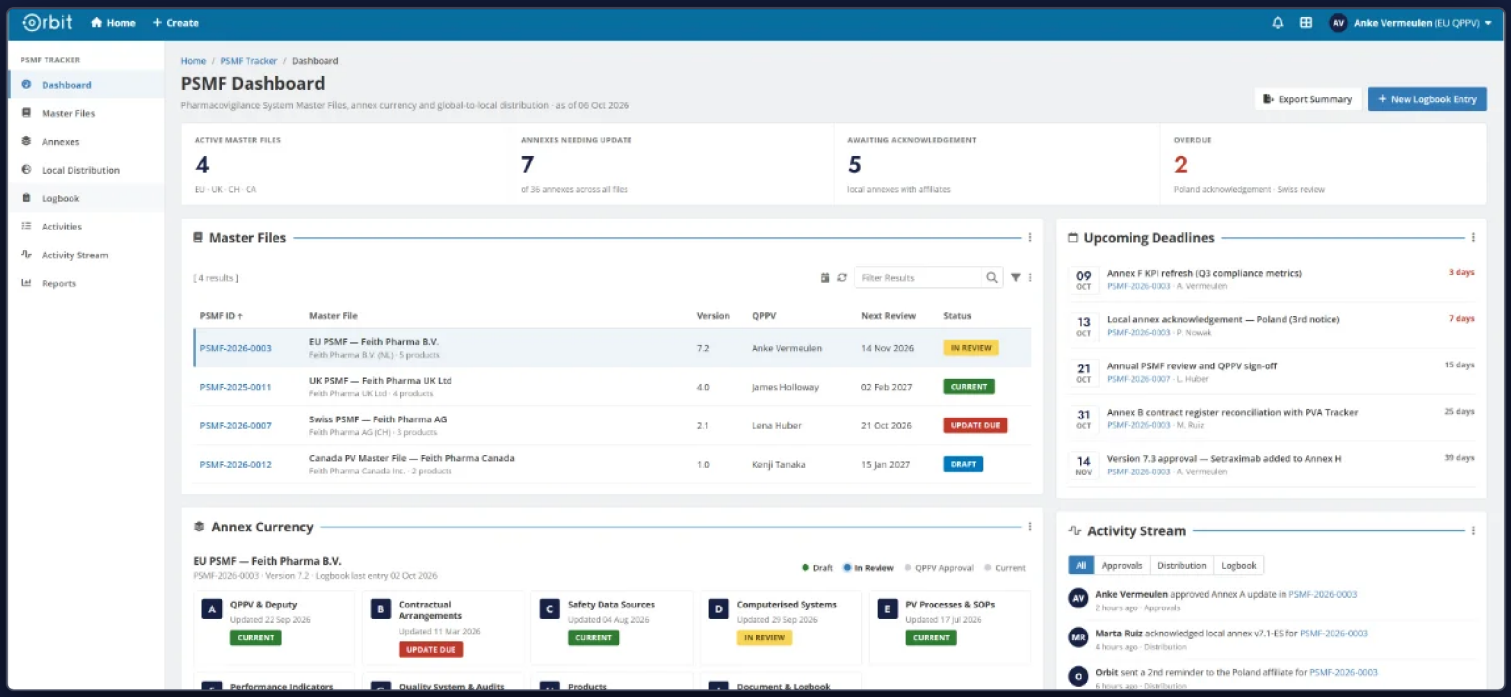
One Master File. Always Current.

Orbit maintains the Pharmacovigilance System Master File as a living record. Section owners keep their content current, annexes version cleanly, and global-to-local distribution reaches every affiliate with a documented acknowledgement.

Section ownership assigned

Annex versions controlled

Distribution acknowledged



PSMF SOLUTION

Keep the master file inspection-ready

Orbit governs the PSMF and its annexes as tracked processes, so every update has an owner, a date, a version and a record of who received it.

Master file oversight

See the status and last review date of every PSMF section and annex at a glance.

Update automation

Periodic review cycles open on schedule and notify the section owner responsible.

Global distribution

Distribute annexes to local affiliates and track acknowledgement market by market.

Inspection-readiness

A complete version and change history sits behind the file for any inspection request.

What the tracker covers

- PSMF sections and annexes
- Periodic review cycles
- Global-to-local distribution
- QPPV oversight record
- Section ownership
- Version and change history
- Affiliate acknowledgement
- Inspection evidence pack

HOW IT WORKS

01
Structure the file
Model the PSMF and its annexes as sections with defined content requirements.

02
Assign the owners
Give each section an accountable owner with review dates and reminders.

03
Review on cadence
Scheduled review cycles capture updates, approvals and version increments.

04
Distribute and confirm
Push current annexes to affiliates and record every acknowledgement received.



About Feith System & Software For over 40 years, Feith has delivered intuitive, versatile, next-generation solutions to highly regulated industries. That experience is the foundation Orbit is built on.

© Feith Systems & Software, Inc. · Confidential & Proprietary