AGGREGATE SAFETY REPORT TRACKER

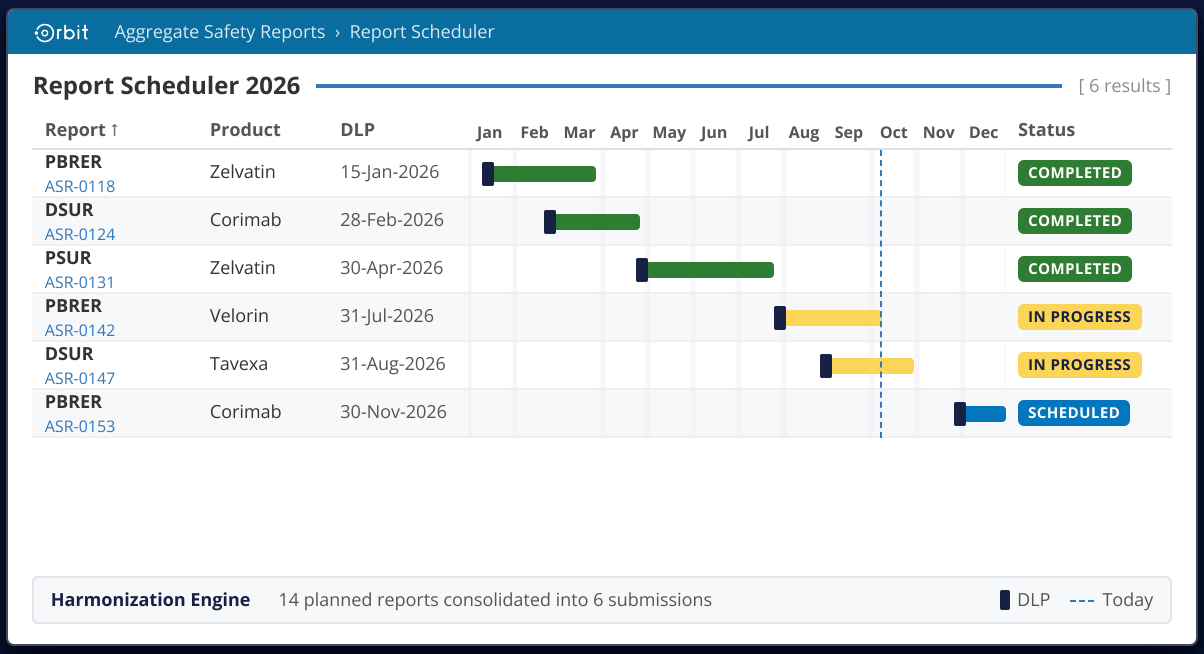
Never Miss a Reporting Deadline.

Orbit plans, schedules and tracks every DSUR, PBRER and PSUR from data lock point through submission. The Report Scheduler builds the calendar automatically, and the Harmonization Engine de-duplicates reports across products, countries and DLPs so your team authors once and submits everywhere.

Automated report scheduling

Harmonized across products and markets

Submission evidence on file



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AGGREGATE SAFETY REPORTING

Bring order to periodic reporting

From scheduling and harmonization through authoring, review and submission tracking, Orbit carries every periodic safety report end to end in one audit-ready source of truth.

Report calendar oversight

See every upcoming DSUR, PBRER and PSUR by product, market and due date in a single view.

Automated scheduling

Due dates generate from DLP, IBD and EURD rules, and reminders reach the right owner on their own.

Harmonization engine

De-duplicate overlapping reports across products, countries and data lock points before work begins.

Submission evidence

Drafts, approvals, health authority acknowledgements and follow-up commitments stay attached to the report.

HOW IT WORKS

01 Build the schedule

The Report Scheduler lays out every periodic report from your product and market rules.

02 Harmonize the scope

The Harmonization Engine collapses overlapping reports into a single planned submission.

03 Author and review

Route authoring, QC and approval activities with owners, timelines and reminders.

04 Submit and evidence

Log the submission, capture the acknowledgement and track every follow-up commitment.

What the tracker covers

- DSUR
- Report Scheduler
- EURD and IBD alignment
- PBRER and PSUR
- Harmonization Engine
- Authoring and review cycles
- ACO and Addendum Reports
- Data Lock Point tracking
- HA submissions and follow-up

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.

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