

Centralize Risk Management. Strengthen Safety Governance.

Managing product risks is one of the most critical responsibilities in pharmacovigilance. HaloPV Risks provides a centralized environment for managing the complete risk lifecycle – improving compliance, enhancing visibility, and streamlining risk management activities across the enterprise.

Why it matters

Increasing regulatory scrutiny

Health authorities expect a structured and traceable approach to risk management.

Complex global operations

Align global risk strategies with local implementation across products and markets.

Too much administrative effort

Reduce manual coordination and let safety professionals focus on science, not process.

What HaloPV Risks delivers



Centralized risk governance

Track submission volumes and health authority correspondence in one place.



End-to-end lifecycle management

Support identification, assessment, mitigation and monitoring.



Automated RMP & REMS generation

Generate compliant documentation using controlled content.



Global & local oversight

Track both strategic and local execution activities.



Workflow automation

Accelerate reviews, approvals and task execution.



Inspection-ready traceability

Maintain a complete audit history of decisions and actions.

BUSINESS OUTCOMES

- ✓ Improved compliance oversight
- ✓ Increased visibility
- ✓ Greater inspection readiness
- ✓ Faster document generation
- ✓ Reduced administrative burden
- ✓ Consistent global execution

Built for modern pharmacovigilance risk management



IDENTIFY



ASSESS



MITIGATE



IMPLEMENT



MONITOR



DEMONSTRATE
COMPLIANCE

HaloPV Risks supports every stage of the risk management process - from registering safety concerns to maintaining regulatory documentation.

Key capabilities

Risk register & safety concern management

Structured repository for risks, activities and assessments.

Risk management strategies

Define and govern risk mitigation approaches.

Risk minimization activities

Track implementation and effectiveness measures.

Risk tree visualization

Visualize relationships between risks and mitigation activities.

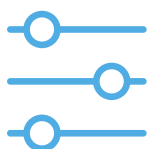
Signal & regulatory alignment

Connect signals, risks and regulatory requirements.

Timeline & activity monitoring

Monitor key milestones and deliverables.

Why HaloPV



Configurable Workflows

Adapt processes to your operating or governance model.



API-Driven Architecture

Integrates with PV, quality and regulatory ecosystems in a modern API-driven environment.



Validated Releases

Continuous innovation backed by full validation documentation.



Modular Expansion

Extend across PSMF, Agreements, Aggregate, Risk and Signal Management.

Move beyond tracking risks. Start governing them.

HaloPV Risks helps life sciences organizations establish a scalable, compliant and inspection-ready approach to risk management.



Identify risks earlier



Coordinate action effectively



Demonstrate compliance with confidence

Qinecsa

Transforming risks complexity into operational confidence.