

A flexible and compliant solution for pharmacovigilance workflows

Efficient adverse event reporting and risk–benefit assessments depend on flexible, compliant, high-quality systems for detecting, collating and assessing drug safety signals from multiple data streams.

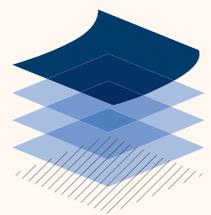
What is QUOSA PV?

QUOSA PV is a GxP-compliant workflow management tool for pharmacovigilance. It centralizes adverse event discovery, providing a complete audit trail and oversight of the literature management process.



How does QUOSA PV help?

QUOSA PV improves efficiency with automation of key literature monitoring and triage tasks in flexible, configurable workflows that support pharmacovigilance and other drug safety tasks.



Pharmacovigilance groups depend on targeted, up-to-date product information and adverse event reporting to meet regulatory requirements. However, many life science enterprises find themselves without a solution that can handle multiple data streams and workflows in an efficient and compliant way.

Key benefits

Coverage of a broad spectrum of literature sources

Use alerts to monitor multiple literature sources for reports of adverse events. QUOSA PV can monitor Elsevier and non-Elsevier literature databases, conference document databases, and journal RSS feeds. What's more, it automatically de-duplicates content, significantly reducing reviewing time.

Rapid assessment of articles

QUOSA PV automates article triage in an efficient and fully trackable process. It alerts users of new information, lets them quickly assess relevance for ICSRs, PSURs or other safety reporting, and refers the articles to specialists for review.

Full compliance with regulatory best practices

QUOSA PV is designed to operate in GxP-regulated environments. All document histories and system changes are recorded for a detailed audit trail.

Improved oversight and efficiency

QUOSA PV optimizes the review process by including workload management tools and dashboard views to monitor trends and incoming alerts. Compliant and comprehensive oversight of the full process is ensured, even when part or all of the work is performed by a CRO.

A scalable central library for lower costs

Literature is stored, tagged and organized in a scalable and secure cloud-based, centralized library, making it easy to review and annotate articles.

Rapid identification of case- and drug-specific data

All articles and adverse event and safety data are stored in a searchable product literature safety database, making it easy to find content and quickly export data in the relevant format for case reports, aggregated reporting and signal detection. What's more, pre-formatted output helps in the efficient building of all required reports.

Flexible workflows and user roles

QUOSA PV can be optimized for your organization's specific processes. It offers configurable workflows, the ability to assign multiple roles to a user, and optional quality control, quality assurance, signal management and medical review steps.

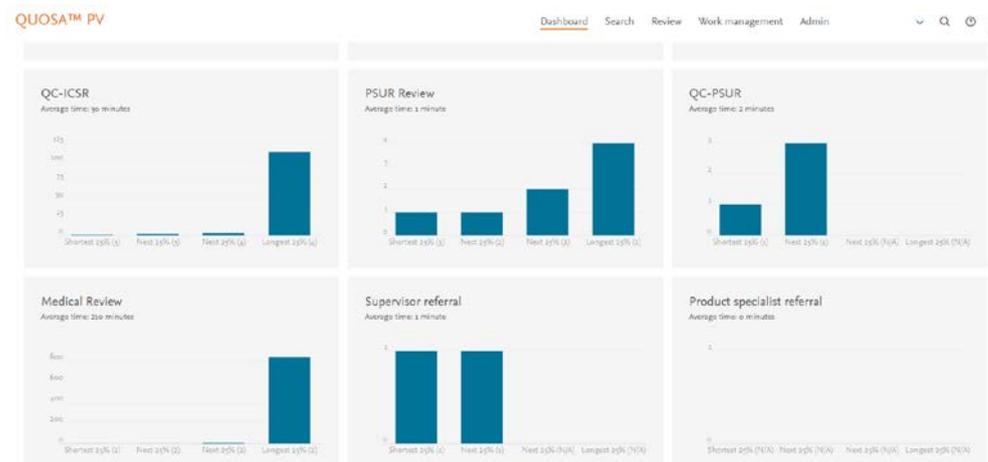


Superior review and workflow management

QUOSA PV is a browser-based tool with a user-friendly interface. Articles can be allocated to the relevant agents automatically or manually.

QUOSA PV makes it easy to find data for export in the relevant format for case reports, aggregated reporting, and safety signal detection needed for risk–benefit assessments.

QUOSA PV gives you the ability to view and export productivity metrics and review histories, and to reassign priorities and agents so that resources are properly managed.



QUOSA PV

QUOSA PV helps customers promote efficiency and compliance by centralizing the discovery of adverse event information in various types of literature, and automating information monitoring and triage in a scalable environment that supports detailed audit trails.

For more information, visit:
elsevier.com/QUOSA

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