

Make the **uncertain**,
certain.

Do you lose sleep
concerned about your
PV and Drug Safety readiness?



We can help.

We are PV professionals who have countless hours in front of worldwide regulators.

Our expertise...



Operational and Inspection Preparedness

We perform detailed audits that encompass pre and post-marketing environments...

Our Gap Assessments are guided by:

- Current Regulations and Guidance Documentation
- Significant inspection experience
- Predictive regulatory authority inspection targets
- Observed industry best practices

PV Functional Builds and Enhancement Expertise

- Including case processing and safety database vendor RFP, selection and deployment guidance
- Establishing effective governance, signal management, global drug safety offices
- Providing certified change management and Lean Six Sigma expertise
- Delivery of detailed, executive-ready project status dashboards



If you want to sleep better,
count on us instead.



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