

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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