

Pharmacovigilance Systems

BKP Technologies, Inc. assists pharmaceutical, biotechnology and medical device firms with the implementation/upgrade of Adverse Event (AE) case data management and regulatory reporting systems. We have 25+ years of experience implementing, configuring and validating product safety system solutions from all major software vendors. Our team have been involved in more than 100 safety system implementations or upgrades for clients of all sizes.



Pharmacovigilance Systems Services

- Extensive knowledge of the leading Pharmacovigilance Systems
 - Oracle's Argus Safety™
 - Aris Global's ARISg/LifeSphere MultiVigilance™ Suite
 - Empirica Signal™
- Evaluating and Selecting Pharmacovigilance Systems
- Installation and Upgrade of PV Systems
- Configuration (Systems, Products, Regulatory Reporting)
- Data Migration from Legacy Systems or Previous Versions
- Electronic Submissions and E2B Gateways (EMA/FDA)
- Validation using a Risk Based Approach
- Standard Operating Procedure (SOP) Authoring
- 21 CFR 11, EU Annex 11, and HIPAA Compliance

Our safety system implementation services are delivered by consultants and engineers with 20+ years of experience in implementing product safety systems in regulated environments. Our team will work with your internal resources to ensure effective knowledge transfer and to provide cost effective solutions and services that meet your regulatory and business requirements.



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