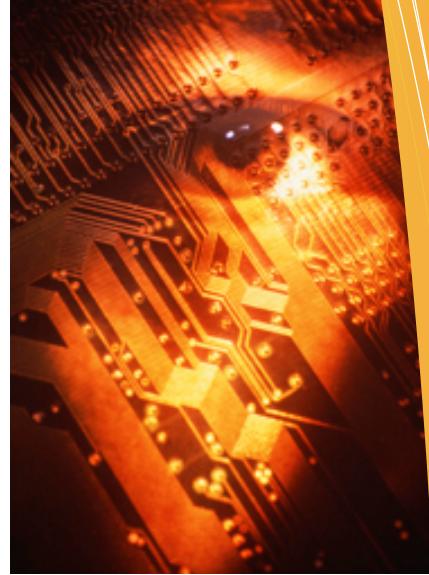


Computer System Validation

BKP Technologies, Inc. has extensive experience assisting life sciences clients with computerized software systems validation (CSV). Whether the need is for computer system validation as part of a new system implementation (in-house or hosted/cloud), upgrading an existing system, assistance with the latest 21 CFR Part 11 requirements, or an audit of your existing systems and validation status – BKP provides professional services to benefit your organization.



Systems Validation Services

- Software/Systems Development Life Cycle (SDLC) Methodologies
- Risk Assessments
- 21 CFR 11 Compliance
- Validation of in-house and hosted/cloud systems:
 - Pharmacovigilance/Safety systems
 - Clinical Data Management systems
 - Electronic Data Capture (EDC) systems
 - Coding Dictionary systems
- Custom in-house application validation
- Retrospective validation
- Standard Operating Procedure (SOP) Authoring
- Systems Compliance Audits

Our validation services are delivered by consultants and engineers with 20+ years of experience in validating computerized 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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We encourage you to contact us for a no-cost discussion to review your company's unique validation needs.