Jason Innes

Jason Innes Consulting, LLC

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An insightful technical and business-process consultant with a broad background in regulated technology environments. Extensive and varied experience designing, managing, delivering, and validating complex business-critical technology solutions for biotechnology, pharmaceutical, and software development clients. Strong ability to mediate between and end-user, technical, quality/regulatory, and business stakeholders to deliver effective solutions.

Professional Experience

Senior Consultant
BKP Technologies, Inc.
(Subcontractor)
July 2005 - Present

Provided a wide variety of services in the biotechnology and pharmaceutical industries as a member of a cross-functional consulting team, with clients ranging from small research biotech companies to the largest global pharmaceutical firms. Roles have included systems validation design and execution, consultation on SOP and SDLC development, project management of software development and data migration efforts, and conduct of vendor audits, with a particular focus in implementation and validation of safety, clinical data management, and research systems. Responsible for all phases of systems implementation and validation, including interfacing with business users for requirements gathering, technical teams for implementation and qualification, and quality groups for documentation.

Selected specific technologies and accomplishments:

- Project management and validation coordination of numerous implementations, upgrades, and data migrations of drug safety systems, including Argus Safety, Oracle AERS, and Phase Forward EmpiricaTrace, for more than 15 clients; worldwide implementations including EU and Japan.

- Requirements gathering, implementation, and validation of BKP Technologies Inc's BKP Codex: Up-Version toolset for performing MedDRA up-versioning.

- Implementation of E2B electronic safety reporting solutions for pharmaceutical clients using Argus ESM, Cyclone Interchange, ARISg ESM, and Empirica Gateway.

- Development of custom Oracle PL/SQL, PHP, HTML5/JavaScript, and ColdFusion applications interfaced with clinical and safety databases.

- Investigation and proposed remediation of data migration issues for a top-three Pharma company, which led the FDA to close out a 483 warning letter previously issued against that company.

- Development and implementation of SOP and SDLC policies, and conduct of SOP and SDLC compliance audits.

- Expert witness / consulting services in support of intellectual property litigation in life sciences technology.

Senior Consultant Versal Technologies, Inc. February 1998 - July 2005	Provided project management and software development to a range of customers, primarily in biotech/pharma. Extensive experience coordinating internal and external resources, such as developers, designers, data managers, and vendors to meet client schedules and budgets. Technical experience in clinical software validation, CDMS implementation, data migration, RDC system design, and distributed data aggregation and integration.

Selected specific technologies and accomplishments:

- Developed Java and Javascript-based web-based clinical data collection system (Versal WebTrial) integrated with the Clintrial CDMS.
- Developed PHP web-based clinical data collection system for a research customer.
- Project management and validation coordination of Oracle Clinical and Domain Pharma Clintrial CDMS deployments and upgrades for 10 clients.
- Setup of clinical trials in CDMS systems including database design and screen/form validation.

Community Editor (ZDU) Ziff Davis, Inc. March 1997 - Feb 1998	Managed development of community components (discussion boards, chat, etc.) of ZDU, a web-based collaborative learning initiative of ZDNet. Responsible for documentation of system requirements based on user feedback, system design, and management of external developers to implement.
Project Leader Houghton Mifflin Co. January 1995 - March 1997	Managed development of educational software products for the Sixth Floor Media group of Houghton Mifflin. Responsible for project management with external developers. Main products were CommonSpace, for networked collaborative writing, and CourseMap, for networked course-management.

Education

B.A, Magna Cum Laude Harvard College Graduated January 1994	Graduated Magna Cum Laude with a B.A. in Media Studies. Thesis examined theory of communication in emerging computer network-based media.

Interests

Hiking and camping, running, STE(A)M education, educational technology and games.