Tribiosys

Expediting decision making in R&D

ABOUT

Tribiosys is a scientific consulting company that designs and develops solutions for analyzing and managing R&D data and processes. Our customers include top-tier pharmaceutical, biotech and medical-device companies, as well as cutting-edge startup organizations.

We work closely with our customers to define strategies and custom solutions around their research, pre-clinical and clinical needs. Our approach employs proven methodologies and best practices around quality and project management that our experienced staff have developed and refined through complex projects.

The Tribiosys team consists of industry-experienced scientists, informaticians, technologists and regulatory experts who work on engagements together to understand our clients requirements, drive end-user consensus and deliver technology solutions.

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SCIENTIFIC COMPUTING SERVICES

Tribiosys informaticians and software developers have used their expertise to help our clients develop custom algorithms and enhance their scientific computing capabilities. Working closely with our clients we have delivered projects in areas such as:

- Developing RNAi picking tools using proprietary parameters
- Formulating enhanced weighted matrices to predict biological activity of predicted RNAi targets
- Evaluating and selecting biological pathway visualization tools for signal transduction, metabolite and cellular pathways
- Parallelization of sequence analysis algorithms to proprietary distributed computing platforms

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LABORATORY DATA AND INFORMATION MANAGEMENT SERVICES

Tribiosys provides technology consultancy and development services to assist R&D organizations in better management of research and development data and processes. Successful integration of unstructured data from disparate sources through the use of LIMS, scientific data management systems and electronic laboratory notebooks provides an infrastructure for the development of effective decision-support solutions.

Tribiosys' cross-trained team of scientists, informaticians and technologists utilize their expertise in drug discovery & development as well as state of the art technologies to craft solutions that enable better, faster scientific research and clinical processes. We have assisted our clients in the evaluation and implementation of integrated laboratory environments that involve multiple instrument types, commercial and custom LIMS and scientific data management systems. These solutions were designed to adhere to 21 CFR Part 11 and cGxP regulations when required.

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CLINICAL DATA AND INFORMATION MANAGEMENT SERVICES

Tribiosys has extensive experience in the clinical trials lifecycle, from design through submission of INDs, NDAs, PMAs, 510Ks and other relevant regulatory filings. Our expertise spans the areas of clinical data and trial management, clinical operations, safety and pharmacovigilance, and biostatistics. In addition, Tribiosys resources possess subject matter expertise in relevant standards (CDISC, DICOM, HL7 etc.), regulatory compliance (e-submissions, Computer System Validation, 21CFR Part 11/ HIPAA, ICH guidelines, Common Technical Document) and GCP/GMP. From a systems standpoint, the Tribiosys team is experienced in various EDC and paper-based systems, document and image management, CDMS/CTMS, statistical and safety systems, and associated technology experience in ETL, data warehousing and mining, dashboards and portals etc. Specifically, Tribiosys has helped its clients design and develop integrated data and information management architectures that enable them to streamline the capture and flow of data from investigator sites to regulatory submission, provide individual trial and cross-trial metrics, increase efficiency in designing case report forms and managing the aggregation/analysis of underlying data, and improve risk management via integrated safety/pharmacovigilance reporting. Such solutions have included integration with relevant products, and incorporation of standards and regulatory requirements to provide secure validated repository, analysis and reporting capabilities. The solutions are designed to enhance critical decision-making capabilities in the drug development and post-approval product life cycle by providing context-sensitive views of data to internal and external organizations (e.g., CROs).

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REGULATORY AND VALIDATION SERVICES

Tribiosys provides technology-based services pertaining to international regulatory compliance (e-submissions, Computer System Validation, 21CFR Part 11/ HIPAA, ICH guidelines, Common Technical Document). Services include validation and 21 CFR Part 11 gap analysis, mitigation/redeployment/remediation, master and system-specific planning, training and SOP development, and archival, storage and retrieval solutions for current and legacy software environments. The Tribiosys computer systems validation approach integrates industry standard software development life cycle (SDLC) and software quality assurance (SQA) methodologies with relevant validation compliance best practices. Specifically, Tribiosys has experience planning and managing validation projects including:

- Validation to GLP, GCP, GMP standards
- Gap Analysis and Risk Assessment
- Development of Validation Documentation Suite including Validation Master Plan, URS and FRS, Traceability Matrix, Policies, SOPs, Work Instructions, Validation Protocols (IQ, OQ and PQ), Validation Reports (IQ, OQ, PQ)
- Change Management and maintaining a continuous validated state
- Rollout of validated applications to additional sites.

Tribiosys also has the expertise to design systems that incorporate cGLP, cGMP and cGCP requirements, as well as systems that support compliance to these quality-related regulations.

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OUR APPROACH

The Tribiosys Solutions Methodology (“TSM”) - the foundation of each client engagement - is an established, quality-driven process based on an integrated set of deliverables that build on each other incrementally to deliver solutions quickly. The process is flexible enough to consider each client's specifics without sacrificing a rigorous quality framework.

The Solutions Methodology Suite includes the following components:

- Program Management
- Project Management
- Strategy Formulation and Validation
- Architecture Assessment and Design
- Package Evaluation and Selection
- Data and Application Integration
- Software Engineering
- Ongoing and ad-hoc data management and exploration

TSM incorporates a phased, iterative approach to solution development. In addition, solutions are rapidly developed and deployed in an iterative manner within each phase. Progress from one phase to the next requires signoff by relevant project stakeholders. TSM is deliverable focused, rather than task focused. Broadly, the activities and deliverables from the various phases within TSM may be modified depending on the client needs and the type of engagement.

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