CrO Biosciences
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CAPABILITIES STATEMENT

WHO WE ARE

CrO Biosciences, Inc., (CrO) is an information management consulting firm located in Temecula, CA. We provide clients Regulatory Submissions, GCP Inspection Readiness, Clinical Trial Support and R&D Systems Exchange services to pharmaceutical, biotechnology and medical device organizations.

CrO is a global, woman-owned, operated and controlled company, which consists of regulatory and clinical operations professionals with over 60 years of combined experience.

Our unique methodologies are up to date with the current rules, regulations, guidances, technologies, and latest industry trends keeping us ahead of the curve every time!

MISSION STATEMENT

To be our client's external full service regulatory, clinical, and quality departments. We provide high quality compliant processes, training, systems and resources to seamlessly make our client's life easier by improving business processes and systems. As companies grow and need immediate assistance, without the stress of onboarding, we are here to provide you with top notch, quality service.

VISION STATEMENT

To become the most trusted organization by providing high quality, efficient, and effective services globally; while creating a personal touch with integrity and experience you can rely on.

Regulatory Solutions
- Strategic Consulting
- Global and Local Regulatory Strategy
- Drugs, biologics and devices
- Orphan Drug Designation
- US FDA regulatory meetings
- US FDA Advisory Committee Meetings
- REMS, TPP, and Labeling (SPL/PLR)
- Expanded access programs
- Regulatory Operations Global Submissions Support
- Electronic datasets

Global & Local Regulatory Strategy
- Strategy with risk assessment and go, no- go decision making criteria throughout products' lifecycle
- Early Phase, Phase II/III, Megatrials III/IV Studies across all therapeutic areas
- Strategic support for risk management approaches including MedGuides and REMS; Post Marketing Surveillance Studies
- Full-service capabilities and customized study design

US Agent and Liaison Services
- US agent with FDA on behalf of Sponsors
- Representation for Sponsors in all types of FDA regulatory meetings and written actions
- Representation for Sponsors in US Advisory Committee Meetings
- Dispute Resolution
- Lead Label negotiations
- Experts in health outcomes, epidemiology, biostatistics, and post-marketing regulations

Submission Planning, Preparation & Management
- Regulatory Application Content Analysis and Preparation Training
- Submission Project Management: Submission planning, forecasting, and tracking
- Submission Publishing: eCTD compilation, validation, quality control, and transmission to regulatory agency

Clinical Solutions
- Strategic Consulting
- Study design and implementation
- Study Management and Monitoring
- Data Management and Statistical Analysis
- PKPB modeling
- Bioanalysis
- Medical writing
- GCP Inspection Readiness Hub of Excellence

Data Management & Statistical Analysis
- Creation of & conversion to Clinical Data Interchange Standards Consortium (CDISC) files
- Statistical analysis services including Tables, Listings and Figures for Study Reports

Bioanalysis
- Extensive expertise in bioanalytical assay development and validation quality control based on FDA guidance

Clinical Pharmacology
- Design and management of Clinical Pharmacology Studies
- Standard and specialized PK/PD analyses, use of validated software, and reports that meet FDA requirements

GCP Inspection Readiness
- Inspection Readiness Expert
- TMF Management Associate
- Inspection Readiness Processes
- eTMF System
- Real Time TMF Management & Maintenance
- TMF Archive

R&D Systems Exchange – (Designed to align people, processes, and technology across your entire R&D platform)
- Change Management
- Data Excellence
- Process Optimization
- System Operability
- System Governance