REGULATORY SUBMISSIONS

Providing the highest standards for submissions

Regulatory submissions are the most critical milestones in your clinical research program. Quality submisssions can accelerate time to market, bring the benefit of new treatments to patients sooner, maximize research investments, and conserve patent life.

At Rho, each deliverable reflects the collaboration of our interdisciplinary team. Throughout the course of a clinical development program, we use a standardized library of document templates, data tools and programs, and processes to produce compliant regulatory submission documentation, reports, and dossiers. We ensure that the quality that drives all of our services is reflected in all of our submissions to regulatory authorities such as FDA and EMA.

Regulatory submissions informed by experience, driven by process

Rho's dedicated regulatory strategy and submissions team is led by professionals with over 25 years of experience in clinical research, product development, data standards, quality assurance, and regulatory affairs. We can support numerous kinds of regulatory authority submissions deliverables including the following:

- **INDs/CTAs/IMPDs**
- **Regulatory Authority Meeting Briefing Packages**
- **NDAs/BLAs/MAAs (including 505(b)(1), 505(b)(2), 351(a), and 351(k) applications)**
- **Regenerative Medicine Advanced Therapy (RMAT) Designation**
- **Annual Reports/DSURs/PSURs**
- **PSPs/PIPs**
- **Orphan Designation Applications**
- **Breakthrough Designation Applications**

Our biostatistics and data standards experts, who are an integrated part of our overall regulatory strategy and submissions team, are extremely well-versed in the regulatory requirements for data collection and presentation to regulatory authorities, such as such as FDA and EMA, and, consequently, we are called upon frequently to assist with the following components of FDA submissions and other FDA submissions:

- **Compound analysis databases**
- **Study analysis databases**
- **Domain databases**
- **Clinical Data Interchange Standards Consortium (CDISC) (Study Data Tabulation Model [SDTM] and Analysis Data Model [ADaM]) databases**
- **Define files (PDF or XML), Readme files**
- **Integrated data sets (for ISE and ISS)**
- **Integrated clinical and statistical analysis plans**
- **Exploratory analyses**
- **Submissions capabilities**

RESOURCES

Visit our website for helpful resources, including:

- Webinars
- Answers from our experts
- A blog discussing current trends in the industry
- White papers
- Much more

HAVE A MORE SPECIFIC QUESTION?

Visit **www.rhoworld.com/rho/why-rho/featured-experts** and click on Free Expert Consultation to talk to one of our regulatory submissions experts.

MEET OUR EXPERTS

DAVID SHOEMAKER, PH.D. | *Senior Vice President, Research and Development*

Dr. Shoemaker has over 25 years of experience in research and pharmaceutical development. He has served as an advisor for multidisciplinary, matrix managed project teams and has been involved with products at all stages of the development process. His primary activities include designing and overseeing the execution of early stage development (Pre-IND/CTA) and late stage to-market strategies, analysis of critical scientific, clinical, and regulatory issues, identifying optimal regulatory pathways, and designing and assessing integrated nonclinical, chemistry manufacturing, and controls(CMC), and clinical programs.

He has extensive experience in the preparation and filing of all types of regulatory submissions including primary responsibility for four BLAs and three NDAs. He has managed or contributed to dozens of INDs/CTAs and over a dozen successful NDAs, BLAs, and MAAs. He has moderated dozens of regulatory authority meetings for all stages of development and supported several companies at FDA Advisory Committee meetings. He has authored or overseen dozens of Orphan Drug Designation applications, has developed several successful Accelerated Approval programs, and has secured several Priority Review applications.

KARL WHITNEY, PH.D. | *Assistant Vice President, Product Development*

Dr. Whitney has over 17 years of experience in the pharmaceutical industry, specializing in clinical regulatory aspects of pharmaceutical development. During this time, he has led multiple integrated drug-development programs spanning the development spectrum, by planning, managing, and overseeing concurrent manufacturing, nonclinical, clinical, and regulatory activities. He has also led the preparation of or helped prepare Investigational New Drug (IND) applications, clinical and nonclincal final study reports, pre-IND and New Drug Application (NDA) meeting packages, annual reports, Investigator Brochures, Fast-Track and Orphan-Drug applications, NDAs prepared in the electronic Common Technical Document (eCTD) format, and numerous other documents.

ROB WOOLSON, J.D., M.S. | *Chief Strategist, Biostatistics & Standards for Regulatory Submissions*

Rob Woolson has over 15 years of experience in the analysis of complex data. He has conducted statistical analyses in all phases of drug development (Phase I through IV, NDAs, and BLAs) and has led SDTM/ADaM dataset conversion projects in multiple therapeutic areas. He has held a leadership role in six CDISC-compliant regulatory submissions, having guided the creation of ISS/ISE statistical analysis plans; integrated analysis dataset design and production; integrated display design and production; and submission-related documentation development. He has authored responses to numerous FDA queries and has represented sponsors at FDA in-person meetings.

Kevin Barber, PH.D. | *Vice President, Regulatory Strategy & Submissions*

Kevin Barber, PhD, VP, Regulatory Strategy & Submissions has more than 20 years of experience in regulatory affairs and product development, working for both sponsor companies and CROs, across all stages of development from pre-clinical through product launch and post-approval life cycle management. He has lead the preparation and execution of integrated regulatory strategy and clinical development plans for drug, biologic, and medical device products in therapeutic areas including dermatology, nephrology, urology, women's health, neurology, cardiovascular diseases, virology, oncology, immunology, infectious diseases, blood products, and gene therapy. Dr. Barber has significant experience preparing and filing regulatory submissions, including more than 40 US INDs and more than 35 marketing applications in the US, Canada, Europe, Latin America, Australia, and New Zealand.