RHOTAU Pharma Services LLC

SPECIALIZING IN PHARMACEUTICAL AND REGULATORY SCIENCES CONSULTING

Robert J Timko, RPH, PHD

Founder & President

Dr. Timko has over 35 years of experience working in the pharmaceutical industry in various technical and managerial positions at Johnson & Johnson and AstraZeneca Pharmaceuticals. Dr. Timko is also an Adjunct Faculty Member in the Pharmaceutical Development Program at West Chester University of Pennsylvania.

Dr. Timko founded RhoTau Pharma Services LLC to provided consulting expertise in the Pharmaceutical and Regulatory Sciences with a focus on assisting clients achieve their product goals of a fast submission and seamless approval, while assuring a cost effective product and secure supply chain.

Dr. Timko has worked with a variety of traditional and novel dosage forms across therapeutic areas, and interacted with global Health Authorities on a diverse range of CMC topics. He is well versed in the technical and regulatory documentation requirements for INDs/IMPDs, NDAs/MAAs, and sNDAs/Variations. Dr. Timko is considered a subject matter expert with in-depth knowledge of Quality-by-Design, Process Analytical Technology, and Real Time Release in the current regulatory environment.

Dr. Timko has utilized his technical and managerial talents within cross- and multi-functional teams, mentoring colleagues and direct reports. He has had responsibility for both domestic and international senior staff, as well as supporting technical development and life cycle management of drug products.

Dr. Timko has been involved in preparing and/or reviewing more than 30 marketing applications either in a pharmaceutical development or regulatory capacity for innovator and generic compounds for a variety of small and large molecule dosage forms including but not limited to, immediate and extended release solid dosage forms, injectables, and liquids. He has hands-on experience in dosage form development, scale-up to commercial manufacture and production troubleshooting, preparing CMC briefing and regulatory documentation, preparing teams, and leading face-to-face meetings with Health Authorities. Additionally, Dr. Timko has provided technical expertise and served as subject matter expert witness on formulation development in patent litigation cases.

Dr. Timko was as a member of a PQRI cross-functional team of industry and FDA representatives who prepared a technical paper on "Current Best Practices Applied to the Development, Scale-up and Post Approval Change Control of IR & MR Dosage Forms," published in the online journal, PharmSciTech. He holds several formulation patents, and has written or co-authored numerous articles for peer-reviewed journals and technical publications. He has also made numerous presentations on formulation and process development and regulatory affairs topics as an invited speaker at association meetings and scientific conferences. He is a co-author of a book chapter on "High-Intensity Mixer Granulators" in Granulation Technology for Bioproducts.

Dr. Timko is an active member of the American Association of Pharmaceutical Scientists (AAPS), the International Society of Pharmaceutical Engineers (ISPE), the International Academy of Compounding Pharmacists (IACP) and the Pennsylvania Pharmacist Association (PPA). He is a Registered Pharmacist in New Jersey and Pennsylvania.

EXPERTISE

RhoTau Pharma Services' goal is to assist our clients, be they consumer product, generic or innovator firms, small start-ups or large, global pharmaceutical or biotechnology companies, with strategic and tactical implementation designed to rapidly bring their small or large molecule products to peak sales in order to fully realize their life cycle potential.

Our experience is evident in every aspect of our services to our clients. We not only consult to develop solutions; we implement, track, and close. Our desire is for an efficient collaboration that is completed on time and within budget. Our expertise includes:

- Active Ingredients (APIs)
- Excipients
- Solid Dosage Forms
- Liquid Preparations
- Injectables
- Combination Products
- Potent Compounds
- Topical Products

DRUG DEVELOPMENT SERVICES

Whether the products are new or existing, we offer practical solutions that consistently maintain quality and compliance to effectively accelerate scale-up through market launch. Services Include:

- Physiochemical review of compounds and selection of appropriate formulation strategies.
- Formulation development and support.
- Equipment and process selection using the SUPAC guidance concepts as well as formulation requirements to facilitate process introduction.
- Technology alignment with Operations to assure a seamless process introduction and product validation which leads to rapid market entry with minimal regulatory impact.
- Provide a common equipment and formulation terminology for crafting CMC documentation for use in internal reports and regulatory submissions.

OPERATIONS SUPPORT

As compounds move through the development process, our Operations Support Services provide the expertise critical to meeting stringent regulatory requirements and bring products to realization. Services offered:

- Compliance Expertise
- CRO/CMO Review and Selection
- Drug Development Program Management
- Life Cycle Management
- Product Stability Program Design
- Production Troubleshooting
- Product Validation
- Technology Transfer

REGULATORY, QUALITY ASSURANCE AND CMC EXPERTISE

From complex regulatory affairs issues to multinational submissions, RhoTau Pharma Services expertise will quickly identify development, manufacturing or stability issues that could impact product registration.

Regulatory, Quality Assurance and CMC Support:

- Due Diligence for Compounds, Products , Process and Supply Chain
- Expert Advice from Submission through Pre-Approval Inspection
- Quality Risk Analysis for Products and Processes
- SOP Review and Preparation

Report Preparation

Throughout the development lifecycle, there may be the need to prepare comprehensive reports to support research and development efforts, regulatory submissions, and product registrations, e.g. CMC documentation for INDs/IMPDs, ANDAs/NDAs/MAAs, sNDAs/Variations. Working collaboratively with your staff, RhoTau's years of technical experience will help create the necessary documentation with the right commentary and analysis to meet your internal and Health Authority requirements.

Intellectual Property, Patents, Product Liability

As a situation may arise during development or after commercialization, we can provide technical expertise and subject matter expert report preparation and expert witness testimony to support patent litigation and product liability situations.

PROVIDING INNOVATIVE SOLUTIONS THAT HELP SPEED PRODUCTS TO MARKET

RhoTau Pharma Services LLC
920 Sassafras Circle
West Chester, PA 19382
484-437-2654
RJTimko@RhoTauPharma.com
www.RhoTauPharma.com