



CHEMISTRY AND ENGINEERING SERVICES FACT SHEET

TRIPHASE Pharma Solutions, LLC, provides discovery, development, engineering, chemistry manufacturing and controls (CMC), and scientific regulatory services to support preclinical, clinical, and commercial products. Our PhD. regulatory scientists and quality assurance experts can provide your team with resources where and when you need them. Whether you are a virtual Biotech that needs help in all areas or you just need to fill a temporary gap, TRIPHASE Pharma Solutions can supply that resource. From the inception of your project to submission we can provide the essential scientific and regulatory guidance, leadership, and technical writing skills required to obtain your approvable letter.

Our mission at TRIPHASE Pharma Solutions is to provide pro-active leadership of your projects and CMO activities, anticipating and managing problems before they surface. We have managed numerous development programs and have extensive knowledge of drug development from early discovery through Phase 1 and on to commercial launch. In addition, we know the CROs and CMOs that work on your projects. We know their strengths and weaknesses. We can match the technical needs of your project with the right vendor and then provide the leadership to ensure your products arrives *on-time, on-quality, and on-budget* and that you have all the data required to support your filing.

Our business model at TRIPHASE Pharma Solutions is to provide the Pharma industry with flexible resources to support your program. In the life span of a typical drug development program, intense efforts and skills are required in many areas such as CMC, Toxicology, Pharmacology, and Bioanalytical. These resources however are rarely required at the same time. For example, in the beginning all efforts are on obtaining initial synthesis (CMC) supplies for your GLP and GMP studies. Once the supplies are in hand however the project emphasis may shift to toxicology. In short, your CMC person may be sitting idle until the next campaign is required. Our network of scientists can provide the knowledge and practical experience necessary to get your product cleared, registered, and launched, all without having to invest in unnecessary corporate infrastructure. Test our model and we promise you will join the ranks of the many satisfied clients.

DISCOVERY / PRECLINICAL

- Medicinal Chemistry
- Lead optimization
- Vendor selection & RFPs
- IP searches, patent strategy
- API synthesis for GLP studies
- Analytical & Specifications

CHEMISTRY & MANUFACTURING CONTROLS

- Process R&D and scale-up
- Dosage form selection
- Drug Product clinical supply
- Salt & polymorph selection
- GMP API and analytical
- Off-shore sourcing

REGULATORY / QUALITY

- cGMP compliance
- FDA meetings
- CMC compliance strategy
- IND/NDA/ANDA/505b2
- CTD and eCTD submissions
- Phase-specific regulatory

VENDOR SELECTION / MANAGEMENT

- Vendor matching
- Off-shore management
- CMO management
- RFP preparation
- Proposal review & negotiation
- Quality assurance compliance

Marc Andersen, Ph.D., RAC President & CEO

Dr. Andersen is regulatory affairs certified (RAC) and has over 20 years experience in the discovery and development of small molecules. Dr. Andersen has held various management positions with increasing responsibility at Glaxo-Wellcome, Cardinal Health, and Aptuit in the areas of Medicinal Chemistry, Chemical Development, Pharmaceutical Sciences, and Regulatory Affairs. Dr. Andersen has been project leader for over 40 different NCEs culminating in the submission of INDs, CTAs, IMPDs, NDAs, 505b2, ANDAs, amendments, annual reports, and DMFs. Dr. Andersen holds a PhD. Degree in natural product synthesis chemistry and engineering and was Assistant Professor at the University of South Carolina for 2 years following his Ph.D. work. Dr. Andersen has authored over 30 scientific articles and patents. Contact Dr. Andersen today to discuss your drug development needs or visit our website and read our white papers and client testimonials:

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