Pharmaceutical Development Solutions

Accela Sciences' consultants and advisors combine high level scientific expertise with decades of pharmaceutical industry experience to provide solutions to your pharmaceutical development problems.

Pharmaceutical Outsourcing

Our broad network in the pharmaceutical contract research and manufacturing space allows us to place programs with the CRO/CMO best suited to your specific needs. We partner with you to establish the best combination of cost, speed, technical and regulatory quality of work. Accela Sciences has the ability to source projects both domestically and internationally, in both small specialty laboratories as well as large integrated service providers.

Program Development and Management

We develop a program based on your needs and regulatory requirements, from early technical assessment, toxicology, formulation, bioavailability and pK studies, to analytical development, scale-up, clinical and commercial manufacturing**.** We will manage this program in the CRO/CMOs to meet your timelines and your budget.

Technical Problem Solving

Whether the problem is a difficult analytical method, development or manufacturing problems, analyses for regulatory response, patent filings or litigation support, we have the expertise and experience to solve your problems. Accela Sciences' consultants and advisors have broad expertise in:

- pre-formulation and formulation science
- analytical and structural chemistry
- synthetic chemistry
- toxicology
- CMC drug development requirements
- GMP/GLP regulations and quality systems

Regulatory Affairs

We can prepare CMC documentation for your IND, NDA, ANDA, NADA, ANADA, and EPA filings. Accela Sciences' consultants and advisors have experience with CDER and CVM, have presented at pre-submission conferences, have trained FDA and EMEA field inspectors, and have extensive experience in providing responses to FDA questions in regulatory filings.

Quality Services

Accela Sciences brings years of experience in regulated environments to guarantee your product quality. We provide:

- GLP and GMP quality audits of facilities
- Technical due diligence in support of licensing activities
- SOP and quality system design
- Business and technical process improvement including value stream mapping, process remediation, and process analytical solutions.

U.S. Agent Services

Accela Sciences will act as a U.S. agent for foreign manufacturers of pharmaceuticals for import into the U.S. or for U.S. regulatory filings, as required under 21 CFR 207.40(c).

Andrew C. Kolbert, Ph.D., M.T.M., President, has fourteen years of experience executing and managing analytical and product development programs, both internally and in external organizations. He holds a Ph.D. in Chemical Physics from M.I.T., a Masters in Technology Management from the Stevens Institute of Technology, and a six sigma green belt in process improvement.

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