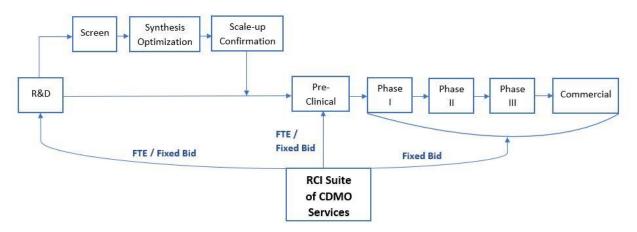


## **Drug Substance Development Options for Effective API Commercialization**

The need for contract API/drug substance manufacturing in the pharmaceutical and biotechnology industries continues expanding. The requirements for complex chemicals to facilitate new innovations in drug development- combined with advances in technology and ever-changing regulatory requirements-pose challenges for all drug development firms. These companies also must determine whether an API candidate's synthesis route can be effectively scaled-up AND eventually commercialized. Richman Chemical Inc. (RCI) guides its clients through this important milestone, as well as through the full gamut of drug substance R&D, pre-clinical evaluations and clinical phase studies.



RCI's ability to navigate and address crucial stages of the synthetic-focused drug development process makes it an invaluable outsourcing partner for API/drug substance manufacturing. When start-up firms prepare to enter pre-clinical/early stage clinical studies, they require smaller amounts of material. Assuming data from early phase work demonstrates promise, they often confront the daunting task of transferring the process to another supplier capable of larger scale-up production consistent with late phase/commercial stage requirements. Instead, RCI effectively handles the *entire* program workflow from R&D through commercial manufacture.

Further, RCI excels at tailoring its various program phase offerings for each client. This includes offering Full Time Equivalent (FTE) options (early development through pre-clinical), Fixed Bid proposals, and/or a combination of each. This flexible approach reflects that the needs of each drug development client differ considerably- RCI understands this, appreciates such complexities, and offers innovative solutions.

Overall, RCI's emphasis on domestic manufacturing and a practical, stage-wise approach to drug substance commercialization makes it an excellent choice as a CDMO partner. From early stage R&D through to commercial production, RCI's suite of services is complete!

To benefit from Richman Chemical's 32+ years of expertise, contact Christopher Kulp, Chief Commercial Officer, at (215) 628-2946 ext 13 or via email at <a href="mailto:clk@richmanchemical.com">clk@richmanchemical.com</a>. For more information regarding our custom service offerings, <a href="mailto:CLICK HERE">CLICK HERE</a>.

**Richman Chemical, Inc.** (RCI) was founded in 1988 and pioneered the independent outsourcing model. It is the only company in the market that provides its services throughout many markets including biotech, pharmaceutical and medical devices, specialty chemicals, nanotechnology, food and beverage, and flavor and fragrance.