



Custom Manufacturing and Fine Chemical Sourcing
768 N. Bethlehem Pike • Lower Gwynedd, PA 19002 USA
Tel: (215) 628-2946 • Fax: (215) 628-4262 • Web: www.richmanchemical.com

HPAPI Manufacturing Capability

By Linda Tedeschi Miller

Richman Chemical Inc. (RCI) has tapped its capable network of partners to now offer high potency chemical manufacturing in a cGMP environment to its customers. A high potency active pharmaceutical ingredient (HPAPI) is a drug that carries a higher strength with a smaller amount of actual active pharmaceutical ingredient. Maintaining safety and efficacy while responding to the time sensitive nature inherent to life science firms needing to manufacture these HPAPIs has placed RCI in a pivotal position to respond to this growing requirement.

Biotech Start-up Needs Scale-up Services for its Drug Candidate—and FAST!

The firm—a virtual corporation—needed a quick response in order to meet internal milestones necessary to secure additional funding from private equity investors.

Client Requirements:

Previous scale was only performed at 100 gram scale, and the firm desperately needed scale-up to 2 kilograms. The firm also needed analytical methods development, and the production of three validation batches—all within a cGMP-compliant HPAPI facility.

End Result:

We were able to successfully assist the upstart firm within a tight, three-month timeline.

Better yet, after the client encountered problems with the vendor selected initially to provide final drug formulation services, we were able to step-in as a turnkey solution provider. We provided top-notch formulation and fill/finish services to meet their clinical trial materials need. This particular drug candidate is now in early stage clinical trials, and additional funding was committed to the firm after their successful collaboration with RCI.

The HPAPI market segment is expected to grow at a higher rate compared with regular APIs. Most commonly, HPAPIs are produced for use in chemotherapeutic drug formulations. As cancer diagnoses continue to occur at ever-earlier time points, so too has the need to shorten the time-to-market for such therapeutics. There is also increased manufacturing potential for HPAPIs based on research demonstrating the ability of such formulations to treat chronic disease. Since specific manufacturing and containment measures are necessary to produce these high potency APIs, only qualified facilities with knowledge intricate to handling these new chemical entities can manufacture them. RCI's experienced affiliate sites meet all the requisite containment and cGMP requirements for manufacturing such compliant active material.

Please contact RCI via Christopher Kulp, Director – Contract Services Business, at 215-628-2946, ext. 13 to find out more about this new capability.