



Custom Manufacturing and Fine Chemical Sourcing  
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## "Richman Chemical: Your Partner for Medical Device Chemistry"

By Christopher Kulp and Linda Tedeschi Miller

Webster's defines the word "device" as "a contrivance; a gadget". In the medical field, however, much can be said, about these so called "devices" that may often prolong human life or are instrumental in providing palliative care to those who suffer a terminal illness.

Several years ago, Richman Chemical, Inc. had the opportunity to work with a medical device company to help locate a pharmaceutical excipient for use within a medical device. Since that time, more than one opportunity such as this one has been presented to Richman. Historically, chemistry has not been a large component of medical device production. However, change is reflected in medical device technology as development now often includes a device that offers a method of drug delivery.

### **EMERGENCY! Need a Novel Chemical Excipient-STAT!**

A medical device company was in need of a crucial excipient for a new product in advanced clinical trials. The excipient was a novel organic compound formulated with the actual medical device to provide the desired properties. The company, however, had a BIG problem: they made medical devices and had no expertise in the synthesis of organic chemicals!

Soon after contacting Richman Chemical, the company's fears were alleviated. We were able to evaluate some rudimentary technology for preparing the molecule provided by the company, and then take it from there. We collectively optimized the synthetic process, scaled it up to the appropriate manufacturing size, and developed an FDA-approved, cGMP manufacturing protocol for successfully making the critical material-all within a span of approximately 18 months.

As a result of our cooperative efforts, enough material was prepared to satisfy anticipated market needs in anticipation of commercial approval. When the new product became commercial shortly thereafter-and thanks to our accelerated project management initiative, supply was able to meet demand for the exciting new medical device.

Richman Chemical Inc. (RCI) has the experience and technology to assist medical device companies who are thinking of incorporating chemicals into their product. As the corporate culture of chemical companies is different than that of medical device companies, RCI also acts as a liaison

between both, ensuring effective communications. In addition, Richman facilitates the regulatory process related to medical device development.

Overall, the outsourcing needs of the medical device and chemical industries mesh nicely with Richman Chemical's project management-focused business model. Beyond providing custom synthesis and processing services via its extensive manufacturing network, RCI project management services also encompass: process development and optimization, pilot scale-up, full raw material sourcing, logistics coordination services, intellectual property advice and dispute resolution.

Founded in 1988 by Edward Richman, Ph.D., RCI has become a well-recognized custom manufacturing company by focusing its efforts on providing timely, cost effective solutions for its diverse client population. RCI has achieved a 45% growth rate over the last 4 years by valuing its human capital and focusing on relationship building. This combination has allowed the company to provide timely, technically superior, and cost effective services to the chemical and life science industries.

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