

“Richman Chemical Celebrates Twenty Years of Excellence in Business”

2008 marks the 20th year anniversary for Richman Chemical Inc. (RCI) a custom synthesis/chemical manufacturing and raw material sourcing provider. RCI also provides project management assistance to the life science and chemical industries.

Founded by Edward Richman, Ph.D., Richman Chemical has become the most well recognized independent chemical/pharma outsourcing company by focusing its knowledge and experience on delivering timely, technically superior, outsourcing production and management services at exceptionally competitive prices for its clients.

The company’s unique business model is based on a customer-centered strategy. RCI represents a worldwide network of manufacturers on a project-by-project or client-by-client basis. Each opportunity is evaluated individually in order to find the *best* fit for the client. The origin of the model dates back to Dr. Richman’s tenure as a director of non-core business units for a Fortune 100 company. He observed first-hand the difficulties of managing non-core projects within a structured organization and parlayed that experience into the establishment of RCI, helping clients use resources more efficiently and spend less time outsourcing and more time in their area of expertise. Results repeatedly demonstrate Richman Chemical adds value by cutting costs, minimizing risk and bringing new products to market faster, freeing their clients to focus on R&D and marketing.

Recently Ed Richman began taking his business model “on the road” to, among others, emerging technology audiences. Ed’s presentation is both interactive and educational and he features case histories where the audience gets a chance to ask questions and try and determine what is wrong with a particular scenario, thus making them familiar with potentially similar situations as they advance their technology. The points are reiterated in the formation of “rules” at the end of each case. “Richman Rules” are distributed at each venue emphasizing the main points of the discussion. Richman Chemical’s

comprehensive project management services are always available to further assist companies.

Each case history echoes a single message such as this rule: “A lab process is good for producing gram scale quantities; it is not a basis for commercial manufacturing”.

Richman begins his talk with “The Dreaded Lab Procedure”, a quick lesson in what to be aware of when bringing technology from lab scale to production for commercialization scale. He presents a straightforward step by step process, outlined in a series of detailed instructions specifying what needs to be done, in what order, with what specific lab equipment. This case gives Dr. Richman the opportunity to convey a very basic but important series of facts regarding project scale ups: 1) Most bench chemists have never seen a chemical manufacturing facility. 2) They use raw materials not commercially available. 3) They use process steps that are not scaleable.

This translates to the fact that the lab process deemed suitable for producing gram scale quantities is not a basis for commercial manufacturing. Dr. Richman discusses the reasons why and allows audience members to contribute their own ideas relative to what might be causing the problem before he actually specifies it.

Dr. Richman cautions emerging technologies to be forthright regarding information they share with a selected outsourcing partner. The rule that results: “If we know the real problems, we have a chance of solving them” ensues from a second case study.

Richman begins this case with the quote, “The customer is always right except when he is wrong” and tells about a Chief Technical Officer (CTO) who is an M.D. from a Venture Capitalist (VC) funded Biotech. The project began with an Investigational New Drug Application (IND) submitted to the FDA. There were several clinical trial candidates and the pre-clinical results were promising. The technical package was compiled by Professors in Mexico. The package contained vague data and there were no cGMP reference standards resulting in poor FDA compliance. They were up against the pressure of a critical timeline to save the project and the potential for money to be lost

and the project to be abandoned was extreme when RCI became involved. After the floor is extended to the audience, Ed adds the following points:

The CTO who is an M.D. is an expert ...in his field. Further, the CTO does not have commercial experience. The idea for the new drug is good, pre-clinical results are promising but the technical package does not reflect cGMP compliance; more importantly, there are no reference standards.

Richman Chemical stepped in and completed a comprehensive evaluation of the technical package and identified the “weak” links. At RCI’s direction, clinical trial batches were prepared with reference standards validation. Additional tests were performed for end formulation, concurrently with stability testing to avoid delays. A dialogue was established with therapeutic and delivery mechanism experts to ensure testing 100% consistent with FDA guidance.

The end result was a successful FDA review and a grant of fast track status.

RCI specializes in the management of custom chemical manufacturing projects (pharmaceutical cGMP processing and unit operations included) and the sourcing of hard-to-find chemicals. RCI’s main focus is on value-added custom synthesis and efficient sourcing solutions on any scale, while always providing expert project management along the way. RCI has a well-earned reputation as an excellent partner for life science, emerging technology and specialty chemical firms.