

Lean Compliance Expert, John Avellanet, Publishes New Case
Study on Product Development Collaborations

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FOR IMMEDIATE RELEASE

December 9, 2008 – Williamsburg, Virginia – John Avellanet, managing director of Cerulean Associates LLC, has published his new case study of a biotechnology and medical device company that bankrupted itself after six critical mistakes.

Drawn from his own experiences as an executive in the firm, Mr. Avellanet’s case study, “Want a Good Partnership? Know How to Ruin One First,” reviews the six decisions that led to the collapse of a promising new company with a combination medical device and nanotechnology-level biologic. Readers can see how the decisions – that looked appropriate at the time – came back to haunt the company, drawing it further and further into a corner from it could not recover.

“When the editors of *BioProcess International* first asked me to write about my experiences and the painful lessons I learned,” said Mr. Avellanet, “I deferred. Then, when I spoke at an industry conference up in New Jersey several months ago, I realized that with the economy the way it is and startup firms struggling, there was an urgent need in the industry for advice from folks who’ve been there before and faced similar dilemmas. I decided to write the article and craft it so that other executives and biotech investors, new medical device investors and small pharmaceutical shareholders will be able to avoid the mistakes we made.”

Mr. Avellanet has nearly two decades of experience with regulatory compliance, research and development product commercialization and quality systems, particularly in the areas of preclinical, quality by design, Part 11 and Annex 11 compliance, and preventing intellectual property theft by insiders and partners. Mr. Avellanet serves as a compliance columnist for the *Journal of Commercial Biotechnology*, *Pharmaceutical Processing* magazine, and is an advisory board member for the BIO-IT Coalition, PharmaObD and the IT Compliance Institute. In addition, Mr. Avellanet writes and publishes the monthly executive compliance intelligence newsletter, *SmarterCompliance*™.

If you are a journalist or editor and would like a copy of the new case study, **or if you’d like to add Mr. Avellanet as one of your source experts**, please contact him directly: john@ceruleanllc.com.

Cerulean Associates LLC is a small, private advisory company that helps executives cut costs, streamline quality systems, speed new drug, biologic or device time to market, and protect their intellectual property from theft. Cerulean publishes the *SmarterCompliance*™ newsletter as part of its FDA executive advisory program, the **SmarterCompliance**™ Toolkit. On the web at www.ceruleanllc.com.

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