

TACTICS FOR ENABLING PROCESS DEVELOPERS TO RAPIDLY EVALUATE NEW TECHNOLOGIES

INDUSTRY CHALLENGE

The biopharmaceutical market is expected to reach US\$300 billion by 2025. Innovative therapeutic modalities and biosimilars for blockbuster biologics coming off patent protection are fueling its growth and are pushing manufacturers of biopharmaceuticals to increase process productivity and efficiencies, implement tighter process controls, and reduce costs.

Process development (PD) teams are at the center of these pressures: they are tasked with developing, evaluating, and implementing new technologies to rapidly develop processes for therapeutic assets with limited resources. PD engineers will often turn to new technologies, e.g. sensors, to support their needs, but run into significant challenges when faced with understanding how to implement such new technologies within their own environments to suit their unique objectives.



CLIENT SITUATION

A PD engineer at a large biopharmaceutical company wanted to evaluate a new sensor for Process Analytics and Technology (PAT) initiatives. This client had learned about the sensor from supplier brochures, scientific publications, and industry conferences.

But, these channels did not provide sufficient information to confidently develop an implementation plan. The client's questions included:

- How should I design experiments and organize my data set?
- What defines success and how do I measure confidence in implementing the sensor in full scale manufacturing?

SOLUTION

To help the client build an implementation plan, Biolympix identified an industry expert who had practical experience with the sensor and connected the expert with the client. The Biolympix approach centered on:

- **The right expert every time:** Biolympix focuses on biomanufacturing so ONLY recruits experts in biomanufacturing. Biolympix identified and vetted experts who have practical experience with Raman spectroscopy, presented their profiles to the client for review, and set up a phone consultation.
- **Speed:** Biolympix recruited, vetted and set up the phone consultation with the expert within two weeks.

RESULTS

As a result of the insights the expert provided, the client was able to confidently modify the experiment, resulting in faster execution, more refined process development objectives, and seamless tech transfer.

TESTIMONIAL

"I used Biolympix for a Raman characterization study. The process was seamless, and the subject matter expert they chose was experienced, qualified, and very helpful. The consultation with the expert enabled me to focus my experience design--reducing studying over 10 parameters to less than 5, which resulted in the need for additional experiments and helped me save time and resources. The consultation also validated my assumptions and saved me time on numerous internal meetings to get a consensus on the path forward."

-- PD engineer, large biopharmaceutical company