

Off and Running

Easing the Transition from Development to Production



Every product starts somewhere. Some are spin offs—improved or modified versions of something previously produced. Others are wholly new; they have no predecessor. In the medical industry, these kinds of products often begin in laboratories and are deemed, for a time, “for research only.” That is, of course, until it’s time to go to market.

Those who aim to bring a physical product to market often have manufacturing line experience. But not always. Because just as every product starts somewhere, so too does every product manufacturer.

Situation

In 2012, a highly funded, medical research start up set out to bring its product to market—an endeavor that, if successful, would bring three years of “for research only” lab work to life. The start up employed many talented scientists and researchers, though the company was not well-versed in manufacturing necessities such as quality control, documentation, traceability, or validation.

Action

Over the course of one year, ILT designed and built a suite of systems capable of manufacturing the start up’s product. More importantly, ILT worked extensively with many layers of the start up’s personnel to not only deliver the necessary documentation, but to teach them how to do it themselves in the process. Ultimately, the start up had every element of documentation—the design specs, test procedures, software tests and verification services—necessary to bring its product to market with FDA approval.

Result

At the time of this writing, the start up has moved beyond the lab and is manufacturing its product in a controlled fashion. Additionally, the start up is in the process of moving a second product into production on its existing ILT systems.



“It’s one thing to exist on investment capital. It’s another thing to go to market.”

Liz Mancuso

Manager, Applications/
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