IN THE ZONE

Going the Extra 10,000 Miles

It was Christmas time, and Todd Reith was traveling with a very important package.

Curiteva, where Reith serves as Inventor and Vice President of Emerging Technology, had received a request from FDA to perform a complete material characterization of their Inspire technology for their 510(k) submission. Their response time to FDA was expiring. Curiteva's material partner, Evonik, said it would perform the tests if Curiteva could quickly get samples to Germany.

Reith printed the porous PEEK cervical interbody fusion device, flew from the U.S. to Germany, took a two-and-a-half-hour train ride and then a taxi to hand deliver the samples to an Evonik scientist. Reith then got back into a cab and retraced his journey. With the samples successfully delivered, he slept on the flight home — the last leg of a nearly 10,000-mile voyage.

"It was the most insane trip," Reith said, comparing it to the 1987 comedy, "Planes, Trains and Automobiles."

I loved this story when Reith and his colleague Erik Erbe told it to me, because they shared it in the context of the "Herculean effort" they said companies take to bring a novel product to market.

When Curiteva received the material characterization request from FDA, Reith had already dedicated five years to the technology's research and development, and the company was 15 months into the 510(k) submission process. Nothing was going to stop them. They ultimately received FDA clearance in February of this year, as we share in our profile of the Inspire technology on page 53.

This issue is filled with experience and advice on pushing boundaries and overcoming challenges. We recap insight that members of our Advisory Board provided during a spring webinar on solving supply chain issues, and we highlight how product development teams can fail fast and limit risk when commercializing innovative technologies.

Our article on Curiteva is one of four on additive manufacturing. We look at ways that additive manufacturing is being used for personalized implants, what questions to consider when choosing a platform and deciding whether to insource or outsource and which materials will be paired with additive technology to manufacture orthopedic implants of the future. Some of the insight for these articles was taken from perspectives given at our OMTEC conference in June. Recordings of those sessions can be found at OMTECexpo.com/video-education. No travel required to learn. — *Carolyn LaWell*

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