



CytexOrtho finalizes textile-based implant for joint restoration in time for clinical trials with SanaVita's contract manufacturing solutions

Challenge

[CytexOrtho](#), founded by Farshid Guilak, PhD; Brad Estes, PhD; and Frank Moutos, PhD, developed a new implant to restore joints in young patients with early joint disease. These patients' joints can become increasingly arthritic until the only remaining solution is total joint replacement. This implant technology is designed to help young patients return to normal activity levels and avoid joint replacement.

Consisting of a high-performance textile combined with a 3D-printed substrate, the porous implant enables tissue to develop in and around its fibers to create a functional, biologically reinforced composite implant shortly after implantation.

After receiving a grant from the National Institutes of Health (NIH), Dr. Estes, CEO, and Dr. Moutos, VP of Technology Development, began their search for a medical textile expert to manufacture the implant for clinical trials. They also needed the support of an experienced, quality-driven contract manufacturing organization (CMO) for production of the implant, which required a highly specialized 3D-printing process, along with packaging and sterilization management.

Solution

Dr. Moutos contacted Secant Group, whom he knew by reputation. Dedicated to designing, developing, and manufacturing implantable textiles, Secant worked with CytexOrtho to transfer production of the custom textile portion of the implant—made from a slow-degrading, biodegradable fiber—to Secant's commercial weaving looms. Upon finalizing the base layer of the implant, CytexOrtho engaged with SanaVita Medical, Secant's sister CMO, to complete the technology transfer of the 3D-printing processes.

SanaVita also managed packaging design and selection, sterilization, and testing qualification and verification.

"We needed a CMO who was willing to take on new processes, including some sophisticated 3D-printing equipment that wasn't 'the norm' for medical device manufacturing. SanaVita embraced the challenge and guided us through the process," said Dr. Estes.

Result

CytexOrtho completed process validation of the implants in time for clinical trials.



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