Artifascia® Case Study

Manufacturing Nanofibre Materials for Clinical Trials

Overview

The Electrospinning Company has supported Nurami Medical with the manufacturing process development of their dura mater repair product (Artifascia®) and is supplying key Artifascia components for clinical trials.

Dura Mater Repair

Patients who have undergone neurosurgery have up to 30% chance of cerebral-spinal fluid (CSF) leakage despite treatment with a graft and a liquid sealant. CSF leakage can result in longer periods of hospitalisation or repeated surgery, which have an adverse effect to the patient's recovery. Currently available grafts are mainly derived from bovine collagen.

Nurami Medical Ltd., a commercial stage medical device company with expertise in brain physiology and biomaterials, has designed a synthetic dura mater graft product to reduce the risk of CSF leakage and enhance patient recovery after neurosurgery. Artifascia is a porous nanofibre material made from electrospun medical grade polymers that degrade naturally over time and is replaced by native tissue. It has excellent mechanical strength and flexibility enabling convenient surgeon handling and it eliminates the need for an additional liquid sealant. Artifascia obtained US FDA clearance late 2023.

The Electrospinning Company Ltd

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Challenge

Nurami Medical had only a small-scale facilities to manufacture the nanofibre component of Artifascia in house and required an ISO 13485-certified development and manufacturing partner.

The Electrospinning Company is an ISO 13485-certified contract design and manufacturing organisation specialised in nanofibre biomaterial design and manufacturing, built around its electrospinning technology platform.

Solution

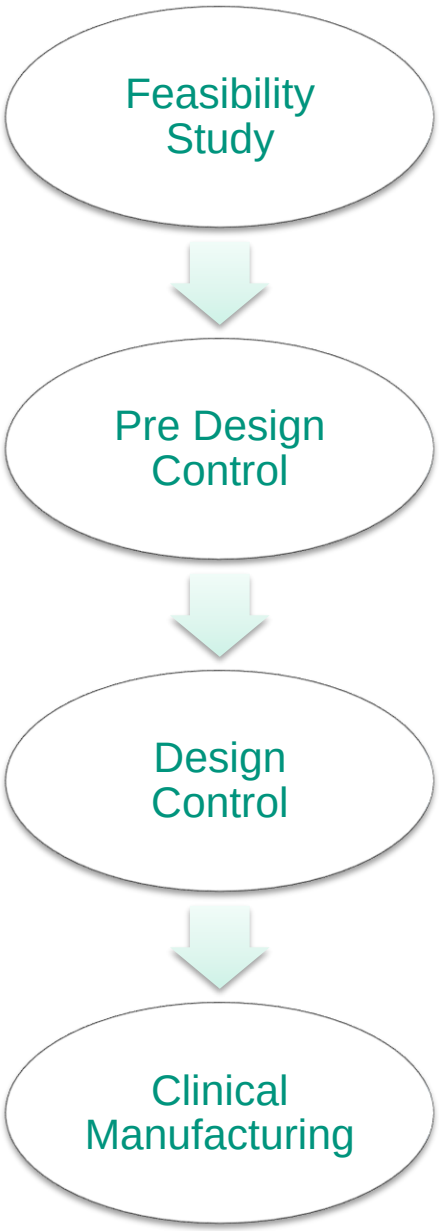
The Electrospinning Company swiftly adopted the Nurami Medical protocol, provided materials for clinical trials and, since late 2023, for commercial manufacturing.

Result

In less than 2 years, the Electrospinning Company has supported Nurami Medical in taking Artifascia from a product development stage to commercial stage.

Process

The Electrospinning Company worked with Nurami Medical, using its tried and tested development process to progress the project through key milestones.



The Electrospinning Company collaborated closely with Nurami Medical's development and quality staff, assuring production of the nanofibre component in compliance to ISO 13485 quality regulation.

"The Electrospinning Company gives high quality outcomes with fast and efficient communication and responsivity. They have a wonderful and reliable professional team who are experts in electrospinning."

Nora Nseir Manassa, CTO Nurami Medical