Viscofan BioEngineering's medical grade collagen production now ISO-certified

Quality system for medical device manufacturing ensures safe applications in tissue engineering and regenerative medicine

Weinheim, January 20, 2021 *– Viscofan BioEngineering, the business unit for biomedical research and development of Naturin Viscofan GmbH has achieved ISO 13485 certification for the manufacturing of collagen materials for medical applications in its Weinheim production plant. The company aims at expanding its business with collagen membranes and mass for innovative applications in medical engineering.*

Ensuring product safety of medical grade collagen

ISO 13485 is an independent standard that internationally recognizes quality management systems in the medical device industry. It is based on the structure of ISO 9001 but includes some particular requirements for medical devices such as risk analysis, manufacturing under sterile conditions and traceability. The certification of the GMP-compliant medical grade collagen production process is a milestone that "shows a continuous improvement in Viscofan's management systems, fulfilling more demanding requirements of the medtech industry" according to Óscar Arroyo, QM Corporate Director Viscofan.

Enabling breakthroughs in medical engineering & regenerative medicine

Viscofan BioEngineering utilizes 85 years of experience in collagen manufacturing for the food sector to develop innovative products for regenerative medicine. Collagen is the most abundant protein in the mammal body and important for cell adhesion, growth and differentiation. Collagen fibers therefore constitute an ideal scaffold to facilitate the regeneration of tissues and organs. The company's product portfolio is based on ultra-pure, native collagen type-I fibers which are offered as viscous mass for medical device coatings or as membranes that act as cell carriers in implantation medicine.

Together with partners, Viscofan BioEngineering is developing its own pipeline of innovative products for regenerative medicine, currently having several products in preclinical and clinical testing. The company intends to expand collaborations and partnering to create more novel medical products and advanced therapies.

As Lluis Quintana, Viscofan Bioengineering Corporate Director, explains: "This certification will allow us to increase our access to international markets and therefore to new customers and partners, by demonstrating that our collagen materials for medical applications are manufactured safely and efficiently."

About Viscofan BioEngineering

Viscofan BioEngineering is the biotech business unit of Naturin Viscofan GmbH – a company of the Viscofan group. We apply partly proprietary technologies and standardized extraction methods to process collagen from bovine skin for the development and industrial-scale production of novel collagen biomatrices in research, medical and food grade. The combination of premium products with an exceptional scientific support positions Viscofan BioEngineering at the forefront of regenerative medicine. The comprehensive portfolio is based on collagen membranes, suspension, solutions and hydrolysate to serve cell biology, biomedical and health food markets. The products are suitable for a broad range of novel applications, such as innovative tissue engineering, new surgical procedures, advanced medical devices or improved nutraceuticals. Together with its partners, Viscofan BioEngineering is also developing its own pipeline of products for regenerative medicine.

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IMAGES

Manufacturing of medical grade collagen membranes at Viscofan BioEngineering's production plant in accordance with the ISO 13485 quality management system

Use of collagen membranes as cell carrying implants in regenerative medicine