

Transferring manufacturing of a PMA product with compressed timeline

Therapeutic area

- **Wound Care Management**

Product

- **Specialized biomaterials manufacturing (SBM)**

Capabilities

- **Biomaterials expertise**
- **Process optimization**
- **Quality assurance & regulatory affairs (QARA) support**



Partnering for the challenge

Our partner is a Fortune 20 medical equipment manufacturer that distributes products throughout the world. The company needed to transfer production of a premarket-approval (PMA) product to a new manufacturer within a compressed timeline.

As the manufacturer of 3.5 million medical components annually from our ISO 13485:2016 and MDSAP-certified facilities, the Biomedical team at dsm-firmenich has honed its strategic biomaterial manufacturing capabilities to enable the transfer of entire product lines.

Why it matters

As many as 93% of patients have been shown to develop adhesions following abdominal surgery, and these adhesions can result in “small bowel obstruction, difficult and dangerous reoperations, and infertility.”¹ Roughly 20% of abdominal surgery patients need a second surgery due to adhesion-related complications.



Our innovation

On behalf of our partner, we're delivering:

- ✓ A combination of biomaterials and process expertise to manufacture a PMA product with natural and synthetic resorbable biomaterials in a cost-effective, risk-appropriate selective-automation, and scalable manner.
- ✓ A modern manufacturing platform to increase the potential capacity of an intermediate complex of natural materials, scaling the process to roughly 130% of current demand and decreasing solvent usage by 95%, and the development and implementation of cost-saving solutions that accelerated commercial launch.
- ✓ Expertise to support customer's US regulatory filings, including documented test methods, process and facility validations, and preapproval site inspections.

Our impact

dsm-firmenich, through our Biomedical team, is moving a legacy PMA product to an innovative technology platform—manufacturing it faster, more reliably, and efficiently—at the scale needed to meet market demand. As a result, our partner is evaluating similar initiatives to leverage our specialized biomaterial manufacturing expertise.

Reference: 1. Becker JM, Dayton MT, Fazio VW, et al. Prevention of postoperative abdominal adhesions by a sodium hyaluronate-based bioresorbable membrane: a prospective, randomized, double-blind multicenter study. *J Am Coll Surg.* 1996;183(4):297-306. Accessed June 2, 2024. <https://pubmed.ncbi.nlm.nih.gov/8843257/>

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