

Quality & Specifications

A startup company developing a novel therapeutic manufacturing process using an NEB enzyme needed to scale up their operations. They contacted NEB's Customized Solutions Team to see how we could help. The client required large quantities of the enzyme to make a clinical-grade product, devoid of animal-derived material, and with a battery of additional quality controls to ensure consistent and controlled production.

CAPABILITY AND SCOPE OF WORK

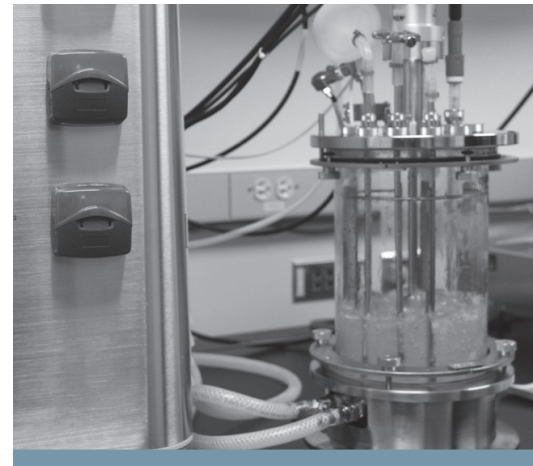
Firstly, our R&D team provided insight into other enzymes that may suit the client's needs and, in practice, simplify their manufacturing process. The client successfully tested the recommended enzyme and then worked with both the Quality and Manufacturing Teams to assess the potential to manufacture the enzyme in our Rowley, MA facility.

This new facility is purpose-built for the manufacture of custom enzymes suitable for incorporation into GMP processes. It is animal-free and includes extensive environmental monitoring systems, ISO 8 cleanroom facilities and ISO 5 filling suites. The manufacturing process starts with characterized master cell banks, dedicated chromatography resins, and extensive in-process and post-processing controls. Products are moved through a battery of qualified assays that assess enzyme activity and levels of contaminants, as well as compendial assays, including endotoxin and bioburden.

OUTCOME

Our Customized Solutions Team worked closely with the client to understand their requirements, and we were able to transition the manufacturing of their product to the Rowley facility. We partnered with the client to ensure the comparability of the new product with their current enzyme. We were able to develop a cost-effective strategy so that GMP-grade manufacturing would not adversely impact their business model or existing cost structure. In looking ahead, we also ensured that the material could be made at scale, to avoid the need to modify our manufacturing process as the company's demand for the product grows.

Our client is continuing to build a manufacturing process that includes our enzyme, and is working with both our Quality and Manufacturing Teams to ensure that the material continues to meet their expectations.



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