

# U.S. Based Independent Biotech Company Finds Success in Syner-G's Capabilities in Manufacturing for Both Pre-Clinical and Clinical Trials

## About

Yumanity Therapeutics, headquartered in Boston, was established in December 2014 as an independent biotechnology company focused on drug development targeting neurological diseases where protein misfolding is a key concept, such as Alzheimer's, Parkinson's disease, and Lou Gehrig's disease (amyotrophic lateral sclerosis).

## Challenge

Bringing new registration-ready drugs through discovery and clinical trials is a resource-intensive process that requires many levels of expertise. As a small company, Yumanity did not have the experienced professionals needed to manage each stage of the manufacturing, quality, and regulatory processes (collectively called CMC – Chemistry, Manufacturing and Controls). It would also not have been practical to hire full-time staff across the each of the CMC functions (e.g., drug substance, drug product, analytical, etc.) for fractional needs.

## Solution

Yumanity chose to partner with Syner-G to manage its CMC processes, regulatory requirements, technical development, and FDA GxP compliance through its CMC360™ solution. Syner-G helps its clients design and implement science and risk-based, phase-appropriate solutions to advance drugs during development expeditiously. Syner-G's CMC 360 and Regulatory Affairs business units operate in an integrated fashion to ensure full compliance with scientific standards and regulatory requirements.

*"The partnership with Syner-G fulfilled Yumanity's CMC needs in an effective and efficient manner. The Syner-G team was easy to work with and in this business, that really matters."*

*Paulash Mohsen, CBO and head of CMC and Program Management*

## Results

Yumanity was pleased with the capabilities Syner-G was able to bring to the table on day one and varied the configuration as the company's needs evolved. Specifically, they built capabilities around manufacturing for both pre-clinical and clinical trials. Syner-G was flexible and provided the guidance and expertise Yumanity needed to ramp up and ramp down as needed. Yumanity found Syner-G's agile methodologies and custom capabilities invaluable.

Syner-G qualities that Yumanity found particularly helpful in delivering results included the following:



High-capability, functional expertise



Flexibility to pivot as needed



Ability to identify needs and execute on deliverables

**Syner-G managed multiple complex processes and provided coordination within Yumanity while staying on time and on budget.**