

## **Oncobiologics opens commercial launch manufacturing facility**

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Oncobiologics, Inc., a biopharmaceuticals company focused on developing and commercializing monoclonal antibody (mAb) biosimilars, has completed the construction of its GMP commercial launch manufacturing facility at its headquarters in Cranbury, New Jersey.

The Cranbury facility is designed to utilize multiple technologies that enable rapid deployment of flexible manufacturing at commercial scale. Through the use of the latest single-use technologies, the facility footprint and associated capital investment is significantly lower than a conventional facility of equivalent capacity. The design and construction of the facility was completed in less than one year, which is less than half the time required for stainless steel-based commercial facilities. Previously, Oncobiologics' in-house clinical manufacturing facility was constructed and validated in less than six months. The new Cranbury facility can be rapidly replicated in the future, thus providing Oncobiologics with significant flexibility in meeting global market demand for its biosimilar portfolio.

Scott Gangloff, Oncobiologics' Senior Vice President of Development and Manufacturing, commented, "The completion of our Biologics Manufacturing Center is a watershed achievement for Oncobiologics, representing the final piece of the BioSymphony business model that we have assembled over the past three years. By fully-integrating our CMC development and manufacturing operations at a single site, we are able to expedite technology transfer, resulting in a streamlined path to commercialization."

Oncobiologics Founder & CEO, Pankaj Mohan, Ph.D., added, "The Oncobiologics team has designed and built a world-class facility in record time. This project is another demonstration of the capital efficiency and speed that we embrace as critical success factors in the emerging mAb biosimilars marketplace. The collaborative integration between critical functional areas enables us to rapidly advance high quality mAb biosimilar candidates, which is proving to be an important differentiator for Oncobiologics."

The new commercial 2000-L facility has already been deployed to manufacture ONS-3010, a Humira®/adalimumab biosimilar candidate, for use in an upcoming Phase III clinical trial. Two of Oncobiologics' eleven mAb biosimilar candidates have entered the clinic within the past year.