

CENTER FOR BIOMANUFACTURING SCIENCE & TECHNOLOGY SEMINAR



NIHAL TUGCU

MERCK RESEARCH LABS

“KEYTRUDA STORY: PROCESS DEVELOPMENT, TECHNOLOGY TRANSFER AND COMMERCIALIZATION OF MONOCLONAL ANTI-PD-1 ANTIBODY”

KEYTRUDA® has been approved by the FDA as the first anti-PD1 therapy in the United States. KEYTRUDA® is an immunotherapy treatment and originally indicated in the United States at a dose of 2 mg/kg every three weeks for the treatment of patients with unresectable or metastatic melanoma. This indication received accelerated approval in September 2014 after being granted breakthrough designation by the FDA in 2013. The initial positive response of patients in clinical studies triggered tremendous acceleration of the development and commercialization programs. Targeted process development initiatives together with a creative manufacturing supply chain enabled the expedited development and assembly of the BLA. Process used for Phase I supply manufacturing had to be quickly optimized in order to allow rapid portability and scale up into a network of manufacturing facilities. The modification and optimization of the process for successful process fit required substantial data to be generated and very close interaction between the development and manufacturing groups. This paper will aim to summarize the focused process development coupled with process technology transfer and scale up, as well as supply chain management strategies, required to bring this much needed breakthrough therapy to market.

BIOGRAPHY

NIHAL TUGCU is in Downstream Process Development and Engineering, Biologics Process Development & Clinical Manufacturing, at Merck Research Labs, Kenilworth, NJ. She received her B.S. in chemical engineering from Bogazici University, Turkey in 1997. She received her Ph.D. in chemical engineering at Rensselaer Polytechnic Institute in 2002 under the supervision of Prof. Steven M. Cramer. Her work focused on designing high affinity displacers to be used for displacement chromatography. She also investigated the effect of resin chemistry and mobile phase conditions on protein retention and displacer efficacy. Since receiving her Ph.D., she has been employed in the Biologics Process Development and Clinical Manufacturing at Merck & Co., Inc. in Kenilworth, New Jersey. In her current position as an Executive Director, she focuses on purification process development for all stages therapeutic proteins as well as CMC leadership. In her role, with her team she also focuses on advanced manufacturing technologies to decrease footprint, increase productivity and decrease COGs along with associated process analytical technologies for enhanced characterization and knowledge built for such processes. Tugcu has been a member of ACS since 1999, and involved with ACS BIOT at different capacities over the last few years. The type of responsibilities included Downstream Processing Area coordination, and co-chairing sessions. She is the programming co-chair for the upcoming 2018 ACS BIOT, has been involved at different capacities in BIOT Executive Committee since 2011, and has also been a member of AIChE (Area 2G: Bioseparations vice chair for 2011) and SBE.



CBST SEMINAR

2/26/2018

1:30 p.m.

366 Colburn Lab

sites.udel.edu/cbst



UNIVERSITY of DELAWARE
Chemical & Biomolecular
Engineering