BTEC 591 & BTEC 691 Seminars *

"Boosting Novel Pharmaceuticals towards Clinics: Technology Transfer and Scale-Up for GMP Compliance"

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*** These seminar series are offered conjointly with the GTU 110 course for the entire Gebze Technical University community.**

Abstract

Many novel nano-pharmaceuticals are being developed across globe which hold strong potential for providing more effective and safer therapies and diagnostic procedures for a wide range of diseases. However, scale-up and GMP production of innovative pharmaceuticals is still challenging to main players due to the lack of GMP manufacturing sites flexible enough to accommodate the vast number of methods and equipment necessary for the broad palette of novel pharmaceuticals that are currently in the development pipelines. Additionally, novel pharmaceuticals are mostly produced in small scale and conventional methods that are present in the labs which are appropriate for small scale production. But most of these methods are not GMP conform and limited with the batch size which is not sufficient to supply clinical trials and stability studies. Thus, there is an urgent need for flexible scale-up approaches for implementation during technology transfer to GMP environment.

The lack of affordable GMP manufacturing facilities and services for successful implementation of the advances novel pharmaceuticals are main obstacles to further enhance the growth and innovation capacity. The most common difficulties faced during tech transfer and scale-up and the gateway that links lab processes to the clinics for the production of novel pharmaceuticals under GMP conditions are visited in this talk and the strategies are introduced to overcome these obstacles as prerequisites for achieving this goal.

Nazende GÜNDAY TÜRELİ

Nazende Günday Türeli is Chief Strategy and Innovation Officer at MyBiotech responsible for defining and executing the long-term strategy and vision roadmap, defining and managing the Research & Development /Innovation landscape and establishing R&D/I partnerships. She is Bogazici University, Chemistry graduate. She has Master`s degree in Biotechnology and PhD in Biopharmacy and Pharmaceutical Technology from Saarland University, Germany.

She is a recognized coordinator and principle investigator of international, multidisciplinary research and innovation collaboration projects with experts and stakeholders across the pharmaceutical field and nanopharmaceuticals, including PHOENIX project: Open Innovation Test Bed for GMP Manufacturing of Nanopharmaceuticals. Nazende led several multidisciplinary and interdisciplinary teams to conduct research in leading international contract research, development and manufacturing organisations. She is a passionate mentor and trainer, dedicated to support younger generations with strong motivation and to identify rising stars. Believes in gender equity and equality being imperative for leaving a better community for future generations.