The National Academies of SCIENCES • ENGINEERING • MEDICINE

Board on Chemical Sciences and Technology

COMMITTEE TO IDENTIFY INNOVATIVE TECHNOLOGIES TO ADVANCE PHARMACEUTICAL MANUFACTURING

WEBINAR WITH CENTER FOR DRUG EVALUATION AND RESEARCH, US FOOD AND DRUG ADMINISTRATION

JUNE 29, 2020

AGENDA

10:30 **Purpose of Open Session**

G.V. Rex Reklaitis

Chair, Committee to Identify Innovative Technologies to Advance Pharmaceutical Manufacturing Burton and Kathryn Gedge Distinguished Professor, Purdue University

10:35 Conversation with Study Sponsor on Regulatory Requirements, Scope of Responsibility, and Preparedness for Innovative Technologies

Sau (Larry) Lee Director, Emerging Technology Team Chair OTR, OPQ, FDA

Katherine Tyner Associate Director for Science (acting) CDER, OPQ, FDA

- 11:50 **Opportunity for Public Comment**
- 12:00 END OF OPEN SESSION