

Introduction and Welcome!

Barbara Scott

Senior Quality Assessor

Division of Lifecycle API, Office of New Drug Products

OPQ | CDER | US FDA

Drug Master File (DMF) and Drug Substance Question and Answer Webinar Following March 3-4, 2021 Workshop

April 9, 2021



Agenda

- Session 1
 - Administrative Information, Communications, Facilities, and Complex API (60 min)
 - Live Panel Q&A (15 min)
 - Break (15 min)



Agenda

- Session 2
 - Starting materials, Impurities, Common Review Issues (60 min)
 - Live Panel Q&A (15 min)
 - Closing Remarks



U.S. FOOD & DRUG
ADMINISTRATION