



Manufacturing, Supply Chain, and Inspections during the COVID19 Public Health Emergency

August 25, 2021 | 9:00 a.m. – 1:00 p.m. (Eastern, UTC-4)

AGENDA

9:00	FDA guidance on manufacturing during COVID-19 and high absenteeism	CDR Tara Gooen Bizjak <i>Director</i> Manufacturing Quality Guidance and Policy Staff Office of Manufacturing Quality of Compliance Office of Compliance CDER FDA CDR Emily Thakur, RPh <i>Team Leader</i> Drug Shortage Staff CDER FDA
10:00	Questions and Panel Discussion	CDR Tara Gooen Bizjak CDR Emily Thakur, RPh
10:20	Risk management and application approaches in responding to supply chain constraints during PHE	CDR Mahesh Ramanadham <i>Associate Director of Scientific Operations</i> Office of Pharmaceutical Manufacturing Assessment Office of Pharmaceutical Quality CDER FDA
11:20	Questions and Panel Discussion	CDR Mahesh Ramanadham Hasmukh Patel <i>Director</i> Division of Post-Market Activities 1 Office of Lifecycle Drug Product Assessment OPQ CDER FDA

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11:40	Inspections and use of alternate tools during the PHE	Laurie Graham <i>Director</i> Division of Internal Policies and Procedures Office of Policy for Pharmaceutical Quality OPQ CDER FDA
12:40	Questions and Panel Discussion	Laurie Graham Derek Smith <i>Deputy Director</i> Office of Pharmaceutical Manufacturing Assessment OPQ CDER FDA CDR Tara Gooen Bizjak Alonza Cruse <i>Director</i> Office of Pharmaceutical Quality Operations, Office Medical Products and Tobacco Operations, ORA, FDA Neil Stiber <i>Associate Director</i> Office of Quality Surveillance, OPQ CDER FDA

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