CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE

WEBINARS

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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** *Director* Manufacturing Quality Guidance and Policy Staff | Office of Manufacturing Quality of Compliance | Office of Compliance | CDER | FDA **CDR Emily Thakur, RPh** *Team Leader* 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** *Associate Director of Scientific Operations* Office of Pharmaceutical Manufacturing Assessment | Office of Pharmaceutical Quality | CDER | FDA
11:20	**Questions and Panel Discussion**	**CDR Mahesh Ramanadham** **Hasmukh Patel** *Director* 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** *Director* 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** *Deputy Director* Office of Pharmaceutical Manufacturing Assessment | OPQ | CDER | FDA **CDR Tara Gooen Bizjak** **Alonza Cruse** *Director* Office of Pharmaceutical Quality Operations, Office Medical Products and Tobacco Operations, ORA, FDA **Neil Stiber** *Associate Director* Office of Quality Surveillance, OPQ | CDER | FDA

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