

# **GDUFA Reauthorization Stakeholder Meeting**

## **April 27, 2021**

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Virtual Meeting

### **Agenda**

#### **Welcome and Overview**

Jacqueline Corrigan-Curay, MD, JD  
*Director, Office of Medical Policy, CDER, FDA*

#### **FDA and Stakeholder Introductions**

#### **Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency – [Guidance for Industry](#)**

Brian Hasselbalch  
Deputy Director, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality, CDER, FDA

#### **Summary of Recent Negotiation Sessions**

Jacqueline Corrigan-Curay, MD, JD

#### **Stakeholder Comments**

#### **Closing**

Carter Beach, JD  
*Deputy Director, Office of Executive Programs, CDER, FDA*

- Next Stakeholder meeting scheduled for May 25, 2021.