

# AGENDA

Tuesday, October 2, 2018

## 2018 Electronic Drug Registration & Listing Using CDER Direct

8:00 AM Registration Opens

9:00 - 9:10 AM Administrative Announcements

Jeff Kelly

9:10 - 9:20 AM EDT

Welcome

Paul Loebach

9:20 - 9:30 AM EDT

Keynote - The State of DRLS

Paul Loebach

9:30 - 10:30 AM EDT

### Session 1: Establishment Registration & Labeler Code Requests

Creation and submission of a Drug Establishment Registration submission using CDER Direct. Includes Updates, No Change Notification renewals, and De-registration. Also the creation and submission of a Labeler Code Request submission using CDER Direct.

Lalnunpuii Huber  
Regie Samuel

10:30 -10:45 AM B R E A K

10:45 - 11:30 AM EDT

### Session 2: National Drug Code Reservation

What is a NDC Reservation, When to use it, Creation and submission of a NDC Reservation Request submission using CDER Direct.

Troy Cu  
David Mazyck

11:30 - 12:45 PM EDT

### Session 3: Drug Product Listing & Listing Certification

A walk through of the creation and submission of a Drug Product Listing submission using CDER Direct. The creation and submission of a Drug Listing Certification submission using CDER Direct.

Julian Chun  
Donovan Duggan

12:45 - 1:45 PM L U N C H

1:45 -2:45 PM EDT

### Session 4: FDA DRLS Compliance Program

Our Helpdesk and Trouble Shooting process, Compliance Cases, Timelines, Top 10 errors and how to fix them. Correct information to supply with your question.

Tasneem Hussain  
Leyla Rahjou Esfandiary

2:45 - 3:45 PM EDT

### Session 5: 503B Product Reporting for Compounding Outsourcing Facilities

A walk through of the creation and submission of a 503B Product Report submission using CDER Direct.

Lysette Deshields  
Soo Jin Park

3:45PM EDT ONLINE ADJOURNMENT

3:45 - 5:00 PM EDT

### Onsite Technical Support

Helpdesk staff will be available to assist onsite participants with submissions using CDER Direct.