Electronic Drug Registration & Listing Using CDER Direct

Thursday, October 5, 2017

8:45-9:00	**Administrative Announcements**	**Jeff Kelly,** SBIA Events
9:00-9:10	**Welcome**	**Brenda Stodart, PharmD** CAPT, USPHS Program Director CDER Small Business and Industry Assistance Division of Drug Information (DDI) Office of Communications (OCOMM) Center for Drug Evaluation and Research (CDER) Food and Drug Administration (FDA)
9:10-9:25	**Keynote: The New 207 and What You Need to Know**	**Leyla Rahjou Esfandiary, PharmD** Team Lead Data Quality and Compliance Team Drug Registration and Listing Staff (DRLS) Office of Program and Regulatory Operations (OPRO) Office of Compliance (OC) | CDER | FDA
9:25-9:55	**Session 1: Establishment Registration** A walk through of the creation and submission of a Drug Establishment Registration submission using CDER Direct. Includes Updates, No Change Notification renewals, and De-registration.	**Regie Samuel** Technical Information Specialist FDA/CDER/OC/OPRO/DRLS **Troy Cu** Technical Information Specialist FDA/CDER/OC/OPRO/DRLS
9:55-10:15	**Question & Answer Panel for Session 1**	
10:15-10:30	**15 Minute Break**	
10:30-11:00	**Session 2: Labeler Code Request** A walk through of the creation and submission of a Labeler Code Request submission using CDER Direct.	**Lalnunpuii Huber** Technical Information Specialist FDA/CDER/OC/OPRO/DRLS **David Mazyck** Consumer Safety Officer FDA/CDER/OC/OPRO/DRLS
11:00-11:20	**Question & Answer Panel for Session 2**	
11:20-11:50	**Session 3: Drug Product Listing** A walk through of the creation and submission of a Drug Product Listing submission using CDER Direct.	**Julian Chun, PharmD** Pharmacist, FDA/CDER/OC/OPRO/DRLS **Tasneem Hussain, PharmD** Pharmacist, FDA/CDER/OC/OPRO/DRLS
11:50-12:15	**Question & Answer Panel for Session 3**	

12:15-1:15	60 Minute Lunch	
1:15-1:45	**Session 4: Listing Recertification** A walk through of the creation and submission of a Drug Listing Recertification submission using CDER Direct.	**Donovan Duggan, MBA** Lead Consumer Safety Officer, Team Lead Helpdesk Operations Team FDA/CDER/OC/OPRO/DRLS
1:45-2:05	**Question & Answer Panel for Session 4**	
2:05-2:35	**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, PharmD** LCDR, USPHS Pharmacist FDA/CDER/OC/OPRO/DRLS **Soo Jin Park, PharmD, MPH** LCDR, USPHS Pharmacist FDA/CDER/OC/OPRO/DRLS
2:35-255	**Question & Answer Panel for Session 5**	
2:55-3:00	**Closing**	**Paul Loebach, Director** Drug Registration and Listing Staff FDA/CDER/OC/OPRO/DRLS
3:00-5:00	**1:1 In-Person Consultations** FDA subject matter experts (Help Desk Consultants) hold 1:1 support consultations for as long as participants seek assistance.	