Potential Medication Error Risks with Investigational Drug Container Labels

Public Meeting Agenda
(Virtual)

May 18, 2021; 1-4pm (ET)

1:00 pm **Welcome**
Susan C. Winckler, RPh, Reagan-Udall Foundation for the FDA

1:05 pm **Opening Remarks**
Gerald Dal Pan, MD, MHS, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, FDA

1:15 pm **Panel 1: Clinical Trial Site Perspectives**
Moderator:
Michael Cohen, RPh, Institute for Safe Medication Practices (ISMP)

Presenters and Contributors:
Sapna R. Amin, PharmD, MD Anderson Cancer Center
Jamie N. Brown, PharmD, Durham VA Medical Center
Han X. Feng, PharmD, National Institutes for Health
Raymond J. Muller, RPh, Memorial Sloan Kettering Cancer Center
Richard Needleman, RPh, Fox Chase Cancer Center

2:15 pm **Panel 2: Supplier/CRO Perspectives**
Neil McCullough, PhD, IQVIA
Tony Heeley, Parexel International

3:00 pm **Panel 3: Industry (Sponsor) Perspectives**
James Duhig, PhD, AbbVie
Alexander Mills, Merck

3:45 pm **Closing Remarks / Adjourn Day 1**

May 19, 2021; 10am-1pm (ET)

10:00 am **Welcome**

10:05 am **Day 2 FDA Remarks**
Jo Wyeth, Center for Drug Evaluation and Research, FDA

10:15 am **Panel 4: International Regulatory Perspectives**
Panelists:
Jason Wakelin-Smith, Medicines and Healthcare Products Regulatory Agency (UK)
Alicja Kasina, Health Canada

Contributors:
Asma Syed, Health Canada

11:00 am **Panel 5: Institutional Review Board (IRB) Perspectives**
Nichelle Cobb, PhD, Smart IRB
Bruce Gordon, MD, Institutional Review Boards
Susan Johnston, PharmD, University of Wisconsin-Madison Medicine

11:30 am **Panel 6: FDA Regulatory Perspectives**
Presenters and Panelists:
Janine Stewart, Division of Medication Error Prevention and Analysis, Center for Drug Evaluation and Research, FDA
Lubna Merchant, Office of Medication Error Prevention and Risk Mitigation, Center for Drug Evaluation and Research, FDA
Janet Donnelly, Office of Clinical Policy and Programs, Office of Good Clinical Practice, FDA
Paul Gouge, Division of Clinical Trial Quality, Office of Medical Policy, Center for Drug Evaluation and Research, FDA
Ryan Raffaelli, Office of Scientific Investigations, Office of Compliance, Center for Drug Evaluation and Research, FDA

Contributors:
Alyson Karesh, Division of Clinical Trial Quality, Office of Medical Policy, Center for Drug Evaluation and Research, FDA
Mona Shing, Division of Clinical Trial Quality, Office of Medical Policy, Center for Drug Evaluation and Research, FDA
Idalia Rychlik, Division of Medication Error Prevention and Analysis, Center for Drug Evaluation and Research, FDA
Ankara Yokum, Division of Medication Error Prevention and Analysis, Center for Drug Evaluation and Research, FDA

12:30 pm **Public Comment**
Public comment is limited to 2 minutes per speaker.

1:00 pm **Closing Remarks / Adjourn**