

4th Category 1 Focus Group Meeting PLUS – Extended Scope June 4th and 5th 2019

Venue: Embassy Suites by Hilton Alexandria Old Town
1900 Diagonal Road, Alexandria, Virginia 22314, US

www.cat1focusgroup.com

Time	Agenda Topics for Day 1 – June 4 th , 2019 - Morning
08:15 – 08:30 AM	Welcome <i>Sebastian Schwier, Grünenthal</i>
08:30 – 09:00 AM	Keynote: The Future of Abuse Deterrence – Where are we going? <i>Joe Rannazzisi, former head of the DEA Office of Diversion Control</i>
Session I	Category 1 - Testing in the Lab
09:00 – 09:30 AM	Recent trends in Standardization <i>Chris Altomare, DrugScan</i>
9:30 – 10:00 AM	Category 1 testing beyond “classical” Opioids (pro-drugs, PEGylated molecules, stimulants) <i>Ike Harper, NMS labs</i>
10:00 – 10:30 AM	Coffee and Networking Break
10:30 – 11:00 AM	Emerging Technologies – Vaping <i>Stephen Hoag, University of Maryland and Chris Altomare, DrugScan</i>
11:00 – 11:30 AM	Introduction to Working Group 1 – Working Group 4
11:30 – 1:00 PM	Working Sessions <ul style="list-style-type: none"> - <i>Working Group 1 – Standardization:</i> Bob Bianchi - <i>Working Group 2 – Manipulation methods and new technologies:</i> Stephen Hoag, Chris Altomare - <i>Working Group 3 – New Generic ADF guidance:</i> Penny Toren and FDA representative (to be confirmed) - <i>Working Group 4 – Statistical Issues with margins introduced with recent guidelines:</i> Beatrice Setnik and FDA representative (to be confirmed)

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Time	Agenda Topics for Day 1 – June 4 th , 2019 - Afternoon
1:00 – 2:00 PM	Lunch
Session II	Regulatory Aspects: New study concepts and Advisory Committees
2:00 – 3:00 PM	FDA perspective on focus group/tampering studies <i>Marta Sokolowska, FDA</i>
3:00 – 4:00 PM	Moving past OPANA ER – Current Challenges of demonstrating i.v. abuse deterrence <i>Chris Miller, 3D Communications</i>
4:00 – 4:15 PM	Coffee and Networking Break
4:15 – 4:55 PM	Panel Discussion Sessions I and II – Category 1 Technologies, Regulatory Aspects and Advisory Committee Meetings <i>Speakers from Sessions I and II and FDA representatives</i>
4:55 – 5:00 PM	Wrap up Day 1
6:00 – 8:00 PM	Networking event <i>BRABO Tasting Room 1600 King St Alexandria, VA</i>

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Time	Agenda Topics for Day 2 – June 5 th , 2019
08:30 – 08:45 AM	Short Welcome
Session III	Safety of Excipients / Category 2&3 Studies
08:45 – 09:15 AM	Safety of excipients – Evolvement of Expectations <i>Peter Persich, Grunenthal and FDA representative (to be confirmed)</i>
09:15 – 9:45 AM	Considerations from the Lab for evaluating excipients in the Category 1 field <i>Eric Kinzler, DrugScan</i>
9:45 – 10:15 AM	Statistical issues during Category 2 & 3 Studies <i>Beatrice Setnik and Colleagues, Syneos and FDA representative (Ling Chen - to be confirmed)</i>
10:15 – 10:45 AM	Coffee and Networking Break
Session IV	Real World Data
10:45 – 11:15 AM	(FDA) Perspective on what sort of data required to demonstrate that ADF works <i>Michael Klein</i>
11:15 – 12:15 PM	Real World Data: Do ADFs change behavior? What current opioid data imply for stimulants in the future <i>Janetta Iwanicki, RADARS</i>
12:15 – 1:15 PM	Lunch
1:15 – 3:00 PM	Working Sessions Presentations Groups 1 & 2 & 3 & 4 and Panel discussion on Safety of Excipients and Real World Data <i>Speakers from Sessions III and IV and FDA representatives</i>
3:00 – 3:30 PM	Wrap Up



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