CCALC

Cross Company Abuse Liability Council

CATEGORY 1 - FOCUS GROUP

In Vitro Abuse-Deterrent Studies

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 4th, 2019
08:15 – 08:30 AM	Welcome *Sebastian Schwier, Grünenthal*
08:30 – 09:00 AM	Keynote: The Future of Abuse Deterrence – Where are we going? *Joe Rannazzisi, former head of the DEA Office of Diversion Control*
Session I	Catergory 1 test in the Lab
09:00 – 09:30 AM	Recent trends in Standardization *Chris Altomare, DrugScan*
9:30 – 10:00 AM	Category 1 testing beyond "classical" Opioids (pro-drugs, PEGylated molecules, stimulants) *Ike Harper, NMS labs*
10:00 – 10:30 AM	Coffee and Networking Break
10:30 – 11:00 AM	Emerging Technologies – Vaping *Stephen Hoag, University of Maryland and Chris Altomare, DrugScan*
11:00 – 12:00 PM	Introduction to Working Group 1 – Working Group 4
12:00 – 1:00 PM	Lunch
1:00 – 2:30 PM	Working Sessions - *Working Group 1 – Standardization*: - *Working Group 2 – Manipulation methods and new technologies*: - *Working Group 3 – New Generic ADF guidance* *Working Group 4 – Statistical Issues with margins introduced with recent guidelines*
Session II	Product Specific guidelines
2:30 – 3:00 PM	FDA perspective Speaker
3:00 – 3:30 PM	Generic industry Perspective

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	Speaker:
3:30 – 4:00 PM	Coffee and Networking Break
4:00 – 4:45 PM	Panel Discussion Sessions I and II – Category 1 Technologies and Product Specific Guidelines Speakers from Sessions I and II
4:45 – 5:00 PM	Wrap up Day 1
6:00 – 8:00 PM	Networking event *Location tbd*

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June 4th and 5th 2019

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

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