

## 4<sup>th</sup> Category 1 Focus Group Meeting PLUS – Extended Scope June 4<sup>th</sup> and 5<sup>th</sup> 2019

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

[www.cat1focusgroup.com](http://www.cat1focusgroup.com)

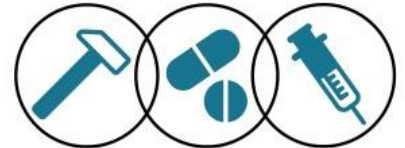
Time	Agenda Topics for Day 1 – June 4 <sup>th</sup> , 2019
08:15 – 08:30 AM	Welcome <i>Sebastian Schwier, Grünenthal</i>
08:30 – 09:00 AM	Keynote: The Future of Abuse Deterrence – Where are we going? <i>Joe Rannazzisi, former head of the DEA Office of Diversion Control</i>
<b>Session I</b>	<b>Category 1 test in the Lab</b>
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"> <li>- <i>Working Group 1 – Standardization:</i> Bob Bianchi</li> <li>- <i>Working Group 2 – Manipulation methods and new technologies:</i> Stephen Hoag, Chris Altomare</li> <li>- <i>Working Group 3 – New Generic ADF guidance:</i> Penny Toren and FDA representative (to be confirmed)</li> <li>- <i>Working Group 4 – Statistical Issues with margins introduced with recent guidelines:</i> Beatrice Setnik and Ling Chen (FDA)</li> </ul>

## 4<sup>th</sup> Category 1 Focus Group MeetingPLUS – Extended Scope June 4<sup>th</sup> and 5<sup>th</sup> 2019

<b>1:00 – 2:00 PM</b>	Lunch
<b>Session II</b>	<b>Regulatory Aspects and Generic Industry Perspective: New study concepts and Advisory Committees</b>
<b>2:00 – 2:45 PM</b>	FDA perspective on focus group/tampering studies <i>Marta Sokolowska, FDA</i>
<b>2:45 – 3:30 PM</b>	Moving past OPANA ER – Current Challenges of demonstrating i.v. abuse deterrence <i>Chris Miller, 3D Communications</i>
<b>3:30 – 4:00 PM</b>	Generic Industry Perspective on ADF Developments <i>Mohsen Sadatrezaei, Rhodes Pharma</i>
<b>4:00 – 4:15 PM</b>	Coffee and Networking Break
<b>4:15 – 4:55 PM</b>	Panel Discussion Sessions I and II – Category 1 Technologies, Generic Industry Perspective, Regulatory Aspects and Advisory Committee Meetings <i>Speakers from Sessions I and II and Ling Chen (FDA)</i>
<b>4:55 – 5:00 PM</b>	Wrap up Day 1
<b>6:00 – 8:00 PM</b>	Networking event <i>BRABO Tasting Room 1600 King St Alexandria, VA</i>

## 4<sup>th</sup> Category 1 Focus Group Meeting PLUS – Extended Scope June 4<sup>th</sup> and 5<sup>th</sup> 2019

Time	Agenda Topics for Day 2 – June 5 <sup>th</sup> , 2019
08:30 – 08:45 AM	Short Welcome
<b>Session III</b>	<b>Safety of Excipients / Category 2&amp;3 Studies</b>
08:45 – 09:15 AM	Safety of excipients – Evolvment of Expectations <i>Peter Persich, Grunenthal</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 Ling Chen, FDA</i>
10:15 – 10:45 AM	Coffee and Networking Break
<b>Session IV</b>	<b>Real World Data</b>
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 Ling Chen (FDA)</i>
3:00 – 3:30 PM	Wrap Up



## 4<sup>th</sup> Category 1 Focus Group MeetingPLUS – Extended Scope June 4<sup>th</sup> and 5<sup>th</sup> 2019

WE THANK OUR SPONSORS



# PinneyAssociates



When you need to know.®