Category 1 Focus Group Meeting -2015

Renaissance Mayflower Hotel, Washington DC

4th November 2015

08:30 - 08:40	Welcome and introduction *Marta Sokolowska, Grünenthal; Karsten Lindhardt, Egalet*
08:40 - 09:10	Final ADF Guideline in April 2015 and Current Experiences with Category 1 data in submissions *Suggested speaker: James Tolliver, CSS/FDA*
09:10 – 09:40	Review of drug preparations utilized by abusers ad how these procedures could be categorized and translated into in vitro testing" *Kerri Schoedel, Altreos Partners*
09:40 - 10:00	AM Break
10:00 - 10:30	Standardization of physical/mechanical manipulation studies *Patricia Haneman, NMS Lab./Bob Bianchi PDRC*
10:30 - 11:00	Managing evolving regulatory demands to Cat 1 labs & Interpretation of manipulation results for design of extraction studies *Anthony Constantino, DrugScan*
11:00 - 11.30	Can we standardize household tools? *Stephen Byrn/Steven Hoag, Purdue/Maryland Universities*
11.30 - 12.30	Panel Discussion: How does Category 1 studies reflect real world product manipulation? *James Tolliver, FDA; Silvia Calderon FDA; Kerri Schoedel, Altereos; Bob Bianchi, PDRC; Ed Cone, Pinney Associates; Steven Byrn, Purdue University; Steven Hoag, Maryland University*
12:30 - 13:30	Lunch Break

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13:30 - 14:00	Product experience from Category 1 studies on Hysingla, Targiniq and Oxycontin OP *Richard Mannion, Purdue Pharma*
14:00 - 14:30	Bridging the gap between in vitro and clinical studies: Strategic design considerations for in vitro studies to support clinical study design (Category 1 and 2) *Beatrice Setnik, INC*
14:30 - 14:45	PM Break
14:45 - 15:15	How to perform "level of effort" studies and use outcome to guide Interpretation of HAL study *Ed Cone, Pinney Associates/Jeffrey Dayno, Egalet*
15:15 - 15:45	Practical solutions: Hammer apparatus and syringability versus viscosity *Sebastian Schwier, Grünenthal/Torben Elhauge, Egalet*
15:45 - 17:00	Panel Discussion: How can Category 1 and "level of effort" studies be more standardized and inform interpretation of HAL studies? Julia Pinto*, FDA; Silvia Calderon, FDA; Richard Mannion, Purdue Pharma; Beatrice Setnik, INC; Ed Cone, Pinney Associates; Jeff Dayno, Egalet; Marta Sokolowska, Grünenthal*
17:00 - 17:10	Wrap up *Marta Sokolowska, Grünenthal; Karsten Lindhardt, Egalet*