

Wednesday - Thursday – April 18-19, 2018
USP Meeting Center: 12601 Twinbrook Parkway, Rockville, MD 20852
PQRI PODP Extractables and Leachables Workshop

| Day 1 – Wednesday, April 18, 2018 | |
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| 8:00 - 8:15 AM | Registration and Continental Breakfast |
| Session A Moderator: Kumudini Nicholas (Health Canada) [invited] | |
| 8:15 - 8:30 AM | Welcome and Opening <i>Desmond Hunt (USP)</i> |
| 8:30 - 9:00 AM | I. Introduction to PODP Recommendation: Risk Based Concepts <i>Diane Paskiet (West)</i> |
| 9:00 – 9:30 AM | II. Derivation of Parenteral Safety Concern Thresholds (SCT) <i>Douglas Ball (Pfizer)</i> |
| 9:30 – 10:00 AM | III. Derivation and Validation of Parenteral Classification Strategy <i>Alisa Vespa (Health Canada) [invited]</i> |
| 10:00 – 10:30 AM | Q&A Panel |
| 10:30 – 11:00 AM | Break |
| Session B Moderator: Michael Ruberto (Material Needs Consulting) | |
| 11:00 – 11:30 AM | IV. Best Practices Generating Extractable Profiles <i>Dennis Jenke (Triad Scientific Solutions)</i> |
| 11:30 AM – 12:00 PM | V. Analytical Technologies and Compound Identification <i>Daniel Norwood (SCIO Analytical, LLC)</i> |
| 12:00 – 12:30 PM | Q&A Panel |
| 12:30 – 1:30 PM | Lunch |
| Session C Moderator: Alan Hendricker (Becton Dickinson) | |
| 1:30 – 2:00 PM | VI. Component Characterization: Sources of Potential Leachables <i>Daniel Norwood (SCIO Analytical, LLC)</i> |
| 2:00 – 2:30 PM | VII. The Analytical Evaluation Threshold: Derivation and Use <i>Thomas Egert (Boehringer Ingelheim)</i> |
| 2:30 – 3:00 PM | Q&A Panel |
| 3:00 – 3:15 PM | Break |

| Session D Moderator: Edward Smith (<i>Packaging Science Resources</i>) | |
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| 3:15 – 3:45 PM | VIII. Purpose of Simulation Studies: a Case Example <i>Dennis Jenke (Triad Scientific Solutions)</i> |
| 3:45 – 4:30 PM | IX. Biologic Quality and Compatibility Considerations <i>Ingrid Markovic (FDA) [invited]</i> |
| 4:30 – 5:00 PM | Q&A Panel |
| 5:00 PM | Close of Day 1 |
| 5:30 – 7:30 PM | Networking Reception Hilton Rockville – Potomac Foyer 1750 Rockville Pike Rockville MD 20852 |

| Day 2 – Thursday, April 19, 2018 | |
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| 8:00 - 8:15 AM | Continental Breakfast |
| Session E Moderator: James Castner (<i>Pharma Interface Analysis</i>) | |
| 8:15 - 9:15 AM | I. Experimental Design Considerations for Ophthalmic Drug Products (ODP) <ul style="list-style-type: none"> a. Chemistry <i>Christopher Houston (iuvo BioScience)</i> b. Toxicology <i>Mary Richardson (iuvo BioScience)</i> |
| 9:15 – 10:15 AM | II. Application and Expectations: Regulatory Perspectives <ul style="list-style-type: none"> a. US Perspective: <i>Tim Robison (FDA) [to be invited]</i> b. Canada Perspective: <i>Alisa Vespa (Health Canada) [invited]</i> |
| 10:15 – 10:30 AM | Break |
| 10:30 – 11:30 AM | II. Application and Expectations: Regulatory Perspectives (Cont.) <ul style="list-style-type: none"> c. EU Perspective: <i>David Jones (MHRA) [invited]</i> d. Japan Perspective: <i>Akihiko Hirose (NIHS) [invited]</i> |
| 11:30 – 12:00 PM | Q&A Panel |
| 12:00 – 1:00 PM | Lunch |
| Session F Moderator: Steve Beck (<i>Xellia Ltd</i>) | |
| 1:00 – 1:30 PM | III. Threshold Concepts Linked to Extractable Profiles <i>Stephen Barat (SCYNEXIS, Inc.)</i> |
| 1:30 – 2:00 PM | IV. The PODP Database <i>William Beierschmitt (Pfizer)</i> |
| 2:00 – 2:30 PM | Q&A Panel |
| 2:30 – 2:45 PM | Break |

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| <p>2:45 – 3:45 PM</p> | <p>V. Case Study Break outs</p> <ul style="list-style-type: none"> a. Small Volume Parenterals Dan Mellon (FDA) [invited] b. Large Volume Parenterals Thomas Feinberg (<i>SCIO Analytical</i>) c. Prefilled Syringes Timothy McGovern (FDA) [invited] d. Ophthalmic Drug Products Christopher Houston (<i>iuvo BioScience</i>) <p><i>Breakout Sessions – there will be four concurrent rooms utilized to discuss the topics to facilitate small group discussion and problem solving.</i></p> |
| <p>3:45 - 4:00 PM</p> | <p>Break</p> |
| <p>4:00 – 4:40 PM</p> | <p>VI. Report out from Breakouts and Discussion <i>Dan Mellon, Tom Feinberg, Tim McGovern and Chris Houston</i></p> |
| <p>4:40 – 5:00 PM</p> | <p>VII. Plans for USP New Chapter and Wrap Up <i>Desmond Hunt (USP)</i></p> |