



**New Advancements in Product Performance Testing Expert Panel**  
**Friday, October 4, 2019**  
**8:30am-5:00pm**  
**USP – U.S., Rockville**

**Agenda - Draft**

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**Goals and Anticipated Outcomes**

- To discuss emergent technologies in major categories of dosage form performance testing.
- To determine a plan and timeline for incorporating these technologies into a written standard.

**Attendees**

*Attendee list provided on the day of the meeting*

**CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS**

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|-----------|---|------------------|
| 8:30 a.m. | <b>1. Closed Procedural Matters and Standards of Conduct</b>  |                  |
|           | a. Welcome, Opening Remarks, Introduction   | Dr. Skwierzynski |
|           | b. Conflicts of Interest, Confidentiality, Code of Ethics   | Dr. Skwierzynski |
|           | c. Review of Agenda for Specific Conflicts of Interest/Topics Needing Final Discussion/Need for Recusal | All              |

**END CLOSED SESSION**

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|-----------|--|------------------|
| 8:45 a.m. | <b>2. Open Procedural Matters</b>  |                  |
|           | a. Welcome   | Dr. Skwierzynski |
|           | b. Meeting Center Announcements  | Ms. White        |
|           | c. Recording Policy and any other Procedural Announcements                         | Ms. von Berg     |
|           | d. Roll Call and Introduction of Members, Government Liaisons, Staff and Observers | All              |
|           | e. Establish Quorum  | Dr. Skwierzynski |
|           | f. Approval of Agenda  | Dr. Skwierzynski |
|           | g. Approval of Minutes of Previous Meeting   | Dr. Skwierzynski |
|           | h. Action Items from Previous Meeting  | Ms. von Berg     |

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| 9:00 a.m. | <b>3. Dosage Forms in USP - NF</b> | Dr. Marques |
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*Informational*

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| 10:00 a.m. | <b>4. Discussion of Solid Oral Dosage Forms Emergent Trends</b><br><i>Discussion</i> <ul style="list-style-type: none"><li>a. Topic Prioritization of Development of Standard</li><li>b. Case Study: Gastro-retentive Pills</li></ul>  | All |
| 10:30 a.m. | <b>Break</b>   |     |
| 10:45 a.m. | <b>Resume Discussion of Solid Oral Dosage Forms Emergent Trends</b>  |     |
| 11:30 a.m. | <b>5. Discussion of Liquid Oral Dosage Forms Emergent Trends</b><br><i>Discussion</i> <ul style="list-style-type: none"><li>a. Topic Prioritization of Development of Standard</li></ul>   | All |
| 12:00 p.m. | <b>Lunch</b>   |     |
| 1:00 p.m.  | <b>Resume Discussion of Liquid Oral Dosage Forms Emergent Trends</b>   |     |
| 1:30 p.m.  | <b>6. Discussion of Topical/Mucosal Dosage Forms Emergent Trends</b><br><i>Discussion</i> <ul style="list-style-type: none"><li>a. Topic Prioritization of Development of Standard</li><li>b. Case Study: Films</li><li>c. Case Study: Chewing Gums</li></ul>                            | All |
| 2:30 p.m.  | <b>Break</b>   |     |
| 2:45 p.m.  | <b>7. Discussion of Injectable Dosage Forms Emergent Trends</b> <ul style="list-style-type: none"><li>a. Topic Prioritization of Development of Standard</li><li>b. Case Study: Subdermal Implants</li><li>c. Case Study: Micro Needles</li><li>d. Case Study: Ocular Implants</li></ul> |     |
| 3:45 p.m.  | <b>8. Discussion of Inhalation Dosage Forms Emergent Trends</b><br><i>Discussion</i> <ul style="list-style-type: none"><li>a. Topic Prioritization of Development of Standard</li></ul>  | All |



4:45 p.m.      **9. Wrap-up/Action Item Review/Next Steps**

5:00 p.m.      **Adjourn**