# Best Practices for Topical Generic Product Development and ANDA Submission

## Virtual Public Webinar

### August 11, 2022

## Agenda

### 9:30 AM – 9:35 AM

- **Opening Remarks**
  - Nora Lim, PharmD
  - Pharmacist, CDER SBIA Program, FDA

### 9:35 AM – 9:40 AM

- **Introduction to the Webinar**
  - Priyanka Ghosh, PhD
  - Acting Team Lead, DTP-ORS/OGD/FDA

## Session 1: Q3 Characterization of Topical Products

### 9:40 AM – 10:00 AM

- **Scientific and Regulatory Considerations for Q3 Characterization of Topical Products**
  - Sam Raney, PhD
  - Associate Director for Science, ORS/OGD/FDA

### 10:00 AM – 10:30 AM

- **Q&A Panel on Q3 Characterization of Topical Products**

  **Moderator**
  - Priyanka Ghosh, PhD
  - Acting Team Lead, DTP-ORS/OGD/FDA

  **Panelists**
  - Rob Lionberger, PhD
  - Director, ORS/OGD/FDA
  - Markham Luke, MD, PhD
  - Director, DTP-ORS/OGD/FDA
  - Sam Raney, PhD
  - Associate Director for Science, ORS/OGD/FDA
  - Pahala Simamora, PhD
  - Director, DLBP-II/OLDP/OPQ/FDA

## Session 2: IVRT Studies with Topical Products

### 10:30 AM – 10:55 AM

- **Practical Considerations for IVRT Studies with Topical Products Submitted in ANDAs**
  - Tannaz Ramezanli, PharmD, PhD
  - Pharmacologist, DTP-ORS/OGD/FDA

### 10:55 AM – 11:00 AM

- **Break**

### 11:00 AM – 11:30 AM

- **Q&A Panel on IVRT Studies with Topical Products**

  **Moderator**
  - Priyanka Ghosh, PhD
  - Acting Team Lead, DTP-ORS/OGD/FDA

  **Panelists**
  - Xinran Li, PhD
  - Staff Fellow, DB-II/OB/OGD/FDA
  - Anil Nair, PhD
  - Team Leader, DB-II/OB/OGD/FDA
  - Hiren Patel, PhD
  - Staff Fellow, DB-II/OB/OGD/FDA
  - Tannaz Ramezanli, PharmD, PhD
  - Pharmacologist, DTP-ORS/OGD/FDA
  - Sam Raney, PhD
  - Associate Director for Science, ORS/OGD/FDA

## Session 3: IVPT Studies with Topical Products

### 11:30 AM – 11:55 AM

- **Practical Considerations Related to IVPT Studies for Topical Products Submitted in ANDAs**
  - Hiren Patel, PhD
  - Staff Fellow, DB-II/Ob/OGD/FDA

### 11:55 AM – 12:25 PM

- **Q&A Panel on IVPT Studies with Topical Products**

  **Moderator**
  - Priyanka Ghosh, PhD
  - Acting Team Lead, DTP-ORS/OGD/FDA

  **Panelists**
  - Usha Katragadda, PhD
  - Staff Fellow, DB-III/Ob/OGD/FDA
  - Archana Manerikar, MS, PharmD
  - Pharmacologist, DB-I/OB/OGD/FDA
  - Hiren Patel, PhD
  - Staff Fellow, DB-II/Ob/OGD/FDA
  - Sam Raney, PhD
  - Associate Director for Science, ORS/OGD/FDA
  - Elena Rantou, PhD
  - Lead Mathematical Statistician, DB-VIII/Ob*/OTS/FDA

### 12:25 PM – 12:30 PM

- **Closing Comments**
  - Priyanka Ghosh, PhD
  - Acting Team Lead, DTP-ORS/OGD/FDA
## Appendix of Abbreviations

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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ANDAs</td>
<td>Abbreviated New Drug Submissions</td>
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<tr>
<td>DB-I</td>
<td>Division of Bioequivalence I</td>
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<td>DB-III</td>
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<td>Division of Biostatistics VIII</td>
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<td>DLBP-II</td>
<td>Division of Liquid Based Products II</td>
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<td>DTP-I</td>
<td>Division of Therapeutic Performance I</td>
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<td>FDA</td>
<td>United States Food and Drug Administration</td>
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<td>IVRT</td>
<td>In Vitro Release Test</td>
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<td>IVPT</td>
<td>In Vitro Permeation Test</td>
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