# Shaping the Future of Pediatric Formulation Development

**Public Workshop**
June 24-25, 2026

**Agenda**

## Wednesday, June 24
## Day 1

7:45 AM – 8:30 AM ***Registration***

**Opening Session: Why Are We Here?**

8:30 AM – 8:35 AM ***Welcome & Workshop Objectives***
**Trupti Dixit, PhD, MBA** Workshop Program Chair, Independent Consultant, Dixit Consulting

8:35 AM – 9:05 AM ***Pediatric Formulations: What is Needed?***
**John Alexander, PhD** Supervisory Physician, DPMH, ORDPURM, OND, CDER, FDA

9:05 AM – 9:35 AM ***The Evolution of Pediatric Product Development: Progress, Remaining Gaps, and Future Directions***
**Joanna Koziara, PhD** Executive Director, Technical Development Strategy and Operations, Gilead; Co-chair IQ Pediatric Working Group

**Session 1A: Patient-Centricity**
**Session Leads:** Dr. Trupti Dixit, Dr. Mona Khurana
**Scope:** Patient-centric product development in the context of pediatric formulation means using a user-focused approach that understands the physiological, developmental and psychological needs of the pediatric population that spans from neonates to adolescence. This translates into tailoring dosage forms to address factors such as dosing flexibility, taste-masking and swallowing abilities across this age group and ascertain that caregivers can deliver these medications where needed to ensure adherence to dosing regimen to impact health outcomes. This concept also applies to easing the burden of clinical studies and arriving at appropriate dosing regimens with minimal hardships on this vulnerable population. This session will present perspectives on some of these aspects to promote understanding and generate discussion on some of these key topics.

9:35 AM – 9:40 AM ***Speaker Introductions***
**Mona Khurana, MD** Lead Physician, DPMH, ORDPURM, OND, CDER, FDA

9:40 AM – 10:10 AM ***Pediatric Patient and Family Perspective***
**International Children's Advisory Network (ICAN)**

10:10 AM – 10:30 AM ***Compounding 101: A Regulatory Framework***
**Dominic E. Markwordt, JD, MBA** Regulatory Counsel, OCQC, OC, CDER, FDA

10:30 AM – 10:45 AM ***Break***

10:45 AM – 11:05 AM ***Pediatric Compounded Medication Safety: Examining Error-Related and Spontaneous Adverse Events***
**Shannon Glueck, PharmD** Branch Chief, DC II, Branch 6, OCQC, OC, CDER, FDA

11:05 AM – 11:25 AM ***Welcome to the Jungle: Real World Challenges with Pediatric Dosage Forms***
**Rachel Meyers, PharmD** Clinical Professor, Ernest Mario School of Pharmacy, Rutgers University, Cooperman Barnabas Medical Center

11:25 AM – 12:00 PM ***Panel Discussion***
*Moderators:*
**Trupti Dixit, PhD, MBA** Workshop Program Chair, Independent Consultant, Dixit Consulting
**Mona Khurana, MD** Lead Physician, DPMH, ORDPURM, OND, CDER, FDA
*Panelists:*
**Dominic E. Markwordt, JD, MBA** Regulatory Counsel, OCQC, OC, CDER, FDA
**Shannon Glueck, PhD** Branch Chief, CB 6, DC II, OCQC, OC, CDER, FDA
**Rachel Meyers, PharmD** Clinical Professor, Ernest Mario School of Pharmacy, Rutgers University; Pediatric Clinical Pharmacist, Cooperman Barnabas Medical Center

12:00 PM – 1:00 PM ***Lunch***

**Session 2A: Formulation and Analytical Aspects of a Pediatric Dosage Form**

***Mini Tablets***

**Session Leads:** Ms. Elizabeth Galella, Dr. David Tan

**Scope:** This session will focus on key aspects of developing mini tablets as a dosage form for pediatrics. This session will provide a forum to discuss acceptability of mini tablets across pediatric age groups, inconsistencies in nomenclature, manufacturing and packaging challenges and limitations, and strategies for identifying appropriate food vehicles**.**

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| 1:00 PM – 1:05 PM | ***Speaker Introductions*** | |
| | **Elizabeth Galella, MS** | Associate Director, Oral Product Development, Bristol-Myers Squibb |
| 1:05 PM – 1:25 PM | ***Overview of the Mini Tablet Formulation with a Focus on Nomenclature*** | |
| | **Stuart Charlton, PhD** | Director, Oral Product Development, Bristol Myers Squibb, UK |
| 1:25 PM – 1:45 PM | ***Mini Tablet Manufacturing Challenges*** | |
| | **Katie Metzler, MS** | Director, Vertex Pharmaceuticals |
| 1:45 PM – 2:05 PM | ***Navigating Packaging Challenges for Mini Tablets*** | |
| | **Kirsten O'Brien, BS** | Director, Packaging Development, Gilead Sciences |
| 2:05 PM – 2:25 PM | ***Tablets and Drug Product Nomenclature*** | |
| | **LCDR Jibril Abdus-Samad, PharmD** | Nomenclature and Labeling Policy Lead, COSS, OPPQ, OPQ, CDER, FDA |
| 2:25 PM – 2:45 PM | ***Food Selection, Compatibility and Testing Strategies*** | |
| | **Anna Externbrink, PhD** | Associate Principal Scientist, Analytical R&D, Merck |
| 2:45 PM – 3:05 PM | ***Case Studies: Enteral Tube Administration of Mini Tablets*** | |
| | **Yemin Liu, PhD** | Senior Principal Research Scientist, AbbVie Inc. |
| 3:05 PM – 3:25 PM | ***Mini Tablet User Experience*** | |
| | **Smita Salunke, PhD** | Chief Scientific Officer, EuPFI |
| 3:25 PM – 3:40 PM | ***Break*** | |
| 3:40 PM – 4:40 PM | ***Panel Discussion*** | |
| *Moderators:* | **Elizabeth Galella, MS** | Associate Director, Oral Product Development, Bristol-Myers Squibb |
| | **David Tan, PhD** | Senior Director, Vertex Pharmaceuticals Inc. |
| *Panelists:* | **Stuart Charlton, PhD** | Director, Oral Product Development, Bristol Myers Squibb, UK |
| | **Katie Metzler, MS** | Director, Vertex Pharmaceuticals |
| | **Kirsten O'Brien, BS** | Director, Packaging Development, Gilead Sciences |
| | **LCDR Jibril Abdus-Samad, PharmD** | Nomenclature and Labeling Policy Lead, COSS, OPPQ, OPQ, CDER, FDA |
| | **Anna Externbrink, PhD** | Associate Principal Scientist, Analytical R&D, Merck |
| | **Yemin Liu, PhD** | Senior Principal Research Scientist, AbbVie Inc. |
| | **Smita Salunke, PhD** | Chief Scientific Officer, EuPFI |
| 4:40 PM – 5:00 PM | ***Day 1 Summary*** | |
| 5:00 PM – 6:30 PM | ***Networking/Posters*** | |

## Thursday, June 25
## Day 2

7:30 AM – 8:00 AM ***Breakfast***

8:00 AM – 8:15 AM ***Day 2 Introduction***
**Steve Hoag, PhD** Professor, Pharmaceutical Sciences; Director, Applied Pharmaceutics Lab, University of Maryland-Baltimore

**Session 2B: Formulation and Analytical Aspects of a Pediatric Dosage Form**
***Excipients for Pediatric Formulations***
**Session Leads:** Dr. Steve Hoag, Dr. Anjali Agarwal, Dr. Sandip Tiwari, Dr. Smita Salunke
**Scope:** This session features presentations on the assessment of excipients for pediatric formulations, including tools such as the IID and ELSA, delivered by FDA experts. Industry perspectives are provided through talks on challenges and considerations in selecting excipients for pediatric products, including the use of the PERA tool. Additional insights focus on excipient needs for special populations—such as neonates. The program concludes with a breakout session on the PERA tool and a forward-looking panel discussion on future needs, research priorities, and regulatory challenges in pediatric excipient development.

8:15 AM – 8:20 AM ***Speaker Introductions***
**Steve Hoag, PhD** Professor, Pharmaceutical Sciences; Director, Applied Pharmaceutics Lab, University of Maryland-Baltimore

8:20 AM – 8:45 AM ***Excipients in Pediatric Formulations: Evolution, Current Use, and Regulatory Considerations***
**Sandip Tiwari, PhD** Head of Technical Services, Pharma Solutions, BASF

8:45 AM – 9:15 AM ***Safety of Excipients for Pediatric Formulation-Assessment, IID, and "ELSA" tool***
**April Braddy, PhD, RAC, SEP** Division Director, DB III, OB, OGD, CDER, FDA

9:15 AM – 9:45 AM ***Experiences and Perspectives with Excipients When Reviewing Regulatory Submissions***
**Ndidi Nwokorie, MBBS** Medical Officer, DPMH, ORDPURM, OND, CDER, FDA

9:45 AM – 10:00 AM ***Break***

10:00 AM – 11:00 AM ***Break Out Session: Industrial Perspective on Excipients in Pediatric Formulation Development***
**Anjali Agarwal, PhD** Executive Director, CMC & Product Supply, Novo Nordisk
**Smita Salunke, PhD** Chief Scientific Officer, EuPFI

11:00 AM – 11:45 AM ***Panel Discussion***
*Moderators:* **Steve Hoag, PhD** Professor, Pharmaceutical Sciences; Director, Applied Pharmaceutics Lab, University of Maryland-Baltimore
*Panelists:* **Sandip Tiwari, PhD** Head of Technical Services, Pharma Solutions, BASF
**April Braddy, PhD, RAC, SEP** Division Director, DB III, OB, OGD, CDER, FDA
**Ndidi Nwokorie, MBBS** Medical Officer, DPMH, ORDPURM, OND, CDER, FDA
**Anjali Agarwal, PhD** Executive Director, CMC & Product Supply, Novo Nordisk
**Smita Salunke, PhD** Chief Scientific Officer, EuPFI

11:45 AM – 12:45 PM ***Lunch***

**Session 1B: Patient-Centricity**
**Session Leads:** Dr. Trupti Dixit, Dr. Mona Khurana
**Scope:** Patient-centric product development in the context of pediatric formulation means using a user-focused approach that understands the physiological, developmental and psychological needs of the pediatric population that spans from neonates to adolescence. This translates into tailoring dosage forms to address factors such as dosing flexibility, taste-masking and swallowing abilities across this age group and also ascertain that caregivers can deliver these medications where needed to ensure adherence to dosing regimen to impact health outcomes. This concept also applies to easing the burden of clinical studies and arriving at appropriate dosing regimens with minimal hardships on this vulnerable population. This session will present perspectives on some of these aspects to promote understanding and generate discussion on some of these key topics.

12:45 PM – 12:50 PM ***Speaker Introductions***
**Trupti Dixit, PhD, MBA** Independent Consultant, Dixit Consulting

12:50 PM – 1:20 PM ***Caregiver Perspective: Acceptability of Pediatric Oral Dissolving Film in a Clinical Study***
**Adrie Bekker, PhD** Neonatologist, Tygerberg Children's Hospital; Prof. of Pediatrics, Stellenbosch University, Cape Town, South Africa

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| | **Lario Viljoen, PhD** | Sociobehavioural Lead**,** Desmond Tutu TB Centre, Department of Paediatrics and Child Health, Stellenbosch University, Cape Town, South Africa |
| 1:20 PM – 1:40 PM | ***Formulation Challenges for Neonatal Dosage Form Development*** | |
| | **Karen Thompson, PhD** | Senior Principal Scientist, Preclinical Development, Merck |
| 1:40 PM – 2:00 PM | ***Challenges in Dose and Dose Delivery Devices for Pediatric Formulations*** | |
| | **Tianyi (Tim) Zhang, PhD** | Human Factors Reviewer, DMEPA I, OMEPRM, OSE, CDER, FDA |
| 2:00 PM – 2:30 PM | ***Panel Discussion*** | |
| *Moderators:* | **Trupti Dixit, PhD, MBA** | Workshop Program Chair, Independent Consultant, Dixit Consulting |
| | **Mona Khurana, MD** | Lead Physician, DPMH, ORDPURM, OND, CDER, FDA |
| *Panelists:* | **Adrie Bekker, PhD** | Neonatologist, Tygerberg Children's Hospital; Prof. of Pediatrics, Stellenbosch University, Cape Town, South Africa |
| | **Lario Viljoen, PhD** | Sociobehavioural Lead, Desmond Tutu TB Centre, Department of Paediatrics and Child Health, Stellenbosch University, Cape Town, South Africa |
| | **Karen Thompson, PhD** | Senior Principal Scientist, Preclinical Development, Merck |
| | **Tianyi (Tim) Zhang, PhD** | Human Factors Reviewer, DMEPA I, OMEPRM, OSE, CDER, FDA |

**<u>Session 3: Imagining the Future of Pediatric Formulation Development</u>**

**Session Lead**: Ms. Erica Long

**Scope:** Since our last pediatric workshop in 2019, we have seen transformational innovations in drug delivery systems, the evolution of complex biologics, as well as new techniques for gene editing and gene therapy. Furthermore, recent advances in pediatric modeling/simulation, and in AI/ML methodologies are having a broad impact on drug discovery and development. In this session, we will briefly discuss these trends and how they will shape the future of developing better drugs and delivery systems for children.

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| 2:30 PM – 2:35 PM | ***Speaker Introductions*** | |
| | **Erica Long, MEng** | Scientist, Pfizer, Inc. |
| 2:35 PM – 2:55 PM | ***Trends in Pediatric Formulations and Delivery Systems*** | |
| | **Daniel Schaufelberger, PhD** | Adjunct Assistant Professor, John Hopkins, School of Medicine |
| 2:55 PM – 3:15 PM | ***Microneedle-Based Biologics: A Next-Generation Platform for Pediatric Delivery*** | |
| | **Sonika Chibh, PhD** | Visiting Scientist, Koch institute for Integrative Cancer Research, MIT |
| 3:15 PM – 3:35 PM | ***Trends in Pediatric Modeling and Simulation-What the Formulator Should Know*** | |
| | **Jon Collins, PhD** | Director, Clinical Pharmacology, ViV Healthcare Inc. |
| 3:35 PM – 3:50 PM | ***Break*** | |

**<u>Collaboration for Kids</u>** ***(across Academia, Health Authorities, Industry, and Non-profit Organizations)***

**Scope:** This session will look towards establishing potential collaboration opportunities through shared understanding of the work done by various organizations such as industry, academia, philanthropic organizations or governments. The distinguished panel members from each of these organizations will share their perspectives through panel discussion. Workshop participants are encouraged to share their questions even ahead of time to enable productive, focused discussion on key topics as they relate to pediatric formulation development.

**Discussion points:** innovation, acceleration, coordination, international harmonization, incentives

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| 3:50 PM – 3:55 PM | ***Panelist Introductions*** | |
| | **Trupti Dixit, PhD, MBA** | Workshop Program Chair, Independent Consultant, Dixit Consulting |
| 3:55 PM – 4:30 PM | ***Panel Discussion*** | |
| *Moderator:* | **Trupti Dixit, PhD, MBA** | Workshop Program Chair, Independent Consultant, Dixit Consulting |
| | **Daniel Schaufelberger, PhD** | Adjunct Assistant Professor, John Hopkins, School of Medicine |
| *Panelists:* | **John Alexander, PhD** | Supervisory Physician, DPMH, ORDPURM, OND, CDER, FDA |
| | **James Cummins, Jr, PhD** | Chief, Preclinical Microbicide and Prevention Research Branch, Prevention Sciences Program, DAIDS, NIAID, NIH |
| | **Steve Hoag, PhD** | Professor, Pharmaceutical Sciences; Director, Applied Pharmaceutics Lab, University of Maryland-Baltimore |
| | **Joanna Koziara, PhD** | Executive Director, Technical Development Strategy and Operations, Gilead; Co-chair IQ Pediatric Working Group |
| | **Sandip Tiwari, PhD** | Head of Technical Services, Pharma Solutions, BASF |
| 4:30 PM – 5:00 PM | ***Closing Remarks & Next Steps, Action Items*** | |
| | **Trupti Dixit, PhD** | Workshop Program Chair, Independent Consultant, Dixit Consulting |

**Daniel Schaufelberger, PhD** Adjunct Assistant Professor, John Hopkins, School of Medicine
**Steve Hoag, PhD** Professor, Pharmaceutical Sciences; Director, Applied Pharmaceutics Lab, University of Maryland-Baltimore