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***
Patient and Family Representatives International Children's Advisory Network (ICAN)

10:10 AM – 10:30 AM ***Compounding 101: Regulatory Framework for Human Drug Compounding***
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:
Patient and Family Representatives International Children's Advisory Network (ICAN)
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
Alyssa Hager, PharmD, BCPPS Department of Pharmacy Informatics, Children's National Hospital

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.

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	***Minitablets and Drug Product Nomenclature***	
	Stuart Charlton, PhD	Director, Oral Product Development, Bristol Myers Squibb, UK
1:25 PM – 1:45 PM	***Dosage Form Nomenclature***	
	LCDR Jibril Abdus-Samad, PharmD	Nomenclature and Labeling Policy Lead, COSS, OPPQ, OPQ, CDER, FDA
1:45 PM – 2:05 PM	***Minitablet (Granule) Development and Manufacturing Considerations***	
	Katie Metzler, MS	Director, Vertex Pharmaceuticals
2:05 PM – 2:25 PM	***Precision Packaging for Pediatric Drug Products***	
	Kirsten O'Brien, BS	Director, Packaging Development, Gilead Sciences
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	***Oral Drug Product Administration via Enteral Feeding Tubes: In Vitro Testing***	
	Yemin Liu, PhD	Senior Principal Research Scientist, AbbVie Inc.
3:05 PM – 3:25 PM	***Will Children Actually Take It? User Perspectives on Acceptability of Minitablet vs Conventional Small Tablet***	
	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 ***Registration***

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 in 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

	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 Development for Neonate Patients-Rising to the Challenge***	
	Karen Thompson, PhD	Senior Principal Scientist, Preclinical Development, Merck
1:40 PM – 2:00 PM	***Considerations for Dose Delivery Devices Intended for Pediatric Population***	
	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

Session 3: Imagining the Future of Pediatric Formulation Development

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.

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 Formulators Should Know)***	
	Jon Collins, PhD	Director, Clinical Pharmacology, ViV Healthcare Inc.
3:35 PM – 3:50 PM	***Break***	

Collaboration for Kids ***(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

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