



**SOT FDA Colloquia on Emerging Toxicological Science:
Challenges in Food and Ingredient Safety**

**May 4, 2023—The Evolving Science in
Developmental Immunology and Immunotoxicity**

Live Webcast

The Evolving Science in Developmental Immunology and Immunotoxicity May 4, 2023

**Co-chairs: Leigh Ann Burns Naas, Magnolia Toxicology Consulting LLC, and
Patrick Crittenden, US FDA CFSAN**

Session Overview

Over the past two decades the interest in developmental immunotoxicology (DIT) has grown substantially as a result of the need to more fully understand age-related susceptibility to a variety of potentially toxic compounds. The immature immune system is especially vulnerable to environmental insults, and immunotoxic exposures during critical prenatal and postnatal periods in development may lead to persistent immune dysfunction. Epidemiological evidence suggests that there is an increasing incidence of immune-mediated developmental disorders in children related to exposures to chemical substances in their environment. In recent years, the role of the microbiome in immune system development has also become evident and this extends to the role of the mother in seeding the fetal/infant microbiome both in utero and at birth, which may impact several aspects of development, including immune system maturation. Therefore, alterations in both maternal and fetal environmental exposures mediated by things such as nutrition and chemical exposure have the potential to result in varied risks to the developing immune system that can influence the risk of immune-related disease in children and adults. Understanding how to assess the risk to the developing immune system in animal studies is of high importance. As interest in DIT has grown, our understanding of the mammalian immune system has continued to swell, including a more sophisticated understanding of the developing immune system and the comparative developmental timelines across mammalian species. While the general stages of immune development are quite similar, it clear is that in terms of temporal development, a rat is not a dog is not a monkey is not a human. This makes it paramount to understand these differences when conducting and interpreting nonclinical safety studies. This colloquium will present the state of the science of developmental immunotoxicology and the challenges to supporting hazard identification and risk evaluation.

Schedule (All times Eastern US, UTC -4)

9:00 am–9:10 am

Welcome from US FDA/SOT: Dori Germolec, PhD, 2023-2024 SOT President, NIEHS-NTP, Durham, NC

9:10 am-10:00 am

Introduction of Speakers

The Evolution of the Discipline of Developmental Immunotoxicology

Leigh Ann Burns Naas, PhD, DABT, ATS, ERT, Magnolia Toxicology Consulting, LLC, Traverse City, MI

10:00 am-10:35 am

Comparative Developmental Immunology and Implications for Testing and Data Interpretation

Hollie Skaggs, PhD, Horizon Therapeutics, Wilmington, DE

10:35-10:45 am Break

10:45 am-11:20 am

The Role of the Metagenome and Microbiome During Pregnancy and Lactation on the Risk of Immune-Related Disease

Kjersti M. Aagaard, MD, PhD, FACOG, Baylor College of Medicine, Houston, TX

11:20 am-11:55 am

Prenatal Immunity Represents a Functionally Distinct Hematopoietic Lineage

Eliver Ghosn, PhD, Emory University School of Medicine, Atlanta, GA

11:55 am-12:20 pm

Paving the Road toward the Development and Acceptance of Alternative (*In Vitro*) Methods to Assess Developmental Immunotoxicity

Fenna Sille, PhD, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

12:20 pm-12:55 pm

Roundtable Discussion

Moderator: Patrick Crittenden, US FDA CFSAN

All speakers