American Society of Gene + Cell Therapy

25TH ANNUAL MEETING
MAY 16–19·2022
ASGCT WASHINGTON DC

PRE-MEETING WORKSHOP

DRIVING STANDARDS TO ACCELERATE DEVELOPMENT: CONVERGENCE OF FDA PERSPECTIVES AND INDUSTRY NEEDS

MAY 15, 2022

Funding Opportunities from the Burroughs Wellcome Fund

Career Awards at the Scientific Interface

www.bwfund.org/casi

- **Amount:** $500,000 over 5 years
- **Eligibility:** Postdocs with bridging funds for faculty appointment
- **Purpose:** To support academics in physical/mathmatical/ computation/engineering sciences working on biological questions
- **Timeline:** Applications portal opens July 2022, Deadline Sept. 2022

Innovation in Regulatory Science Awards

www.bwfund.org/irsa

- **Amount:** $500,000 over 5 years
- **Eligibility:** Faculty
- **Purpose:** To fund innovative approaches in Regulatory Science
- **Timeline:** Applications portal opens Oct. 2022, Deadline Feb. 2023

BWF strongly encourages applications from persons historically underrepresented in science.

To learn more about our grant programs visit bwfund.org.

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The Burroughs Wellcome Fund serves and strengthens society by nurturing a diverse group of leaders in biomedical sciences to improve human health through education and powering discovery in frontiers of greatest need.

DRIVING STANDARDS TO ACCELERATE DEVELOPMENT: CONVERGENCE OF FDA PERSPECTIVES AND INDUSTRY NEEDS

SUNDAY, MAY 15, 2022

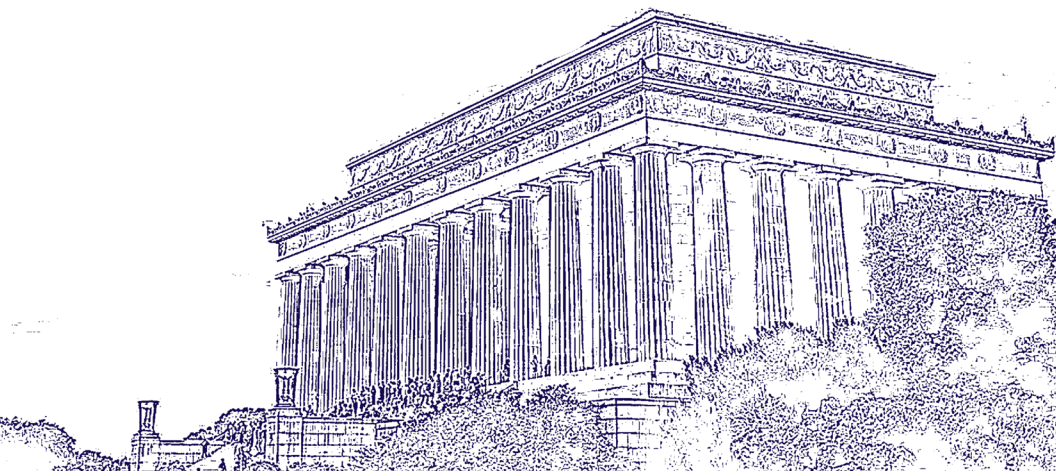
All times listed below ET

Planned in Collaboration with FDA and NIST

Co-chairs: Judith Arcidiacono, FDA
Samantha Maragh, PhD, NIST
Timothy MacLachlan, PhD, Novartis

Description

The workshop will discuss the role of documentary standards and reference materials in the context of product development and meeting FDA regulatory expectations. Speakers will address national and international standards development efforts including consortia models for filling scientific gaps that can foster standardization and the development of reference materials. Developers will share their perspective on needed manufacturing standards.



DRIVING STANDARDS TO ACCELERATE DEVELOPMENT: CONVERGENCE OF FDA PERSPECTIVES AND INDUSTRY NEEDS

Schedule

All times listed below ET

1:00–1:40 PM

Session 1 Standards and the Regulatory Perspective

Overview of Standards and SDOs/Standards Development Entities
Judith Arcidiacono, FDA

Regulatory Perspective on the Use of Standards
Bao-Ngoc Nguyen, PhD, FDA

1:40–2:15 PM

Session 2 Standards Development Use Cases

PDA National Standards Body: Cryopreservation
Darius Pillsbury, ValSource

ISO International: Cell Characterization
Sumona Sarkar, PhD, NIST

2:15–2:30 PM

Break

DRIVING STANDARDS TO ACCELERATE DEVELOPMENT: CONVERGENCE OF FDA PERSPECTIVES AND INDUSTRY NEEDS

2:30–3:50 PM

Session 3 Consortia Models and Collaborative Efforts for Developing Standards

Public-private Partnerships to Advance Measurement Science Underpinning Standards Development
Sheng Lin-Gibson, PhD, NIST

NIST Genome Editing Consortium Update
Samantha Maragh, PhD, NIST

Flow Cytometry Consortium Update
Heba Degheidy, MD, PhD, FDA

Viral Vectors Inter-lab/Collaboration/VCN Cell Lines
Edward Kwee, PhD, NIST

3:50–4:10 PM

Session 4 Standards Coordinating Body Coordination

Facilitating the Creation and Implementation of Current Consensus Standards in Cell and Gene Therapy
Catherine Zander, PhD, Standards Coordinating Body

4:10–4:55 PM

Panel Discussion: Developers' Perspective
Frederic Bushman, PhD, University of Pennsylvania
Aparna Subramanian, PhD, Kite Pharma
J. Fraser Wright, PhD, Stanford University

Moderated by: Timothy MacLachlan, PhD, Novartis,
Anna Kwilas, MD, FDA

4:55–5:00 PM

Closing Remarks
Judith Arcidiacono, FDA

THANK YOU

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