

*The National Academies of*  
**SCIENCES • ENGINEERING • MEDICINE**

*Forum on Regenerative Medicine*

**Applying Systems Thinking to Regenerative Medicine  
A Workshop**

**October 22-23, 2020**

Virtual Workshop

**TIMELINE:**

October 22: 11:00 AM – 4:00 PM ET

October 23: 10:00 AM – 2:00 PM ET

**WEBCAST:**

<https://www.nationalacademies.org/event/10-22-2020/applying-systems-thinking-to-regenerative-medicine-a-workshop>

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**STATEMENT OF TASK:** The current approach to characterizing the quality of a regenerative medicine product and the manufacturing process often involves measuring as many endpoints as possible, but this approach has proved to be inadequate and unsustainable. To explore how cross-disciplinary systems thinking approaches can support the identification of relevant quality attributes and streamline manufacturing and regulatory processes of regenerative medicine products, a planning committee of the National Academies of Sciences, Engineering, and Medicine will hold a one-day public workshop. Speakers at the workshop may be asked to discuss new advances in data acquisition, data analysis and theoretical frameworks, and how systems approaches can be applied to the development of regenerative medicine products that can address the unmet needs of patients. Discussions may explore how systems thinking is currently being applied in clinical and manufacturing settings. The planning committee will develop the workshop agenda, select and invite speakers and discussants, and may moderate the discussions. A proceedings of the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

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**DAY 1: October 22, 2020**

**11:00 a.m. ET Welcome from the Forum Co-Chairs**

TIM COETZEE, *Forum Co-Chair*

Chief Advocacy, Services, and Research Officer  
National Multiple Sclerosis Society

KATHY TSOKAS, *Forum Co-Chair*

Regulatory Head of Regenerative Medicine & Advanced Therapy  
Johnson & Johnson

11:10 a.m.     **Introduction and Charge to the Workshop Speakers and Participants**  
ANNE PLANT, *Workshop Planning Committee Co-Chair*  
Fellow  
National Institute of Standards and Technology (NIST)

KRISHNENDU ROY, *Workshop Planning Committee Co-Chair*  
Robert A. Milton Chair Professor  
Director, NSF Engineering Research Center (ERC) for Cell Manufacturing Technologies (CMaT)  
Director, Marcus Center for Therapeutic Cell Characterization and Manufacturing (MC3M)  
The Wallace H. Coulter Department of Biomedical Engineering at Georgia Tech and Emory

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## **SESSION I. INTRODUCTION TO SYSTEMS THINKING CONCEPTS**

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*Moderator: Claudia Zylberberg, Akron Biotech*

Session Objectives:

- Provide important background and an introduction to systems thinking approaches and related terminology.
- Explore specific examples of how systems thinking has been applied to areas of health and medicine, including potential opportunities in the regenerative medicine space.

11:20 a.m.     **An Introduction to Systems Thinking**

William Bialek  
John Archibald Wheeler/Battelle Professor in Physics, and  
Lewis-Sigler Institute for Integrative Genomics  
Princeton University

11:35 a.m.     **Applying Systems Thinking to the Development of Regenerative Medicines**

Peter Zandstra  
Director, Michael Smith Laboratories  
Director and Professor, School of Biomedical Engineering  
University of British Columbia

11:50 a.m.     **Computational Approaches for Systems-Level Data Collection**

Sui Huang  
Professor  
Institute for Systems Biology

12:05 p.m.     **Q&A with the Speakers and Participants**

12:30 p.m.     **Break**

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## SESSION II. THE CHALLENGE OF CRITICAL QUALITY ATTRIBUTES: THE ROLE OF SYSTEMS THINKING

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*Moderator: Anne Plant, National Institute of Standards and Technology (NIST)*

Session Objective:

- Understand the challenges associated with identifying critical quality attributes in the discovery, regulation, and manufacturing of regenerative medicine products and how systems thinking approaches may be applied.

1:00 p.m.      **Fireside Chat: Systems Thinking and the Regulation of Regenerative Medicine Products**

Amy Abernethy  
Principal Deputy Commissioner of Food and Drugs  
U.S. Food and Drug Administration (FDA)

1:15 p.m.      **Q&A with the Audience**

1:30 p.m.      **Costs Associated with *Not Implementing* Systems Thinking Approaches – A Panel Discussion**

***Moderator:***  
Jane Lebkowski  
President  
Regenerative Patch Technologies

***Panelists:***  
Adrian Bot  
Vice President and Global Head, Translational Medicine  
Kite Pharma, Inc.

Bala Manian  
CEO  
Mojave Bio, Inc.

Douglas Olson  
President and CEO of BUHLMANN Diagnostics Corp.  
Scientific Advisory Board Member, Cell Manufacturing Technologies

Sally Temple  
Scientific Director, Principal Investigator, and Co-Founder  
Neural Stem Cell Institute

2:15 p.m.      **Break**

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## SESSION III. CHALLENGES ASSOCIATED WITH DATA COLLECTION, AGGREGATION, AND SHARING

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*Moderator: Sadik Kassim, Vor Biopharma*

Session Objective:

- Discuss how big data can be leveraged to identify which patients will respond best to a particular regenerative medicine.
- Highlight challenges in data collection and data sharing such as small sample size in clinical trials, proprietary issues, and patient privacy.

2:45 p.m.      **Data Challenges with Omics Analysis and Disease Modeling**

Larsson Omberg  
Vice President, Systems Biology  
Sage Bionetworks

3:00 p.m.      **Using Big Data for Clinical Stratification of Patients**

Atul Butte  
Priscilla Chan and Mark Zuckerberg Distinguished Professor  
Director, Bakar Computational Health Sciences Institute  
UCSF

3:15 p.m.      **Moderated Panel Discussion**

3:45 p.m.      **Reflections on Day 1 and Preview of Day 2**

ANNE PLANT, *Workshop Planning Committee Co-Chair*  
Fellow  
National Institute of Standards and Technology (NIST)

KRISHNENDU ROY, *Workshop Planning Committee Co-Chair*  
Robert A. Milton Chair Professor  
Director, NSF Engineering Research Center (ERC) for Cell Manufacturing Technologies (CMaT)  
Director, Marcus Center for Therapeutic Cell Characterization and Manufacturing (MC3M)  
The Wallace H. Coulter Department of Biomedical Engineering at Georgia Tech and Emory

4:00 p.m.      **Adjourn Workshop Day 1**

## DAY 2: October 23, 2020

### 10:00 a.m. ET **Welcome and Overview of Day 2**

ANNE PLANT, *Workshop Planning Committee Co-Chair*

Fellow

National Institute of Standards and Technology (NIST)

KRISHNENDU ROY, *Workshop Planning Committee Co-Chair*

Robert A. Milton Chair Professor

Director, NSF Engineering Research Center (ERC) for Cell Manufacturing Technologies (CMaT)

Director, Marcus Center for Therapeutic Cell Characterization and Manufacturing (MC3M)

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## SESSION IV. CHALLENGES AND OPPORTUNITIES ASSOCIATED WITH SYSTEMS LEVEL ANALYSIS AND MODELING

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*Moderator: Malcolm Moos, FDA*

### Session Objectives:

- Discuss the current state-of-the-art of systems thinking approaches and how these approaches are being used to inform identification of important variables to measure.
- Illuminate current gaps in knowledge and areas for further study.

### 10:10 a.m. **Developing Algorithms for Single Cell Genomics**

Elana Fertig

Associate Professor, Oncology

Johns Hopkins University

### 10:25 a.m. **Adopting Metabolic Modeling Tools in the Biopharmaceutical Industry**

Anne Richelle

Senior Specialist, Metabolic Modeling

GSK

### 10:40 a.m. **Modeling Dynamic Data to Identify a Reduced Variable Space**

Paul Francois

Associate Professor, Department of Physics

McGill University

### 10:55 a.m. **Moderated Panel Discussion**

### 11:15 a.m. **Break**

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## SESSION V. ADDRESSING REGENERATIVE MEDICINE MANUFACTURING AND SUPPLY CHAIN CHALLENGES WITH SYSTEMS-LEVEL APPROACHES

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*Moderator: Krishnendu Roy, Georgia Institute of Technology*

Session Objectives:

- Highlight opportunities where systems thinking approaches could address inefficiencies with manufacturing and the supply chain related to regenerative medicine.

11:45 a.m.     **Overview of AI in Cell and Gene Therapies**

Iya Khalil  
Global Head of the AI  
Innovation Center  
Novartis

Seshu Tyagarajan  
Global Head, Late Stage CMC Strategy, NTO-  
CGT  
Novartis

12:00 p.m.     **Modeling the Manufacturing Process in Regenerative Medicine**

Theresa Kotanchek  
CEO  
Evolved Analytics, LLC

12:15 p.m.     **Supply Chain and Cost Modeling**

Ben Wang  
Gwaltney Chair in Manufacturing Systems  
Professor and Executive Director  
Georgia Tech Manufacturing Institute

12:30 p.m.     **Moderated Panel Discussion**

1:00 p.m.     **Break**

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## SESSION VI. EXPLORING ISSUES OF WORKFORCE DEVELOPMENT RELATED TO SYSTEMS THINKING

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1:20 p.m.     ***Challenges and Opportunities for Training and Workforce Development in Data Science, Artificial Intelligence, and Computational Biology: A Panel Discussion***

***Moderator:***  
Tom Bollenbach  
Chief Technology Officer  
Advanced Regenerative Manufacturing Institute (ARMI)

***Panelists:***

John Balchunas  
Workforce Director  
The National Institute for Innovation in Manufacturing Biopharmaceuticals  
(NIIMBL)

Alison Gammie  
Director Training, Workforce Development and Diversity  
National Institute of General Medical Sciences  
National Institutes of Health

Dawn Tilbury  
Assistant Director, Engineering  
National Science Foundation

Robert Zambon  
Senior Director, Data Strategy & External Innovation  
Johnson & Johnson

1:50 p.m.      **Reflections from the Workshop and Final Comments**

ANNE PLANT, *Workshop Planning Committee Co-Chair*  
Fellow  
National Institute of Standards and Technology (NIST)

KRISHNENDU ROY, *Workshop Planning Committee Co-Chair*  
Robert A. Milton Chair Professor  
Director, NSF Engineering Research Center (ERC) for Cell Manufacturing Technologies  
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2:00 p.m.      **Adjourn Workshop Day 2**