University of Rochester
Eighth Annual

"*America's Got Regulatory Science Talent*" Student Competition

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Clinical and Translational Science Institute

FDA Presentation
May 27, 2021

MEDICINE *of the* HIGHEST ORDER

UNIVERSITY of ROCHESTER MEDICAL CENTER | CTSI CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

"*America's Got Regulatory Science Talent*" Student Competition

	Team Name	Members	FDA Regulatory Science Priority Area
1	CMTI Cardio 1	Mitchell Hoestermann, Katherine Gregory, Andrew Hirsh	5 – Harness Diverse Data through Information Sciences To Improve Health Outcomes
2	Team Organoid	Yunpeng Pang	1 – Modernize Toxicology to Enhance Product Safety 2 – Stimulate Innovation in Clinical Evaluations & Personalized Medicine to Improve Product Development and Patient Outcomes 4 – Ensure FDA Readiness to Evaluate Innovative Emerging Technologies
3	Crash Course Medication	Emma Vogan, Christian Oveson, Samantha Ring	8 – Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions About Regulated Products
4	Selfonan	Shruti Aryal	4 – Ensure FDA Readiness to Evaluate Innovative Emerging Technologies
5	The Interoperators	Srihari Chari, Talia Cohavi, Alicia Bell, John Adib	4 – Ensure FDA Readiness to Evaluate Innovative Emerging Technologies 5 – Harness Diverse Data through Information Sciences To Improve Health Outcomes
6	SupMed	Phuc Do	5 – Harness Diverse Data through Information Sciences To Improve Health Outcomes
7	3D BioPrinting	Charles Patterson, Emily Palacio, Jared Ocasio, Nina Stash	4 – Ensure FDA Readiness to Evaluate Innovative Emerging Technologies
8	510(k) Improvement	Anil Adharapurapu	5 – Harness Diverse Data through Information Sciences To Improve Health Outcomes
9	End User Direct Reporting	Jake Gilman, Arjun Ashok, Regina Yu	7 – Facilitate Development of Medical Countermeasures to Protect Against Threats to US and Global Heath and Security
10	My Health	Aliza Panjwani	8 – Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions About Regulated Products
11	Blood Contacting Device Testing without the Bloodhound	Julia Schroth, Matt Izard	1 – Modernize Toxicology to Enhance Product Safety
12	Preparing for POC: A Proposed Infrastructure for 3D Printing in Hospitals	Alex McMullen, Aaron Craig, Megan Luzenski	4 – Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

2021
Advancing Regulatory Science at FDA:
FOCUS AREAS OF REGULATORY SCIENCE (FARS)

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Strategic Initiative	Focus Area of Regulatory Science	Regulated Product Lifecycle			
		Product Characterization, Manufacturing, and Quality	Non-Clinical Pre-market Evaluation	Clinical Pre-market Evaluation	Post-market Activities
Public Health Preparedness and Response	Medical Countermeasures and Preparedness for Emerging Infectious Diseases	✓	✓	✓	✓
	Technologies to Reduce Pathogen Contamination	✓	✓	✓	✓
	Substance Use Disorders	✓	✓	✓	✓
	Antimicrobial Resistance	✓	✓	✓	✓
	Food Safety	✓	✓		✓
	Quality of Compounded Drugs				✓
Increasing Choice and Competition through Innovation	Individualized Therapies and Precision Medicine	✓	✓	✓	✓
	Complex Innovative Trial Design			✓	
	Microbiome Research	✓	✓	✓	✓
	Novel Foods and Food Ingredients	✓	✓	✓	✓
	Regenerative Medicine	✓	✓	✓	✓
	Advanced Manufacturing	✓			✓
	Increasing Access to Generic Alternatives for Complex Drugs	✓	✓	✓	✓
	Biomarkers	✓	✓	✓	
	Novel Technologies to Improve Predictivity of Non-Clinical Studies and Replace, Reduce, and Refine Reliance on Animal Testing	✓	✓		
	Model-Informed Product Development	✓	✓	✓	
Unleashing the Power of Data	Product Safety Surveillance				✓
	Artificial Intelligence	✓	✓	✓	✓
	Digital Health	✓	✓	✓	✓
	Use of Real-World Evidence to Support Medical Product Development and Regulatory Decision-Making			✓	✓
Empowering Patients and Consumers	Patient and Consumer Preferences and Perspectives	✓	✓	✓	✓
	Patient-Reported Outcomes and other Clinical Outcome Assessments			✓	✓
	Empowering Patients and Consumers to Make Better-Informed Decisions				✓

Thanks to our judges:

Khaled Bouri, PhD
Senior Science Advisor to the Director
Office of Critical Path Programs at FDA

Milton Marshall, PhD, DABT
Director of Regulatory Affairs, Protospheric Products, Inc.
President, Marshall and Associates

Mary Clare McCorry, PhD
Advanced Regenerative Manufacturing Institute (ARMI) BioFabUSA

https://www.urmc.rochester.edu/clinical-translational-science-institute/education/regulatory-science-training-programs.aspx

Education

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Training Resources

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America's Got Regulatory Science Talent

Faculty Career Workshops

Clinical & Translational Science Institute / Education / Regulatory Science Training Programs

Make a Gift

Regulatory Science Training Programs

The National Institutes of Health (NIH) and Food and Drug Administration (FDA) have launched a number of Regulatory Science and Translational Science programs to enhance the translation of research into products that benefit patients, while also improving the success rate of developing safe and effective medical products. The FDA defines Regulatory Science as "the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products." More information on Regulatory Science.

The UR CTSI has launched a range of programs focused on advancing training, career development and research in Regulatory Science

Advanced Certificate in Regulatory Science

The UR CTSI, in partnership with the Department of Public Health Sciences, has created an advanced certificate in regulatory science designed to produce a cadre of highly trained professionals able to contribute to the development of new medical interventions by enhancing the innovation, efficiency, and quality of the medical product development pipeline. This NYS-approved certificate covers areas of experimental therapeutics, medical product innovation, ethics, biostatistics, FDA regulatory process, intellectual property, and science, technology and health policy.

America's Got Regulatory Science Talent Competition

This annual student competition is an interactive and innovative approach to increase student awareness and interest in Regulatory Science. Each year, winners of local competitions at the UR CTSI and the University of Maryland's Center of Excellence in

Regulatory Science Portal

- Education and Training
- News and Funding Opportunities
- Institutes and Centers

Contact Us

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2021 Top Teams

First place:

Preparing for POC: A Proposed Infrastructure for 3D Printing in Hospitals

Alex McMullen, Aaron Craig, Megan Luzenski

Second place:

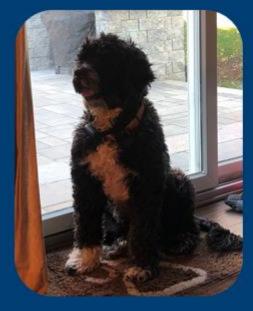**Blood Contacting Device Testing Without the Bloodhound**

Julia Schroth, Matt Izard

Third place (tie):

Team Organoid

 Yunpeng Pang

My Health

Aliza Panjwani