

**University of Rochester 2021 America's Got Regulatory Science Talent Competitions
Presentation Abstracts & Student Biographies**

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| University of Rochester | |
| 1st Place Team | <p>“Preparing for POC: A Proposed Infrastructure for 3D Printing in Hospitals”</p> <p>Point-of-Care (POC) 3D printing of medical devices is now feasible as a result of advances in 3D printing technology. This team outlined a regulatory framework to help ensure these devices are safe and effective, using a combination of databases for reporting, training, and a system for validating the POC 3D printing equipment and the implants.</p> |
| Team Member | Alex McMullen, Aaron Craig, Megan Luzenski |
| Presentation Abstract | <p>In the future, advances in additive manufacturing technology will make it possible to 3D print organs in the hospital. It is already possible for manufacturers to 3D print orthopedic implants, and hospitals are increasingly using on-site 3D printers to create anatomical models for surgical planning and rehearsal. However, there are currently no regulations or standards in place to address the issue of 3D-printed implants at point-of-care (POC) facilities. We propose a solution that focuses on data, validation techniques, and training to ensure the safety and efficacy of the 3D-printed POC implants. Data will be acquired through a database to track implant quality production over time and any nonconformances. Validation techniques will focus on both the implants and the machines used to print them through design validation of the implants and evidence of maintenance and calibration on the 3D printer. Training will be required to certify that operators working on the machines are qualified and manufacturing representatives will be provided to each site.</p> |
| Team Member Bios | |
| Alex McMullen | <p>Alex McMullen is a first-year Biomedical Engineering PhD student at the University of Rochester, with research interests in biomechanics. Alex also has a passion for medical device development and is completing an MS through the University of Rochester's Center for Medical Technology and Innovation (CMTI) program during the first year of his PhD. Prior to attending graduate school, Alex received a BS in Mechanical Engineering from Ohio Northern University in 2016 and proceeded to work in the medical device industry for four years in a variety of Quality and Regulatory positions for Zimmer Biomet and Omnicell.</p> |

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| Aaron Craig | Aaron Craig received a B.S. from the University of Rochester in Biomedical Engineering with a concentration in biomechanics. He is currently working toward an M.S. in Biomedical Engineering through the Center for Medical Technology and Innovation (CMTI) program. Aaron has previous experience in clinical research where he worked in the NYU Langone Adult Reconstruction Division within the Orthopedic Department. He worked on a project focused on patellar complication rates related to different types of patellar buttons used with total knee arthroplasty systems. Aaron is looking forward to pursuing a career as a quality engineer in the medical device industry. |
| Megan Luzenski | Megan Luzenski is completing an MS in Biomedical Engineering through University of Rochester's Center for Medical Technology and Innovation (CMTI) program. Megan received her BS in Mechanical Engineering from Michigan State University and is interested in mechanical design and product development. |

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| 2nd Place Team | <p>“Blood Contacting Device Testing without the Bloodhound”</p> <p>In an effort to more closely model the use of a blood contacting medical devices and reduce animal use in research, this team proposed a new <i>in vitro</i> blood flow assay. The assay would use human blood and would more easily control and monitor a host of blood and vessel characteristics, while providing the same or better safety evaluation than currently accepted <i>in vivo</i> tests methods.</p> |
| Team Members | Julia Schroth and Matt Izard |
| Presentation Abstract | <p>The current method to evaluate blood contacting medical devices for thrombogenicity was first developed in 1976, has had little technical advancements since, and still involves the sacrifice of canine models. This test method has a number of weaknesses including the use and amount of heparin given being the most influential factor on thrombus formation, as opposed to the device being tested, and a low number of test replicates. We propose the validation of an <i>in vitro</i> blood flow assay as an alternative to the <i>in vivo</i> canine thrombogenicity test. This <i>in vitro</i> assay would utilize human blood, pulsatile flow, easy introduction and monitor of heparin, and controlled wall shear stress to better represent human susceptibility to a thrombogenesis reaction from a medical device. The benefits of validating this <i>in vitro</i> assay as an alternative to the current <i>in vivo</i> method include better evaluation of a device’s effect in humans, increased number of test replicates for statistical accuracy, lower cost, and a significant reduction in the use of canines and large animal models.</p> |
| Team Member Bio | |
| Julia Schroth | <p>Julia Schroth will graduate from the University of Rochester’s CMTI Master’s program in May 2021. She previously worked in Quality at Medtronic and performed biocompatibility assessments and adopted a dog this year, which together was the inspiration behind the “Blood Contacting Device Testing without the Bloodhound” regulatory science idea. She is currently looking for a role in medical device development after graduating, with a special interest in orthopedic and spinal devices.</p> |

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| Matthew Izard | Matthew Izard will graduate from the CMTI program at the University of Rochester in December 2021 with a Master's in biomedical engineering. He is also an alumni of the University of Rochester's class of 2020 with a Bachelor's degree in biomedical engineering. Matt is also a dog owner, and this was the rationale for pursuing the change to canine testing models for thrombogenicity testing. He is hoping to explore any area of biomedical engineering through an internship in the summer of 2021 and following graduation in December hopes to work in the field of neuroengineering. One of his long-term goals is to use his experience in neuroengineering to pursue medical devices related to concussion prevention and mitigation. |
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Thank you to the Judges for 2021 University of Rochester America's Got Regulatory Science Talent Student Competition:

- Khaled Bouri, PhD, Science Advisor to the Director, Office of Regulatory Science Innovation, Office of the Chief Scientist, 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