2ND INTERNATIONAL MICROFLUIDICS CONGRESS

May 23-24, 2019 | Las Vegas, USA

CDRH-on-a-chip: Advancing medical device innovation with microfluidics

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The multi-disciplinary field of microfluidics, popularly called lab-on-a-chip, is expanding, with recent technological advancements now enabling the commercialization of microfluidic medical devices, Exciting microfluidics research is being done in diverse areas of early cancer detection via liquid biopsy, target cell separation and enrichment, and point-of-care diagnostics. The objective of this presentation is to discuss three key steps that FDA's Center for Devices and Radiological Health (CDRH) is taking to advance microfluidics-based medical devices: (i) facilitating innovation, (ii) understanding new technologies and applications, and (iii) developing test methodologies for supporting device evaluation. To facilitate innovation, FDA encourages companies to engage with us early in their product lifecycle. By incorporating a regulatory perspective in the design process through early interactions with FDA, before device design is finalized, high-quality medical devices have a greater likelihood to be on the U.S. market faster and more efficiently. Such interactions can also help companies avoid common pitfalls and device complications. For microfluidics to be an effective technology in the biomedical field and for us to better understand technology in the development pipeline, FDA would like to gather real-world data from health-care providers, end-users of devices, manufacturers and academia. By understanding the knowledge gaps and modes of failure in microfluidic devices, we can start to identify commonalities between different device types that may lead to development of standardized test methodologies and technical guidelines. Currently, our research efforts are focused on identifying challenges, assessing quality control and characterizing flow phenomena in cell sorting microfluidic systems. By designing, fabricating and testing microfluidic devices in our laboratory, we are uniquely positioned to support this high-impact and fast-growing industry. We are interested in strengthening collaborations in the microfluidics community to ensure that novel, safe and effective medical devices are readily available to patients in the U.S.

Biography

Rucha Natu is from Pune in India. She has completed her PhD from Clemson University, SC, USA with focus on dielectrophoretic cell sorting. Her research focused on continuous cell separation using dielectrophoretic and fluid flow. She has also worked on single cell separation using a robotic dielectrophoretic setup. Currently she is working on her post-doc at US FDA. Focus of her work lies in identifying flow-based challenges in microfluidic cell sorting devices. This work is targeted to enable US FDA to identify challenges, assess quality control and characterize flow phenomena in cell sorting microfluidic systems. Her research interests are electro-kinetics, microfluidics and microfabrication.

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