



## FDA Signs Collaborative Agreement with Emulate, Inc. to Use Organs-on-Chips Technology as a Toxicology Testing Platform for Understanding How Products Affect Human Health and Safety

Cooperative Research and Development Agreement (CRADA) to advance and qualify 'Human Emulation System' to meet regulatory evaluation criteria for product testing

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**BOSTON, Mass.** – Emulate, Inc. announced today that it has entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. Food and Drug Administration's (FDA) Office of Foods and Veterinary Medicine. Under this multi-year CRADA, Emulate and FDA will collaborate to evaluate and qualify the use of Emulate's Organs-on-Chips technology as a platform for toxicology testing to meet regulatory evaluation criteria for products – including foods, dietary supplements and cosmetics. The CRADA studies will use Emulate's Human Emulation System™, comprised of Organ-Chips, instrumentation and software apps. The system recreates the natural physiology of specific human tissues and organs, and is designed to provide a predictive model of human response to diseases, medicines, chemicals, and foods with greater precision and detail than other preclinical testing methods, such as cell culture or animal-based experimental testing.

“We are excited to begin this relationship with FDA as a potential first step toward accelerating the adoption of our Human Emulation System for broad application as a new testing platform for a wide range of products that are reviewed and approved by regulatory authorities to protect and improve human health.”

The collaborative research under the CRADA will be led by FDA's Division of Toxicology, within the Office of Applied Research and Safety Assessment, which will have an onsite installation of the Human Emulation System for experimental testing at FDA. The near-term goal of the collaboration is to evaluate and qualify the human-relevant testing capabilities of the Human Emulation System, including correlation with existing cross-



species toxicology data on human health effects of chemical and microbiological contaminants in food, dietary supplements, and cosmetic products.

“We are looking forward to combining our expertise with leading researchers at FDA to explore how our Organs-on-Chips technology integrates with existing product testing frameworks – opening the potential for a new paradigm for establishing improved standards, creating more predictive models, and helping to better evaluate safe products for human use,” said Geraldine A. Hamilton, Ph.D., President and Chief Scientific Officer of Emulate. “We are excited to begin this relationship with FDA as a potential first step toward accelerating the adoption of our Human Emulation System for broad application as a new testing platform for a wide range of products that are reviewed and approved by regulatory authorities to protect and improve human health.”

The collaborative studies under the CRADA will utilize the Human Emulation System, specifically various Liver-Chips developed by Emulate, in an applied toxicology setting to assess the system’s capabilities to predict the effects on human biology of chemical and microbiological hazards found in foods, cosmetics and dietary supplements. These activities will enable FDA to review and provide feedback on the performance and application of the Emulate system for FDA research. It will also enable Emulate to use the information obtained from FDA during this study for further development and improvement of its Human Emulation System. In the collaboration, FDA and Emulate researchers will initially use Emulate’s Liver-Chip from multiple species (Human Liver-Chip, Dog Liver-Chip, and Rat Liver-Chip), to conduct studies to assess the cross-species differences in toxicology data between humans and animal species. The collaborators plan to publish the data and findings from the CRADA studies.

The CRADA collaboration agreement allows for future expansion to additional Organ-Chips, including the Intestine-Chip, Lung-Chip, and Cardiac systems. Depending on the evolution of the research and additional areas of interest, Emulate may conduct further training of FDA researchers on the Human Emulation System.

#### **About the “Human Emulation System” Powered by Organs-On-Chips Technology**

Based on the Organs-on-Chips technology, Emulate has created a new living Human Emulation System™ that provides a real-time window into the inner workings of human biology and disease – offering researchers a new technology designed to predict human response with greater precision and detail than today’s cell culture or animal-based experimental testing. Each of Emulate’s proprietary Organ-Chips – such as the lung, liver, brain or kidney – contains tiny hollow channels lined with tens of thousands of living human cells and tissues, and is approximately the size of an AA battery. An Organ-Chip is a living, micro-engineered environment that recreates the natural physiology and mechanical forces that cells experience within the human body.

#### **About Emulate, Inc.**

Emulate Inc. is a privately held company that creates living products for understanding how diseases, medicines, chemicals, and foods affect human health. Our Human



Emulation System™ sets a new standard for recreating true-to-life human biology and is being used to advance product innovation, design, and safety across a range of applications including drug development, agriculture, cosmetics, food, and chemical-based consumer products. Emulate continues to develop a wide range of Organ-Chips and disease models through collaborations with industry partners and internal R&D programs. Emulate is also working with clinical partners to produce Organ-Chips personalized with an individual patient's stem cells, for applications in precision medicine and personalized health. Our founding team pioneered the Organs-on-Chips technology at the Wyss Institute for Biologically Inspired Engineering at Harvard University. Emulate holds the worldwide exclusive license from Harvard University to a robust and broad intellectual property portfolio for the Organs-on-Chips technology and related systems.