

# 2023 Frost & Sullivan Technology Innovation Leadership Award

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The North American Organ-on-a-Chip Platform Industry  
Excellence in Best Practices

## Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Emulate excels in many of the criteria in the North American organ-on-a-chip platform industry.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Business Impact</i>
Commitment to Innovation	Financial Performance
Commitment to Creativity	Customer Acquisition
Stage Gate Efficiency	Operational Efficiency
Commercialization Success	Growth Potential
Application Diversity	Human Capital

### ***Pioneering Organ-on-a-Chip Platform with Improved Human Organ Mimicking for Drug Testing and Validation***

Pre-clinical studies for drug development mostly use animal models, as they provide a deep understanding of how drug molecules function within a living system. Animal studies for drug discovery have remained a crucial decision-making step in conventional drug development for decades, but they remain controversial among scientists for various reasons such as animal cruelty, the high cost of maintaining vivariums, sustainability, and inaccurate data for comparison with human systems. Although animal studies have limitations, they remain a part of pre-clinical studies due to a lack of alternate, accurate options that can support pre-clinical studies.

Technology developments and R&D efforts in microfluidics, bioengineering, and life sciences have led to exceptional innovations, including the development of Organ-on-a-Chip platforms and organoids. Through these platforms, scientists aim to develop a chip with human-organ mimicking characteristics for use as models in pre-clinical studies, thus minimizing animal studies. The US Food and Drug Administration (FDA) Modernization Act, which was signed into law in December 2022, encourages and supports drug developers using Organ-on-a-Chip platforms. The FDA will now accept pre-clinical drug safety and toxicity assessment data collected from Organ-on-a-Chip models.

As interest grows in developing Organ-on-a-Chip models globally, Emulate has emerged as a notable player in the advanced Organ-on-a-Chip platforms industry. Emulate's Organ-Chip has a distinct design

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**Research Analyst**

and is easy to manage while performing experiments. The company aims to address the limitations of using animal models in pre-clinical studies, because human biological processes cannot be precisely mimicked in animals. Emulate's Organ-Chip mimics physical functionality and complex intra-cellular biological networks, making it a promising alternative *in vitro* model that could transform the way pre-clinical trials are conducted.

### ***Organ-on-a-Chip Models to Accelerate Drug Development Timelines and Minimize Costs***

Emulate, launched in 2014, is a spin-off from the Wyss Institute of Harvard University, and it is one of the pioneers in developing Organ-on-a-Chip models. Emulate's integration of microfluidics, bioengineering, and live cells helps create all the essential features of human biological systems. The company has been successful in developing advanced *in vitro* Organ-Chip models that can effectively recreate the cellular microenvironment cells see inside the human body to emulate human response, which cannot be done in animal models.

The Human Emulation System combines instruments, consumables, and software to develop high-quality Organ-on-a-Chip models for different organs. Indeed, the system provides the complete Organ-on-a-Chip solution—from the physical Organ-Chip to the software analysis platform that can interpret data. The Human Emulation System is easily portable, unlike conventional animal models, and has several components that make its functioning seamless. The system has evolved well since its first iteration created at Wyss Institute, wherein it had had complex, manual, and error-prone syringe pump and tubing

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setups. These have been replaced with an integrated and automated platform. The evolved system makes it possible to visualize and analyze cell-drug interactions in real time. The Organ-Chip through which the culture cells and flow media pass has distinct channels to mimic cell-cell interactions, hence the improvement in physiological relevance. The Pod® Portable Module is responsible for introducing nutrient media and controlling dosing for downstream analysis. Zoë Culture Module provides automated, precise microphysiological conditions to maintain the Organ-Chips' functionality and can culture up to 12 chips simultaneously. Performance monitoring is done

by the Orb® Hub Module, which sends notifications to help maintain optimal study conditions. The Organ-Chip is designed to support remote studies through remote control and cloud-based monitoring.

Emulate has successfully designed and developed several functional Organ-Chips. The Emulate human Liver-Chip can perform toxicity studies exceptionally well and has demonstrated efficacy in identifying drugs that cause liver damage. Emulate's pre-clinical data using the EMulate Liver-Chip showed 87% sensitivity compared animal models that showed 0%. The company has completed studies faster and with reduced costs. Emulate has developed single Organ-Chip models for specific disease-models and drug testing: the Lung-, Brain-, Colon-, Liver-, Kidney- and Intestine-Chips are used in drug development pre-clinical studies for some disease areas with high occurrence and clinically unmet needs. Organ-Chips are flexible, as they are made from polymer materials that allow them to replicate the mechanical forces involved in human body functioning—like the lungs stretching of while breathing in the Lung-Chip. Emulate's Organ-Chip models have different cell types and work on complex biological networks, like in the Brain-Chip, which features endothelial-like cells, pericytes, glia, and cortical neurons while maintaining BBB (blood-brain-barrier)-permeability at *in vivo*-relevant levels. These features help immensely in disease and pathology studies and accelerate drug discovery by giving deep understanding of complex brain networks, signaling, and activity.

The key advantage of using accurate Organ-Chip models is that it reduces dependency on animal models and animal cruelty in clinical studies. Pharma companies consider the data obtained using Organ-Chip models to be more accurate for safety and toxicity studies. Emulate's Organ-Chips enable discovery and validation of novel, targeted drugs and combinatorial therapeutic strategies across various diseases and is highly beneficial for the pharmaceutical industry. Based on the end-user's study requirements, several end point analyses can be selected for an Organ-Chip, such as image, omics, and effluent analyses.

Frost & Sullivan applauds Emulate for its efforts in developing an advanced Organ-Chip platform that is highly beneficial in predicting human organ responses to drug molecules and accelerating drug development.

### ***Growing Adoption of Organ-on-a-Chip Platforms Worldwide***

Emulate's Organ-on-a-Chip technology platform is evolving and being adopted widely across the world. The company has a well-established network across the United States and many European countries. The FDA is using Emulate Organ-Chips in COVID-19 drug development and drug repurposing efforts, and the company works closely with FDA labs to improve the functionality of the Organ-on-a-Chip platform. Emulate's customers include 21 of the top 25 pharma companies, and it has placed more than 430 instruments in labs worldwide, making it the most prominent company in the Organ-Chip industry. The company's primary focus is on developing single Organ-Chip models over multi-Organ-Chips, which has given them an edge in generating human-based advanced cell models with an accurate transcriptome profile and physiologically relevant morphology when compared to its competitors, whose focus is on multi-Organ-Chip models and thus has limited applications due to technological challenges.

Emulate's Organ-Chip models can be adopted for drug-induced liver injury, toxicity assessment, drug transport, on-target and off-target tumor assessment, absorption and bioavailability, anti-inflammatory compound testing, immunomodulators, immuno-oncology, barrier integrity, gene delivery testing, and bacterial culture. For example, Cantex Pharmaceuticals submitted pre-clinical data obtained using Emulate's Organ-Chip model to the FDA for pre-clinical studies, which the latter found satisfying. The

company has also expanded into the Asia-Pacific region by deploying close to 40 platforms in this region, penetrating new markets without a significant presence of Organ-on-a-Chip technology. The company has close to 300 issued or allowed patents, meaning it possesses exclusive ownership of its technological assets.

In 2021, Emulate carried out a notable round of series E funding worth \$82 million led by Northpond Ventures. Emulate has received support from DARPA to develop multi-Organ-Chips, which will be the next step in this technology. Combining two or more Organ-Chips to develop a multi-Organ-Chip will help researchers understand the overall picture of different organs' responses to drug molecules. The company is also integrating organoid models to its system to build a superior model with improved accuracy. Emulate's platform is open, and more than 75 different types of models and applications are currently under development. The company has reported an annual sales revenue of \$22 million in 2022 and will continue to grow thanks to its high revenue magnitude potential and increasing global collaborations.

The opportunities are immense, as the technology plays a crucial role in personalized medicine, drug development, and disease modelling for various disease like cancer, neurological diseases, infectious diseases, inflammation, and immunological conditions.

Since its launch, Emulate has received multiple awards and grants and has emerged as a leading player in the field of Organ-on-a-Chip platforms. Frost & Sullivan recognizes Emulate as a transformative company based on its capabilities for replacing animal studies and providing better clinical data with Organ-on-a-Chip technology for pre-clinical studies.

## Conclusion

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Emulate has developed a strong, sustainable, effective, and long-term solution to address key challenges in scientific models for drug development and an alternative to the cruel and expensive practices of animal models. The company has been successful in developing Organ-Chip platforms that can mimic physical forces acting on organs and complex intracellular networks with high accuracy. Emulate helps its customers overcome their dependence on animal models for clinical studies and provides a better and accurate alternative. The growing accuracy, ease in usage, affordability, and portability makes Organ-Chip platforms the next step in models for pre-clinical studies.

For its strong overall performance, Emulate earns Frost & Sullivan's 2023 Technology Innovation Leadership Award in the North American organ-on-a-chip platform industry.

## What You Need to Know about the Technology Innovation Leadership Recognition

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Frost & Sullivan's Technology Innovation Leadership Award recognizes the company that has introduced the best underlying technology for achieving remarkable product and customer success while driving future business value.

### Best Practices Award Analysis

For the Technology Innovation Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

#### *Technology Leverage*

**Commitment to Innovation:** Continuous emerging technology adoption and creation enables new product development and enhances product performance

**Commitment to Creativity:** Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

**Stage Gate Efficiency:** Technology adoption enhances the stage gate process for launching new products and solutions

**Commercialization Success:** Company displays a proven track record of taking new technologies to market with a high success rate

**Application Diversity:** Company develops and/or integrates technology that serves multiple applications and multiple environments

#### *Business Impact*

**Financial Performance:** Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

**Customer Acquisition:** Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

**Operational Efficiency:** Company staff performs assigned tasks productively, quickly, and to a high-quality standard

**Growth Potential:** Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

**Human Capital:** Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention



