

Modernizing Drug Discovery & Development with Organ-Chip Technology

Dr. Lorna Ewart

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Lorna Ewart is Chief Scientific Officer at Emulate. She brings over 20 years of experience in the pharmaceutical industry, spanning Bioscience and Drug Safety. In her role at Emulate, Ewart provides oversight for the company's scientific vision and advancement with academic, industry, and regulatory partners. Lorna additionally provides scientific supervision for the Emulate R&D and Services teams while also serving as the company's European leader.

Prior to joining Emulate, Ewart created Veroli Consulting Limited. At Veroli, she served as an independent scientific consultant directing academics, start-up biotechnology companies, and pharmaceutical companies working with Organ-Chips and organoids. Within the pharmaceutical industry, Ewart rapidly developed a reputation as a valued partner with academic institutions, regulatory bodies, and technology developers and successfully established the Microphysiological Systems Centre of Excellence within AstraZeneca's R&D Biopharmaceuticals Unit in Cambridge, UK. Under her leadership, AstraZeneca was positioned at the leading edge of industrial adoption of Organs-on Chips technology.

Earlier in her career, Ewart was the therapy area lead toxicologist for Respiratory and Inflammation in AstraZeneca's Gothenburg R&D site in Sweden. Following her Ph.D., she joined the Respiratory and Inflammation research area within AstraZeneca,

optimizing efficacy in small molecules before moving into preclinical Drug Safety where she led a Safety Pharmacology team delivering GLP data across multiple therapeutic areas.

Ewart is a classically trained pharmacologist and obtained her honors degree at the University of Aberdeen and her Ph.D. at the William Harvey Research Institute in London. She has authored over 35 publications and is a fellow of the Royal Society of Biology and British Pharmacological Society.

There is no doubt that scientific progress has accelerated the discovery and development of innovative medicines, a phenomenon acutely visible through the rapid advancement of vaccines against SARS-CoV-2. Outside of dealing with a global pandemic, the process of drug discovery and development remains painfully slow, extremely costly and can, despite appropriate measures, result in patient-safety concerns. Because only around 12% of drugs that enter clinical trials make it to approval, governments in the United States and Europe are taking steps towards modernizing the process of drug discovery and development. Whilst several solutions will ultimately be required, there are growing calls for the utilization of 21st century tools within drug discovery pipelines. One such tool is organ-on-a-chip technology that employs microfluidic systems engineering to recapitulate *in vivo* cell and tissue microenvironments in an organ-specific context. This is achieved by recreating tissue-tissue interfaces and providing fine control over fluid flow and mechanical forces, optionally including supporting interactions with immune cells and microbiome, and reproducing clinical drug exposure profiles.

This seminar will showcase the Emulate Organ-Chip platform and will present the findings of the first of its kind Organ-Chip study which utilized the pharma consortium Innovation and Quality (IQ) roadmap for developing *in vitro* liver models for the prediction of drug-induced liver injury¹. Using 780 Liver-Chips across a test set of 27 small molecule drugs, data will be presented indicating that the Liver-Chip has a 87% sensitivity and 100% specificity, thus making it a highly predictive tool compared to animal models and prior preclinical *in vitro* models. The seminar will complete with an overview on how such a tool can be implemented into drug discovery workflows whilst providing adopting organizations a significant productivity gain.

Reference:

Baudy et al., (2020) Liver microphysiological systems development guidelines for safety risk assessment in the pharmaceutical industry Lab Chip, 20, 215