mRNA Series One / Lecture Four

GUEST SPEAKERS

Dr Natalie Curach

Senior Director Business Development, Gingko Bioworks

Natalie Curach is leading the Australian operations for Ginkgo Bioworks – a synthetic biology CRO with the leading horizontal platform for cell programming. Ginkgo applies machine learning with high throughput automation to enable small molecule and biologics discovery and manufacturing, cell and gene therapies, RNA therapeutics and vaccines.

Natalie has been at the forefront of the growth of Synthetic Biology in Australia commencing with the establishment of the Synthetic Biology Research Priority at Macquarie University and led the Synthetic Biology investments for Bioplatforms Australia. Natalie co-authored the Australian Government's Synthetic Biology infrastructure investment plan which culminated into the opening of the Australian Genome Foundry. She was instrumental for the creation of the Australian Research Council's Centre of Excellence in Synthetic Biology and was the Chief Scientific Officer at Eden Brew for its founding year.

Natalie conducted her PhD on recombinant protein production in filamentous fungi, has a Graduate Diploma in Business Management and is a member of the Australian Institute of Company Directors. Natalie has been invited to present at numerous international meetings and is well published in peer review journals and thought leadership papers such as for the World Economic Forum. Natalie has worked as a scientist in biotechnology research within startups, university and government laboratories before transitioning into business development, leadership roles and Directorships in building a thriving startup and biotechnology ecosystem in Australia. Natalie recently served as President of the Synthetic Biology Australasia Association, Co-Chair of the Global Biofoundry Alliance and Chair of HydGene Renewables.

Professor Frank Caruso

Melbourne Laureate Professor | NHMRC Leadership Fellow, The University of Melbourne

Frank Caruso is a Melbourne Laureate Professor and an NHMRC Leadership Fellow at the University of Melbourne. He received his PhD degree in 1994 from the University of Melbourne, and from 1994–1997 was at the CSIRO Division of Chemicals and Polymers in Melbourne.

He was an Alexander von Humboldt Research Fellow and group leader at the Max Planck Institute of Colloids and Interfaces (Germany) from 1997–2002. From 2002–2012, he was an ARC Federation Fellow and from 2012–2017 an ARC Laureate Fellow at The University of Melbourne.

His research focuses on developing materials for biomedical applications. He has published over 550 peer-reviewed papers with more than 60,000 citations and is a highly cited researcher. He is an Executive Editor of the ACS journal Chemistry of Materials and serves on the Editorial Advisory Board of 10 other scientific journals. He was elected a Fellow of the Australian Academy of Science in 2009 and of the Royal Society of London in 2018. He is the co-inventor of 33 patents. He is co-founder of Messenger Bio Pty Ltd (2021), a company that focuses on mRNA technologies.

Dr Craig Sheehan

Senior Scientist, IDT Australia

Craig Sheehan is a member of IDT Australia's R&D group, and played an integral role in a collaboration with the Monash University Institute of Pharmaceutical Sciences to complete Australia's first cGMP manufacture of a mRNA vaccine clinical trial candidate.

IDT Australia's R&D group translates bench scale processes to manufacturing scale under cGMP to enable first in human clinical trials that address unmet patient needs. IDT's development expertise is vertically integrated, manufacturing Active Pharmaceutical Ingredients (new chemical entities) and formulating them into Finished Dosage Forms.

Craig has over twenty years' experience in commercial contract research organisations including Mimotopes, Epichem and IDT Australia Ltd. His development experience includes process development to translate laboratory processes to plant scale manufacture under cGMP, small molecule preclinical drug discovery and the manufacture of pharmaceutical reference standards. He completed a PhD in organic chemistry at the University of Sydney and post-doctoral studies at Innsbruck University, Austria.

FACILITATOR

Professor Michelle McIntosh

Director, Medicines Manufacturing Innovation Centre (MMIC), Monash University

Professor Michelle McIntosh is the Director of Monash University's Medicines Manufacturing Innovation Centre (MMIC) and has led expansion and growth of the Centre since its inception in 2017. As the Centre Director, Professor McIntosh plans and implements strategy and future directions of the Center including investigating ways to expand capabilities, opportunities to leverage funding, and opportunities to maintain the continued growth of MMIC. Her additional responsibilities also include lecturing in pharmaceutical science Director of the HMST Analytical Laboratory and Leader of the Drug Delivery, Disposition and Dynamics (D4) Theme at the Monash Institute of Pharmaceutical Science (MIPS). Professor McIntosh has extensive experience in commercial negotiations and a successful track record of partnering with global philanthropists, companies and foreign and domestic government entities.

Professor McIntosh completed her PhD degree at Monash University with a research focus on the delivery of poorly water-soluble drug molecules and understanding of how they are transported in the body within plasma lipoproteins. She then undertook a post-doctoral fellowship in the United States at the Center for Drug Delivery Research (CDDR) at the University of Kansas for seven years before she returned to Monash University as a lecturer and research leader.

CDDR is an institute sitting at the interface of academia and industry and focuses on the commercialisation of university-based intellectual properties. With CDDR being her first role after her PhD, she developed an industry mindset with an understanding of technology translation in the very early stages of her career.

Professor McIntosh always had a passion for improving the quality of life of patients and improving access to life-saving medication in rural areas and the developing world. Her most significant project has been developing aerosol delivery of oxytocin to women after childbirth for the prevention and treatment of postpartum haemorrhage. As part of the development process Professor McIntosh visited remote and rural areas in India and interviewed healthcare providers, midwives, birth attendants, and mothers to understand

the health challenges they are facing as well as how an inhaled product would be perceived by the community and how it could be incorporated into existing birthing practices.

After field research on several continents, Professor McIntosh said a key learning for global drug development was “developers of new products need to be very sensitive to culture and tradition, and not to come in with preconceived ideas that our way is the right way or the better way.”

Professor McIntosh was also a member of the UN Commission on Life-saving Commodities for Women and Children Technical Advisory Group where she provides her expert opinion to improve access and use of essential healthcare support for women during pregnancy, childbirth, and into childhood. Professor McIntosh has also served several years on a Victorian Government Ministerial Panel for Advanced Manufacturing.