

AVVISO DI SEMINARIO

Dott. Nicoletta Muner

MPharmSci GAICD

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Canary Regulation Affairs

Level 17, 31 Queen St, Melbourne, Australia

Planning for Regulatory success in the US and EU

Pianificazione per un processo normativo di successo negli Stati Uniti e nell'UE

Mercoledì **16 Aprile 2025** ore **16:00**

Aula LIM - Il piano – C11

Tutti gli interessati sono invitati a partecipare

CV

Nicoletta Muner graduated in Chemical and Pharmaceutical Technologies at University of Trieste in 1995, then moved to Australia, where she obtained a Master in Pharmaceutical Sciences at Monash University before embarking on a career in the pharmaceutical industry.

In 2020, Nicoletta founded Canary Regulatory Affairs after obtaining market authorisation from the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for a first-in-class orphan drug as the Global Director of Regulatory Affairs of an Australian ASX listed company.

Under her leadership Canary guides both Australian and international clients, ranging from innovative entrepreneurs to private and publicly traded companies, through their development process by ensuring regulatory compliance throughout the manufacturing process, overseeing non-clinical development programs and by contributing to the design of clinical studies, including First in Human (FIH) trials.

Nicoletta has assisted clients in the preparation and filing of US Investigational New Drug (IND) applications and steered them through Scientific Advice meetings with the FDA, EMA and MHRA. Canary's expertise ranges across multiple therapeutic areas including neurology, oncology, anaesthesiology, dermatology, cell and gene therapies and infectious disease.

Nicoletta further supports innovation by volunteering as an advisor to early-stage entrepreneurs in the life sciences and by participating in capital raisings in the sector.

As a graduate of the Australian Institute of Company Directors Nicoletta also served on the Board of a country hospital and is the Deputy Chair of a Foundation supporting research in melanoma.

Il Direttore
Prof. Paolo Tecilla

