

Gabaldo, Michela

Fondazione Telethon



Michela Gabaldo is Head, Alliance Management & Regulatory Affairs at Fondazione Telethon in Milan, Italy where she joined in 2011. As Head of Alliance Management she was responsible for the execution of the first strategic Alliance of Telethon/OSR with GSK managing gene therapy projects at different stage of development ranging from preclinical, to clinical, to Registration & market access. With her capability to work in a matrix, she paved the way for the very first ex-vivo gene therapy (Strimvelis) to move from clinical trial to market, ensuring alignment and understanding between stakeholders from different areas and entities. Through her collaborators she's also responsible for the execution of the other strategic alliances established by Telethon at both the internal Institutes (i.e., SR-TIGET and TIGEM). Michela is also Head of Regulatory Affairs at Fondazione Telethon supporting internal Institutes through the clinical development. After graduation in Pharmaceutical Chemistry and Technology from the Padua University, she joined GSK in 2001 where she was involved in drug development working in Clinical Operations and CMC Regulatory Affairs areas. She then granted a Master Degree in Regulatory Affairs and Market Access for NCE and Biopharmaceutical products from Novara University in 2010. Winner of 2017 edition of TopRA Award in the Future category, Michela offers up to date knowledge of the most recent regulation in ATMPs and is frequently invited as speaker at international events on the subject. She's currently a member of the IRDIRC Scientific Committee.