

## **ESBES – ACS BIOT COVID19 Webinar series**

**Speaker: Piergiuseppe Nestola, PhD**

**Manager of Process Technology Consultants at Sartorius responsible for providing scientific, technological and process leadership in the field of viral-based therapeutics**

**Title:**

**mRNA Manufacturing: Removing Bottlenecks in PD and Manufacturing Process**

**Abstract:**

In vitro-transcribed messenger RNA-based therapeutics represent a relatively novel and highly efficient class of drugs. Current clinical efforts encompassing mRNA – based drugs are directed to three categories: mRNA vaccine, mRNA therapy and protein replacement therapy. As mRNA vaccine became the frontrunners to fight the COVID-19 pandemic, challenges surrounding their process development and manufacturing became readily apparent: (i) mRNA manufacturing is not yet a platform approach. Standardized products along the processes are needed. (ii)mRNA is a relatively large molecule, which leads more challenges for downstream purification. (iii)mRNA is intrinsically unstable and prone to degradation. (iiii) High raw material cost is limiting mRNA commercialization. This presentation provides a detailed overview of current mRNA manufacturing approaches, summarize the latest findings in cost of goods, highlight challenges and recent successes, and offer perspectives on the future of mRNA manufacturing.