



FALL VIRTUAL CONFERENCE

S1.5: Commercialization of Surgical Face Masks

Michael Corbat
Rensa

ABSTRACT

With the explosion of facemasks including a shortage of them in health care facilities during the current COVID-19 pandemic, it is important to review the requirements needed to enter the medical market. It will include and overview ASTM F2100 testing procedures of face masks along some testing requirements that are not explicitly stated in ASTM but are required for FDA approval.

There will be a review of the process of submitting formal paperwork to the FDA, the processes involved. The Emergency Use Authorization regarding facemasks will also have a brief overview.

Finally, literature, manufacturing requirements, quality systems, and other items requirements needed to minimize risk following product commercialization along with steps needed to modify the product.

Important points of note, this presentation will not explore respirators which include N95. Efficacy of non-surgical style masks will also not be discussed. Lastly the discussion will not involve the importance of wearing masks during the pandemic.