

#ISPESingapore21

I've had an amazing opportunity to attend ISPE Singapore Conference 2021. I attended the webinar on day 2, and I've managed to pick up a lot of knowledge on different aspects of the industry. One of the topics is auditing in the pandemic. With the ongoing worldwide outbreak, auditing has had its changes and challenges. Instead of following the auditors' schedules, nowadays, they would have to follow the sites' operating hours where some would have to work from home on certain days to limit the number of people working on site. Knowing that they have to be more sensitive to the pandemic situation, preparations on sites happen from weeks to months before auditing by making a virtual tour of the manufacturing sites and laboratories to help ease the auditing process.

Besides the auditing and their solutions to the pandemic's challenges, I learned more about Cell & Gene Therapy Manufacturing, a one batch-type manufacturing process that aims to treat, prevent, or potentially cure diseases. Both approaches have the potential to alleviate the underlying cause of genetic diseases and acquired diseases. This therapy is highly costly and ranges from 373k - 475k USD to make it more affordable. I've also acquired knowledge on CAR-T therapy and its challenges. The manufacturing produces an artificial T cell receptor for use in immunotherapy and it has its challenges. With the unknown characteristics of CAR-T cells, it is hard to standardize the process as it deals with a highly variable material. It also requires high stringency of controls as it is an aseptic process from beginning to end which makes the manufacturing attributes highly critical. The whole process's robustness, scalability and operability define the costs of goods in which the economics of it depends on the economic scale of the manufacturing of the therapies.

By the end of the webinar, I am very impressed by the progress of the pharmaceutical industry and the efforts in making the processes more efficient and manageable for all. It was such a beneficial experience, and I became inspired to do better. As the HR Director of ISPESC, I can apply this knowledge and grasp accommodating one's needs to make the process more efficient. I managed to gain so much from the conference and it has been a meaningful experience for me. Thank you, ISPE Singapore Affiliate, for giving me the opportunity.

--- Mahira Ikram, Graduate from NYP Chemical and Pharmaceutical Technology
ISPE Singapore Student Chapter, HR Director

