Drive and Leverage Innovation for Pharma -- 2019 ISPE Europe Annual Conference

The pharmaceutical industry is evolving so rapidly, with agility and flexibility, we will all have to advance and adapt ourselves to innovative technologies and approaches. To solve the challenges facing patients, i.e. drug shortage, drug price and to solve the challenges facing manufacturers, including patent cliff, long approval cycle, etc.

My major takeaways from the conference could be best summarized in a few key areas:

Digitalisation:

The concept of 'Pharma 4.0' was raised a few years back, when it seemed a myth to the industry – everyone was talking about it but very few had a clear picture on: what to be implemented, where to start, pre-requisites, and most importantly – why?! Only in recent years can we see more and more real-life case studies. To quote a few examples to help visualise the digitalised facility – the facility of the future:

- Digital twin of bioreactor, enables smoother scale-up & tech transfer, as well as preventive analysis for process and maintenance needs. The digital twin could also be developed and studied by equipment suppliers, who become an extension of the production and tech transfer. The stronger link between supplier and manufacturer is also a consequence from more extensive application of single-use equipment, as manufacturers depend increasingly on suppliers for design and testing.
- VR visit of the facility, reduces the number of visitors in the cleanroom hence reduces the potential risk imposed to production and environment, meantime provides comparable presentation of the production suits to the visitors.
- Machine learning, where data are collected and analysed real-time to understand the equipment and process performance. On some specific site, potential failure could be predicted 56 days prior to its actually happening, hence measures can be taken accordingly.

Digitalisation is built on a solid foundation of data: the extensive amount of data being collected; how it is processed – off-line and in-line; and the application of data analysis – from predictive process and maintenance to real-time release. This also raises the Data Integrity awareness to a new level, and certainly it's still a long journey to reconcile the demand, current limitations and concerns, i.e. trusted organisation for data collection, secured data storage, as well as the intensive cost and effort required to transform existing facilities.

Despite the limitations and concerns, we witness the digital journey of manufacturers, and on the other hand, the accompamying digital transformation of suppliers and service providers. We see more suppliers presenting VR technology in various domains: training, sampling etc. Also, we see the traditional engineering firms presenting design model on VR platform.

Fast

It's one of the main certainties that our industry needs to move fast and faster. The industry has been making great effort on various dimensions through the whole product life cycle, just to name a few:

- Fast R&D and drug approval is encouraged to enable innovative medicines to launch into markets more efficiently. A mind-shift of regulatory authorities is observed for faster drug approval, as well as more efficient ways of handling post-approval changes which is the core of ICH Q12.

- Manufacturing facilities are built with modular approach which enables faster project delivery. More facilities are built for platform process with single use technology to enable faster adaptation to new products.
- In-line measurement and analysis helps eliminate certain scale-up studies, remove certain parameters from Established Conditions, hence ease the post-approval changes process, as well as enable real-time release.
- Continuous manufacturing technology offers shorter process time, as well as smaller scale production – this also brings us the next key word.

Small

Besides continuous process, smaller scale is a consequence of various technologies:

- Personalised medicine -- a batch is for one patient only. Also, it requires faster production and release to patient, as current Advanced Therapies are targeting more severe medical conditions, in which time is of the essence.
- Higher titre of fermentation and cell culture guarantees same or higher production capacity with smaller bioreactors.
- Single use technology is limited in size by its nature, however it allows us to develop the 'scale out' approach instead of 'scale up', hence saving risks associated with scale-up.

Sustainable

Regardless of how advanced the technology is, without a sustainable solution, we will not go far. A lean approach needs to be implemented in every aspect of our work, to reduce the material and manhour waste, to make medicines more available and affordable. Lean approach is absolutely enhanced by digitalisation as well – it's a convergence of operation and digital excellence.

More importantly, our technologies need to be environmentally sustainable. More and more manufacturers have recognised our responsibility, to society, to our environment, to reduce our carbon footprint.

Overall the conference was very diverse and eye-opening, it would be impossible to quote every valuable information shared but a strong message sent from all the speakers could be the highlight of the conference: Be ready for the changes, be ready for the future.