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What are the facility design requirements to fit biologics pipeline demands?

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Decisions to install new facilities are typically driven by pipeline or capacity demands. While extensions to existing capacity typically restrict the level of freedom to design, this is different for pipeline products. Due to numerous unknowns in the development of drug candidates in a pipeline, maintaining a large degree of flexibility in future facility design is the most widely accepted de-risking concept. Looking more closely into the development of a biologics pipeline, certain elements help to control and limit the design space while others just effectuate the opposite.

Without question the key guiding principle for these future products is to develop them according to the targeted product profile (TPP) with a focus on the patient needs first. However, manufacturability and further industrialization aspects should also influence process development in a way that the newly developed processes match predefined criteria. For instance, the capability to rely on a well-developed technology platform will help to accelerate development times and guarantee the fit of the process to already known processing modules. Having said that, the facility design will still need to be flexible enough to accommodate the evolution of a technology platform.

Criteria that drive process development can vary significantly and will have to be revisited several times during the development of a new product. Major drivers include the results of clinical trials that will narrow down the TPP step by step, the change of a targeted indication incorporating estimations of future market demands, and competition or price sensitivity of the product that translates into cost of goods challenges. Additionally the pipeline attrition risk has to be considered in proposing a future facility. Depending on the strength of the pipeline, a future facility may accommodate just one technology platform or the risk may be arbitrated by designing the facility in such a way as to host several technologies or at the least have the ability to switch between technologies easily as needed. Other pipeline driven aspects include the desired process integration from drug substance manufacturing to drug product manufacturing and device assembly, suitability of the plant for clinical and commercial manufacturing, technological limitations for the use of disposable technologies, etc. A careful analysis of all these drivers will define the main dimensions of flexibility that have to be considered for facility design: cost, volume, technology, and time.

Finally, specific aspects of facility design are related to the processing mode. If the product leaves us the choice, are we going for fed-batch or continuous processing? Which of the above described drivers will help us to make the choice? What is the point in time during development to make a decision for one or the other mode? Is it reasonable to design a facility that it can host both? How flexible is a pure continuous plant with respect to late pipeline entries, e.g. though licensing and acquisitions?