„Mini-Monoplant Technology for Pharmaceutical Manufacturing”

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Continuous processes are often related to the concept of process intensification as the unit operations are optimized and intensified by using the best in class technology. In other words, the equipment is selected to fit the optimal process rather than the process is fitted into the available equipment. However, this manner of operation is by far more complex and prone to extended R&D development time. Thus, for drug substances in clinical development phase, flow process steps or even full flow processes have not been considered until recently on a broad basis. A later or in-parallel developed continuous process or process step may encounter additional hurdles as it has to outperform the current process or process step significantly in order to justify a change in regulatory documents. Another important aspect that must be considered is the capital investment into new equipment upon scale up.

In this talk the concept of mini-monoplant technology will bediscussed and how the concept can provide a more attractive approach towards the development of continuous processes or process steps for API manufacturing. Some recent and published examples will be given to demonstrate the versatility of continuous processing in the field of API manufacturing.

[1] Brendon J. Doyle, Petteri Elsner, Bernhard Gutmann, Olivier Hannaerts, Christof Aellig, Arturo Macchi*, and Dominique M. Roberge, *Org. Process Res. Dev.*, **2020**, accepted.