Innovative Journey to Continuous-Flow Industrialization

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The development of continuous-flow pharmaceutical production processes typically progresses through three key stages:

Lab-Based Development: The journey begins in a secure laboratory, where miniplant process development is carried out. This environment enables chemists and engineers to focus on value-generating features such as novel reaction pathways, intensified reactors, and automation. At this stage, innovative continuous processes can be explored using compact setups with flexible throughput, allowing for studies on scale-up and process robustness.

Pilot/Plant Integration: Once lab-scale development is complete, the miniplant can be transferred—or replicated—within existing plant infrastructure. This transition provides access to large-volume feed and product storage tanks. The use of predesigned and GMP-prequalified multipurpose unit operation modules significantly reduces the time required to introduce new technology into a GMP pharmaceutical production facility (see Figure 1). Throughput can be increased to meet the demands of clinical trials.

Commercial Production: Upon reaching the commercial market phase, dedicated production assets become an attractive option. A designated area within the factory can be used to install the process, now termed a mini-monoplant. At this stage, the process can be scaled temporally, allowing for year-round operation to accommodate fluctuations and uncertainties in product demand.

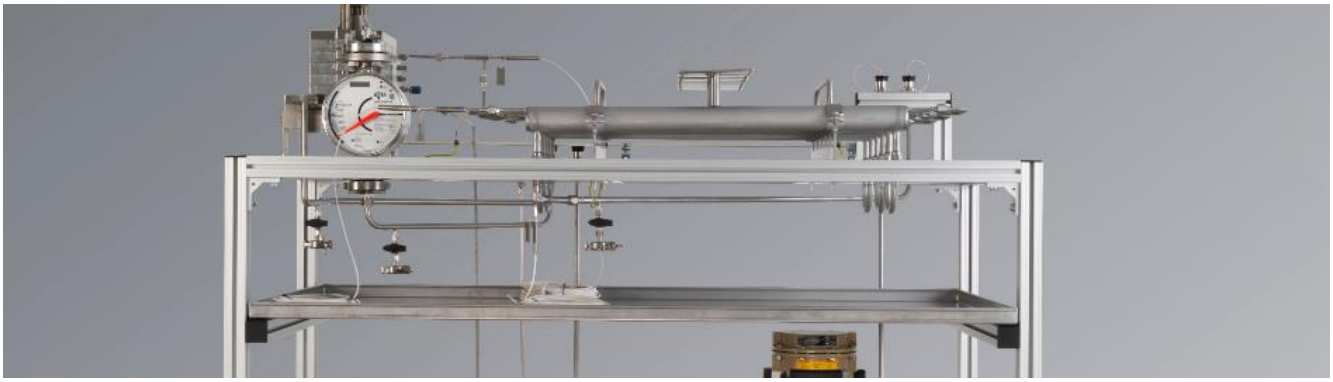

Figure 1: Example of a GMP-ready, modular, skid-mounted reactor module (Image courtesy of Fluitec).

References

[1] B.J. Doyle, P. Elsner, B. Gutmann, O. Hannaerts, C. Aellig, A. Macchi, and D.M. Roberge*, *Organic Research & Development*, **2020**, *24*, 2169-2182.