

Optimised Experimental Design Platform for Continuous Flow Reactors



Continuous flow processes for design and production

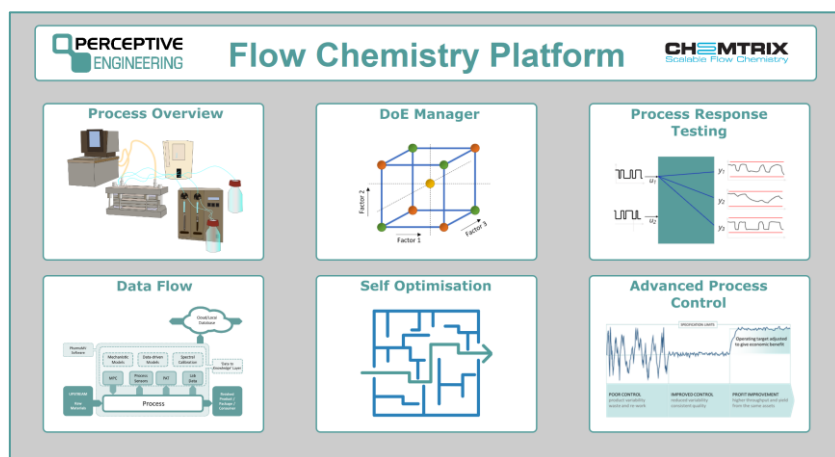
The increasing desire for new variants of products is constantly driving the need for innovation in research to work with agile development and scale-up platforms to create robust production-scale manufacturing. The commercial success of new personalised products, from skin care lotions to vaccines, often lies, not only in safely controlling the characteristics of the active ingredients and in the reproducibility of the formulation, but also in delivering the end product to market quickly and at scale.

Where the cost of the active ingredients is a significant consideration and the move towards personalised products results in smaller volumes and a higher number of product variants, bringing the benefits of continuous manufacture, to traditional batch driven applications, can deliver the required quality and flexibility.

Challenges

Developing new products brings many challenges beginning with the design of experiment (DoE) process which typically is iterative, time and material intensive, increasing the cost of innovation. A second challenge is to create a platform where a variety of sensors, PAT, automation modules and operation workflows ease the experimental task and create a versatile 'plug and play' capability.

The integration of Optimised Experimental Design with Advanced Process Control (APC) for flow chemistry systems gives a path for efficient development and increased confidence in quality. With the benefit of reduced reagent, active ingredient and energy consumption, continuous manufacturing processes can be readily developed for low-volume high-value products.



Benefits

- Automated optimisation of experimental design, reduces number of experiments, speeding up product development
- Early-stage confidence in scale-up to commercial, continuous manufacturing
- Single platform to perform automated DoE, calibration modelling and process control
- Precise equipment control allows robust, low-volume high-value manufacturing
- Reduced energy and material costs
- Improved process safety
- Fast track to prove new product viability and a quicker route to full-scale manufacture

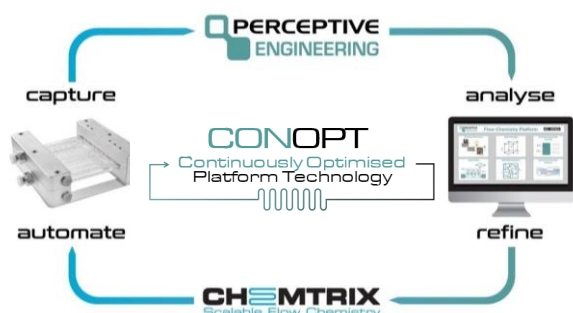


Continuous Flow Reactor Optimisation

Design and Optimise from R&D to manufacturing

While flow reactors are a recognised technology, they require skilled scientists to interpret and frequently adjust the process. The Perceptive 'Continuous Flow Reactor Optimisation Module' delivers automation to enhance the efficiency of product development using continuous flow reactor technology.

The module enables the adoption of Modern Experimental Design, integration of PAT and precision model-based control, all embedded into a single containerised platform, to simplify the management of flow reactors throughout the development and production stages.



Applications

This technique of automated DoE with continuous flow manufacturing streamlines new product development or process refinement from R&D, through pilot plant scale-up to commercially viable manufacturing volumes. The scale and precise control of this technique enables continuous production under extreme processing conditions, managing aggressive media, handling unstable intermediates and potentially hazardous reactions not feasible under batch conditions.

Solution

Driven through the PerceptiveAPC® software, the continuous flow, automated DoE application is demonstrated using the Chemtrix Protrix® flow reactor, sized for process development and small volume production. The development phase is directly scalable to the Plantrix® MR555 industrial flow reactors enabling controlled manufacturing at the multi-tonne scale.



The platform is designed with intuitive dashboards to enable:

- **Customisable Operator Interfaces for regulatory automation of equipment**
 - Temperature, flow, pressure, pump speed remote setpoints
 - Extensive data tools for collection, analysis and reporting
- **Advanced Automated DoE Manager**
 - Classic DoE
 - Self-optimisation routines
- **Comprehensive PAT interfaces including:**
 - NIR, FTIR, UV-Vis, Raman, FBRM, NMR
 - Built-in chemometric toolbox
- **Model Predictive Control**
 - Model based multivariable control for complex reactions
 - Linear and non-linear systems
- **21 CFR part 11 compliant**
 - For product development and commercial GxP manufacturing

Delivering high-value, low-volume products to market

The 'plug and play' automated DoE manager, applied to continuous flow reactors, uses modern computational DoE techniques to unravel the complexity of innovation. This market-ready process is ideally suited to developing or manufacturing products using limited volumes or expensive active ingredients found in complex products such as pharmaceuticals, chemicals and personal healthcare products, enabling development teams to bring commercially viable new products to market, quickly and confidently.

