



CONTINUUSTM
pharmaceuticals





CONTINUUS Pharmaceuticals is a spin-out company from a multi-year collaboration between MIT and Novartis on Continuous Manufacturing.

We are specialized in end-to-end Integrated Continuous Manufacturing (ICM), with the application of novel process technologies that enable rapid production of pharmaceuticals at significantly reduced costs and better quality.

With ICM, we will improve affordability and accessibility of pharmaceuticals on a global scale.

On-Demand Manufacturing of Pharmaceuticals

Rather than producing medicines through batch-wise, step-by-step processes, CONTINUUS Pharmaceuticals offers a breakthrough Integrated Continuous Manufacturing (ICM) technology for small molecule pharmaceuticals.



continuous manufacturing



cost reduction vs. batch



lead time reduction



plant footprint vs. batch



PERCENT
100

quality control





Feeding, Dissolution and Clarification

Integrated gravimetric feeders allow precise solids metering of starting raw materials through ratio control.

Homogeneous mixing of the pre-reaction mixture is achieved in the dissolution vessel. In-line Process Analytical Technologies (PATs) allow for real-time measurement of reactants.

The novel clarification bypass unit ensures in-line continuous solid-liquid separation, which enables the system to process different grades of raw material. Automated Clean-In-Place mechanisms allow for continuous operation.

API Reaction and Crystallization

An automated Continuous Stirred Tank Reactor (CSTR) cascade with in-line PATs performs both the reaction and crystallization.

PATs are implemented for in-line measurements, such as impurity concentration and API chord length distribution.

The CSTR cascade is modular in its configuration and number of stages. It can easily be replaced by other technologies, such as a Plug Flow Reactor (PFR).





Filtration

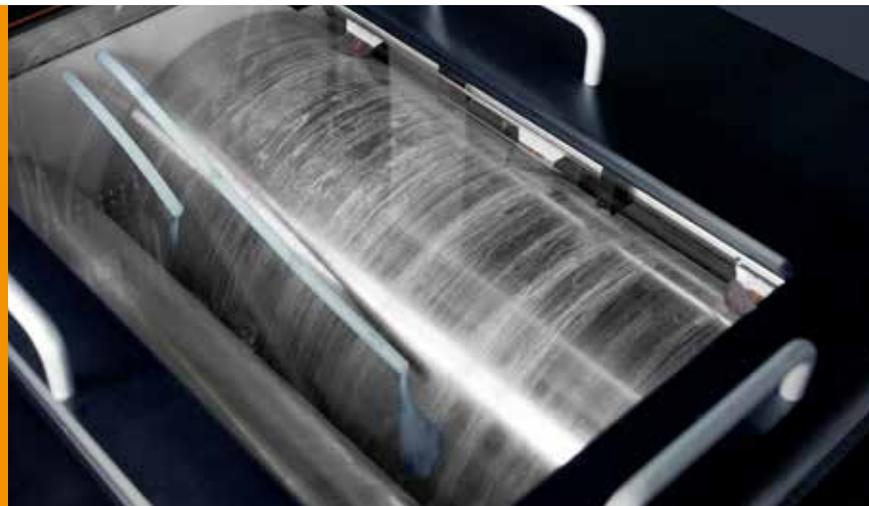
A Continuous Rotary Filter purifies the crystallization slurry, removing unwanted impurities from the Active Pharmaceutical Ingredient (API) or intermediate product. The slurry is deposited on a rotating porous plate, where the mother liquor is filtered out through a high vacuum system.

The thin (~1 mm) wet-cake is effectively and efficiently purged of impurities through the application of multiple wash stations, after which it is transported to the next unit.

A built-in Clean-In-Place mechanism restores the filter plate, while the purified wet-cake is analyzed with in-line PATs for real-time purity and concentration. The system has the ability to segregate filtrate streams, enhancing solvent recovery.

Drum Drying

A Continuous Drum Dryer converts concentrated or diluted suspensions containing the API into a dry, flowable powder. The suspension is deposited onto two heated rotating drums, forming thin layers that are quickly dried. Concurrently, a specified load is applied between the two drums, reducing particle size to the desired specification. The entire system is under vacuum, allowing the process material to be maintained at lower temperatures. The dried API is then conveyed through a cyclonic separator, before it is sent to the next unit operation. In-line PATs allow for real-time measurement of particle size, residual solvent and crystal form.



Extrusion

Molding

Coating (EMC)

An Integrated Extrusion-Molding-Coating process produces pharmaceutical-grade coated tablets in a continuous fashion.

The API and required excipients are fed into the unit, where they are heated and mixed, resulting in a uniform melt, or extrudate.

Coated tablets are then produced as this process material is molded and coated in subsequent sections of the unit. In-line PATs allow for real-time measurement of content uniformity and crystal form.

The entire system operates solvent-free.



Solvent Recovery System

A Thin Film Solvent Evaporation technology is used to clean and separate solvents. The system consists of a multi-stage cascade evaporator train, where solvents are recovered and then reused in a closed-loop fashion.

Control System

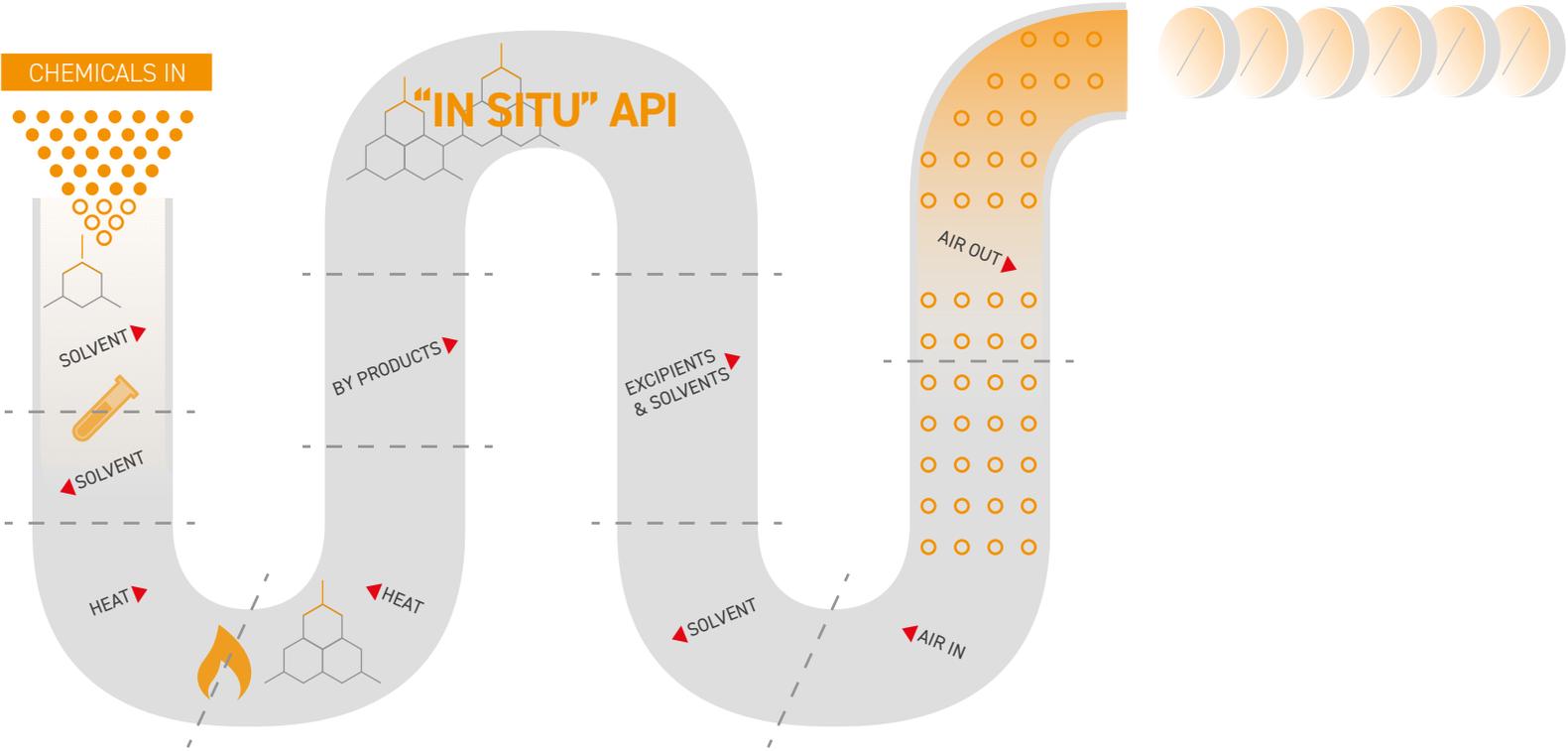
An end-to-end integrated process control system with in-line PAT maintains the process in a state of control.

The application uses Emerson's DeltaV® software and incorporates feedforward and feedback control actions as part of an advanced control strategy.

A dynamic process model is implemented for model predictive control.

Direct critical quality attribute (CQA) measurements *via* PATs, combined with sophisticated mathematical models, which combine first principle understandings and empirical data, enable real time release testing (RTRT) of pharmaceuticals.

Fully automated process



Product offering

CONTINUOUS Pharmaceuticals is leveraging the experience, know-how, and novel process technologies developed at the Novartis-MIT Center for Continuous Manufacturing to advance the state of manufacturing within the pharmaceutical industry.

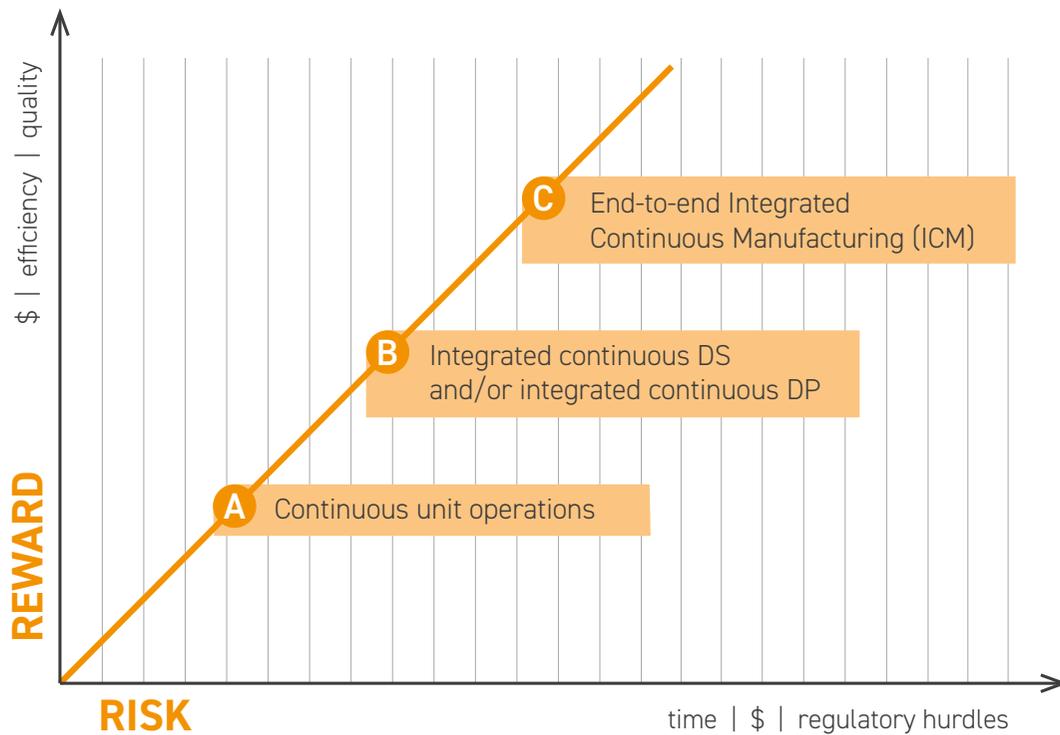
It is our vision that, through our advanced technology platform, we can help innovator and generic drug companies develop and manufacture higher quality drugs in a more efficient and cost-effective manner. Our product offerings are tailored to provide

clients with the best solutions for their pharmaceutical development and manufacturing needs. They include the following:

- Integrated Continuous Manufacturing (ICM)
- Targeted Solutions

These product offerings provide clients with a range of opportunities with varying risk-reward profiles.

Targeted solutions will help clients solve specific challenges encountered with current batch processes, while implementation of ICM lines will completely transform their manufacturing operations.





The novel technologies that comprise our Integrated Continuous Manufacturing lines provide advantages over existing conventional batch technologies.



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