



Optimize Pharmaceutical Operations Through Continuous Manufacturing



The benefits of implementing continuous manufacturing – from greater quality and reduced operational expenses to shrinking time to market – are well understood by industry. Nevertheless, widespread adoption of this technology in the pharmaceutical industry is slow due to potential financial risk. Partnering with Pharmatech Associates enables you to lower that risk. With decades of market-specific experience, we are the ideal partner to help you reach your pharmaceutical continuous manufacturing (PCM) goals as painlessly and cost-effectively as possible.

We start with your product

By standardizing and simplifying product development, better preparing producers to address CMC and manufacturing challenges, and by enabling digital twin models for drug development, PCM has an impact on all value-adding processes. The advantages of PCM include:

- **Viable BCS II and IV Compounds** As an enabling technology, PCM provides access to previously non-viable BCS II and BCS IV therapeutic agents.
- **High Quality, Lower-Cost Therapies** By increasing production efficiency of drug substances, products, and ingredients, PCM reduces operational expenses and increases supply chain resilience.
- **Sustainable Manufacturing** Implementing PCM can help you meet net zero strategies by increasing the sustainability of your entire supply chain.

EXECUTING ON USP'S MISSION TO MAKE PCM ACCESSIBLE FOR INDUSTRY

USP's dedication to creating practical and easy-to-apply guidance and reference documents for all aspects of PCM for industry complement Pharmatech's experience and knowledge in implementing PCM.

How does Pharmatech Associates help you achieve the benefit of PCM?

A Product-Centric Approach

- We help you intensify your processes so you can gain tighter control of critical process parameters which means greater process predictability and higher yields
- Our expertise helps you reduce the risk of tech transfer through scale-out rather than scale-up
- We assess your current workflows and help you improve OEE so you can achieve higher productivity and, ultimately, faster ROI/NPV

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When I visited a [client's] production site recently, the team of operators was proud to highlight a 12-hour equipment clean time between batches – a process that normally takes three days with traditional equipment.
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RICHARD STEINER
Senior Manager, Business Strategy

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 The business case for orphan drug breakthrough designation is clear. The potential exists to reduce time to market by at least three months with less API needed for product development. One product launched can pay for the entire program from development to manufacturing.
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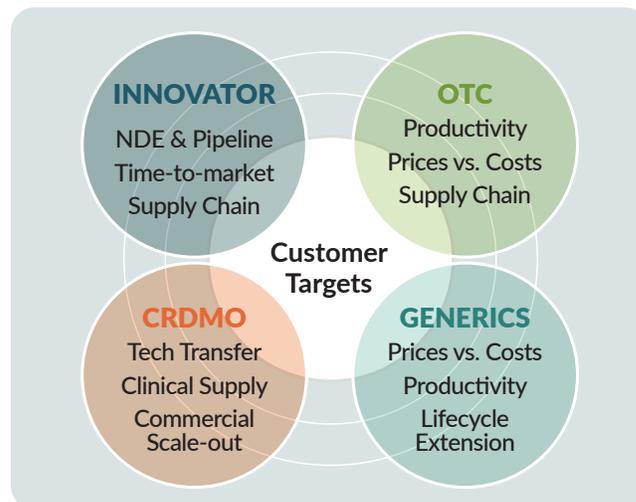
PCM BUSINESS SUMMIT 2023 SPEAKER

Upholding the Highest Quality Standards

- We help you achieve 6-Sigma process capabilities: meaning zero waste and no re-work
- Higher process capability means lower total cost of quality and overall lower COGS

Accelerate Patient Access

- For drug therapies with an accelerated regulatory pathway, PCM simplifies the jump to commercial readiness, lowering overall program readiness costs and risk
- Provides instantaneous capacity for therapies where forecast volumes and adoption rates are difficult to develop with accuracy
- Platform and modularized process design makes it easy to duplicate processes for multiple markets



Pharmatech Associates serves four customer targets with distinctly different needs and challenges.

PCM tailored to your business

We understand that the business considerations for CDMOs are not the same as a generic drug manufacturer, OTC or drug innovators.

For Innovators and CDMOs, our domain knowledge and tech transfer expertise allow a lower risk adoption of PCM.

For Generic and OTC Drug Producers, we help you implement PCM to solve process inefficiencies and quality issues caused by traditional batch processing.

PCM Leads to US Market Entry

A regional generics producer in Mexico faced process inefficiencies and quality issues using traditional high sheer granulation technology. By employing continuous twin screw wet granulation technology, they manufactured more than 10 tons of product material in 12 years – without a single rejected batch. They have now converted eight additional products to twin screw granulation technology, and in 2022 received FDA approval to supply these products to the US market.

Evaluate the benefits of PCM and discover how to lower the risk. Call us at 1.877.787.0177 or email contact@pai-qbd.com to schedule an initial consultation.