

Innovations in Sustainable Pharmaceutical Manufacturing

Equipment Commissioning: Commercial-Scale Spray Dryer Now Operational

Asymchem has successfully commissioned **the PSD-2 large-scale spray dryer** at its dedicated TIDES facility, significantly expanding commercial-scale GMP manufacturing capabilities for TIDES therapeutics. Built on a proven, high-performance spray drying platform, the system delivers precise control over **particle size distribution** and **bulk density** to ensure optimal product quality and yield. With an exceptional output capacity of up to **30 kg/day**, this addition drastically increases throughput, meeting the growing market demand for enhanced bioavailability and large-scale TIDES production.



Celebrating BMS's 2026 Peter J. Dunn Award

Asymchem extends its warmest congratulations to Bristol Myers Squibb (BMS) on receiving the prestigious **2026 Peter J. Dunn Award for Green Chemistry & Engineering Impact (Small Molecule Category)**. Asymchem's Center of Synthetic Biology Technology (CSBT) is incredibly proud to have partnered with BMS on this award-winning collaborative project.

Working in close alignment, the joint team successfully re-engineered the manufacturing route for **a next-generation tyrosine kinase inhibitor API**. By combining BMS's visionary process goals with Asymchem's advanced technology platforms, the collaboration delivered profound sustainability and efficiency gains:

A **4-fold** yield improvement

A reduction in isolation steps from **10 down to 6**

The complete elimination of **dioxane** and **all halogenated solvents**

Biocatalytic Innovation: Deployed a **2nd-generation enzymatic route** for a key raw material, replacing harsh chemical steps with clean, renewable technology.

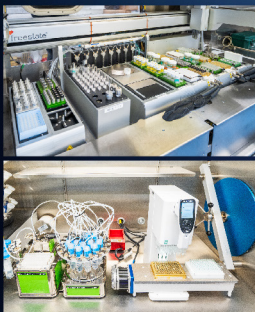
These process advancements drove a **43% to 73% reduction** across key lifecycle assessment (LCA) metrics. This recognition highlights the power of strategic partnership and underscores our shared commitment to integrating sustainable design with cutting-edge process innovation in pharmaceutical manufacturing.

Data-Centric Process Design: A Systematic Framework for the Design of Robust Commercial Pharmaceutical Manufacturing Processes

At Asymchem's Sandwich site, we implement **Data-Centric Process Design** to advance synthetic routes into commercially viable manufacturing processes. Leveraging our advanced technologies and deep expertise, our matrix teams take a holistic approach to designing robust processes that meet established **SELECT** criteria.

1. Planning

Collaboratively define project scope and identify key drivers specific to the target compound and client to guide decision-making.



2. Fundamental Data Generation

Utilize **state-of-the-art high-throughput experimentation platforms** to rapidly generate core data that underpins effective process design:

- Solubility
- Reaction screening
- Kinetics
- Liquid-liquid extraction screening
- Solid form screening



3. Process Design

- Leverage fundamental data to brainstorm vision processes from the ground up.
- Engage matrix teams to secure subject matter expert input from process genesis.
- Refine process design through practical evaluation guided by data and client drivers.
- Simultaneously develop process and analytical methods in a harmonized approach to build towards the control strategy.



4. Process Confirmation

Critical assessment of the lead process for commercial suitability, early risk identification, and thorough documentation of the development chronology and decision-driving factors:

- **Robustness assessment** of key transformations (including DoE) to ensure a suitable operating space.
- **Engineering and scale-up assessment** through practical and in silico approaches.
- **Stability and hold-point studies** to demonstrate robustness of key unit operations and manufacturing flexibility.
- **Small-scale demonstration** of the final process to author the technical package and process description.

CASE STUDY: Commercial Process Design

Initial Process



Final Process



Yield

51%

77%

39% increase

PMI

183

50

73% decrease

Unit Op's

14

9

36% decrease

Analytical
Methods

18 Developed

Scope of Work:

- Nominate the optimum SM1
- Identify an SM3 analogue with superior physical and processing properties
- Avoid isolation of solvated form of A
- Deliver a safe, efficient, and robust process
- Develop analytical methods for SM's, IPC's and isolated compounds
- Establish an impurity map to support the control strategy
- Execute a demo lab run and author the technical package