Industry
Pharmaceutical

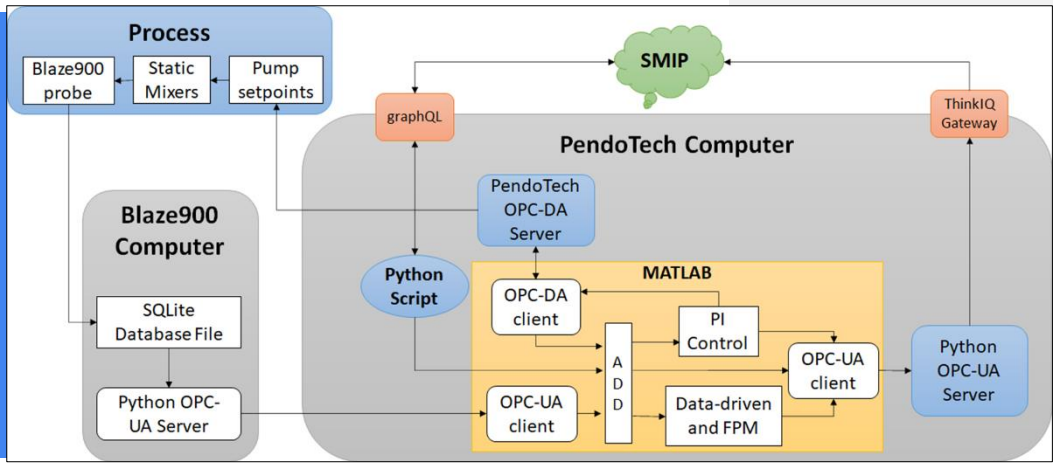
Applications
Data Modeling
Data Analytics

Solutions
Operational Efficiency

CESMII
THE SMART MANUFACTURING INSTITUTE

PROJECT CASE STUDY

Smart Downstream Processing of Monoclonal Antibodies



PROJECT LEAD

RPI

PROJECT TEAM

Penn State, Johnson & Johnson/Janssen Pharmaceuticals

PROJECT OBJECTIVE

Implement a novel antibody purification process that utilizes precipitation and dewatering. The process controls and predictive models for the new process will be implemented on the CESMII Smart Manufacturing Innovation Platform (SMIP).

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Experimental Pharmaceutical Production Process Reduces Raw Material and Water Consumption by 50%

BENEFITS TO OUR NATION

Improving pharmaceutical manufacturing operational efficiency leads to increased production capacities and reduced operating costs, enabling pharmaceutical companies to make medications more affordable and accessible to patients across the nation. Advancing pharmaceutical manufacturing processes not only supports American public health, but also strengthens the nation's position as a world leader in pharmaceutical manufacturing.

BENEFITS TO INDUSTRY

Reducing raw material and water consumption in pharmaceutical manufacturing reduces the sector's carbon footprint and enhances its reputation with consumers. Implementing eco-friendly production practices aligns with the growing global demand for environmentally responsible products, giving pharmaceutical companies a competitive edge. Improving cost-efficiency also yields higher profit margins and enables pharmaceutical companies to reinvest in research and development, contributing to the long-term growth of the industry.

PROJECT DESCRIPTION

TECHNICAL APPROACH

- Develop empirical models for precipitate and dewatering processes
- Install sensing/measuring instruments on precipitation and dewatering equipment modules
- Develop model-based feedback control of precipitation module
- Develop model-based feedforward control of dewatering module
- Create Module Smart Manufacturing Profiles
- Integrate edge devices with Smart Manufacturing Innovation Platform (SMIP)

ACCOMPLISHMENTS

- Developed SM Profile for the precipitation module.
- Developed SM Profile for the dewatering module.
- Demonstrated precipitate particle morphology and critical filtration flux prediction models in the Smart Manufacturing Innovation Platform (SMIP) environment.
- Implemented model-based controls using the CESMII Smart Manufacturing Innovation Platform.

DELIVERABLES

- Delivered Precipitation Module SM Profile
- Delivered Dewatering Module SM Profile
- Delivered Precipitate Morphology Model
- Delivered Critical Flux Model

REUSABLE OUTCOMES / SM MARKETPLACE

- Precipitation Module SM profile
- Dewatering Module SM profile
- Precipitate Process Model
- Dewatering Process Model

RESULTS

↓ 50%

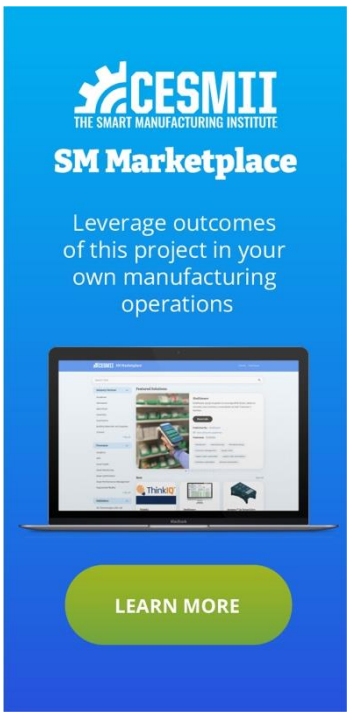
Estimated 50% reduction in raw material costs when implementing new precipitate and dewatering process.

↓ 50%

Estimated 50% reduction in water consumption when implementing new precipitate and dewatering process.

↑ 3X

Estimated 3X increase in volumetric throughput when implementing new precipitate and dewatering process.



PROJECT DETAIL
Budget Period: BP4 – BP5
Submission Date: 02/26/2023
Sub-Award (contract) Number:
4550 G ZA025
SOPO: 2339

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