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MAKING PLANTS  
SMARTER AND SAFER

## **FALCONEER™ IV Suite**

### **FDA's Process Analytical Technology Initiative**

FALCONEER Technologies provides control software and technical services for process control systems over a wide range of industries. Target industries with respect to the Process Analytical Technology (PAT) initiative include pharmaceutical and food manufacturing companies. The goal of FDA's PAT is "to understand and control the manufacturing process, which is consistent with the current drug quality system: ***quality cannot be tested into products; it should be built-in or should be by design.***"

### **Our Technology, FALCONEER™ IV is Process Analytical Technology:**

- FALCONEER™ IV is an integrated system for analyzing and controlling manufacturing through timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality.
- FALCONEER™ IV is a real-time process monitoring & diagnostic tool that provides an effective and efficient means for:
  - acquiring & reporting information to facilitate process understanding,
  - develop risk-mitigation strategies,
  - achieve continuous improvement, and
  - share information and knowledge.
- FALCONEER™ IV incorporates data acquisition and analysis tools, process and endpoint monitoring and control tools, continuous improvement and knowledge management tools.
- FALCONEER™ IV may be applicable to a single-unit operation, or to an entire manufacturing process and its quality assurance.

An achievable goal using FALCONEER™ IV within the PAT framework is to provide real-time information from existing processes to consistently ensure a predefined quality at the end of the manufacturing process. Our technology is consistent with the basic tenet of quality by design and could reduce risks to quality and regulatory concerns while improving efficiency. Gains in quality, safety, and/or efficiency will vary depending on the product and are likely to include the following:

- Prevent rejects, scrap, and reprocessing.
- Reduce the likelihood of real time releases.
- Increase automation to improve plant safety and reduce human error.
- Facilitate continuous processing to improve efficiency and manage variability.
  - Applicable to both small-scale equipment (to eliminate certain scale-up issues) and dedicated manufacturing facilities.
  - Improving energy and material use and increasing capacity.