

Process Analytical Technology (PAT) Services

Specialized PAT Solutions for the Biopharm Industry

Foster Wheeler Biokinetics possesses a multi-disciplined staff of engineers with expertise and a targeted tool set in the realm of Process Analytical Technology (PAT). PAT is defined as a system for designing, analyzing, and controlling manufacturing through timely measurements of critical quality and performance attributes of raw and in-process materials and processes, with the goal of ensuring final product quality. By utilizing the concepts of PAT, Foster Wheeler Biokinetics engineers can work with manufacturers to gain a thorough understanding of their process, and therefore consistently ensure a predefined quality at the end of the manufacturing process.

Benefits include:

- Reducing production cycle times by using on-, in- and/or at-line measurements and controls
- Preventing rejects, scrap, and re-processing
- Releasing product in real-time
- Increasing automation to improve operator safety and reduce human errors
- Improving energy and material use while increasing capacity
- Facilitating continuous processing to improve efficiency and manage variability

CONSULTING SERVICES

Foster Wheeler Biokinetics is capable of providing consulting services across the broad spectrum of PAT. These include:

- **Development of PAT “Master Plan”**

Foster Wheeler Biokinetics will work with your organization to develop a philosophy for addressing PAT needs and selecting appropriate projects.

- **Application of On-Line Measurement Tools**

Foster Wheeler Biokinetics is an industry leader in the specification and integration of proven on-line sensor and analyzer technology. Our engineers have the expertise to select and

implement the ideal on-line solutions to provide real time measurement in your application.



- **Application of Process Control Tools**

Our engineers are experts in the design of control systems to provide the appropriate level of instrumentation, automation, archiving and reporting to ensure complete control of all critical attributes.

- **Statistical Analysis**

The availability of data and the use of computer-based statistical tools, including multivariate analysis, when combined with our process engineering expertise and knowledge, results in a unique and effective problem solving approach for our clients.

- **Development of DOEs**

Basic design of experiments is an essential part of the PAT procedure. Our engineers will strategically plan and execute experimental designs to reveal the true controlling factors in your process.

- **Identification of Critical Quality Attributes (CQAs)**

The identification of CQAs is the cornerstone of any PAT process. Our engineers are experts in biopharm processing and have experience with the CQAs that drive your process.

Process Analytical Technology (PAT) Services

- **Process Simulation**

Our simulation tools allow for the modeling of your systems in order to enhance process understanding and identify areas for process improvements.

- **Continuous Improvement & Knowledge Management**

Our PAT approach results in an enhanced level of process understanding giving us the capability to lead or assist our clients in predictive continuous improvement programs based on solid operating data and the ongoing management of the evolving knowledge base.

- **Risk Assessment**

Foster Wheeler Biokinetics has expertise in a myriad of risk assessment tools, including FMEA, HACCP, and cGMP analysis.

FOSTER WHEELER BIOKINETICS EXPERTISE

- Implementation of Statistical Process Control (SPC) methods related to PLC and DCS systems
- Specification and implementation of proven on-line analyzers to replace outdated off-line methods.
- Use of statistical analysis to pinpoint critical quality attributes, analyze operations and solve operational problems
- Utilization of risk assessment methods to evaluate the risks associated with potential process changes

- Process improvement studies such as FMEA analysis of automated process systems and implementation of Six-Sigma
- Macro level process simulation modeling to identify the capital and operating cost savings associated with the implementation of on-line sampling and real-time release
- Utilization of numerous process and unit operation modeling software packages

PROJECT APPROACH

The Foster Wheeler Biokinetics approach to PAT is to apply our process expertise and the appropriate elements of our “tool set” to the challenge at hand, resulting in a solution to current challenges and a roadmap for future performance enhancements. This method allows us to tailor a solution that is optimum for your process needs.

Using the PAT Master Plan Framework and the targeted tool set, the Foster Wheeler Biokinetics team will compile a package to address the your specific needs. A typical package would include a reviewed and approved PAT Master Plan, a data summary report following historical data review presenting conclusions and recommendation for further development, recommendations for additional process instrumentation/controls, and details of additional tests performed required with results and a summary.

CONTACT US

For more information, please contact FW Biokinetics at 215.656.2500, or Email us at info@fwbiok.com, or visit our website at www.fwbiok.com.

