



# Process ANALYTICAL TECHNOLOGY Implementation

Tunnell Consulting is responding to the FDA's vigorous interest in robust product and process reliability by implementing integrated PAT strategies that fully respond to regulators' demands. Our structured PAT approach includes five key elements: a focused vision and strategy, identification of critical process parameters, development of advanced on-line analytical technology, data integration, and essential organizational change.

## Key Elements of a Robust PAT Initiative



## Our Integrated PAT Strategy Reflects the Benchmark FDA View

“ It is important to note that the term *analytical* in PAT is viewed broadly to include chemical, physical, micro-biological, mathematical, and risk analysis conducted in an integrated manner. ”

– PAT Draft Guidance  
August 2003

## Our PAT Strategy Delivers:

Improved process capability and control

Identification of critical sources of variation

Reduced compliance risk

Improved management problem solving

Development of data-driven decision making

Creation of a continuous improvement culture

Tunnell Consulting will partner with you to facilitate a customized PAT solution that becomes a competitive advantage. Our integrated approach will enable you to do the following:

#### DEVELOP A PAT VISION AND STRATEGY



Create a compelling PAT vision that mobilizes and aligns your organization, and a strategic plan that integrates the critical goals of key functional groups.

#### DEFINE CRITICAL PROCESS PARAMETERS



Identify critical parameters that drive variation through the use of tools such as regression analysis, design of experiments (DOE), and capability analysis, and develop and implement variation reduction strategies.

#### IDENTIFY AND DEPLOY ANALYTICAL TECHNOLOGY



Define your data requirements, and develop and apply appropriate on-line, at-line, and in-line analytical technology.

#### CREATE A DATA MANAGEMENT INFRASTRUCTURE



Design a data collection, analysis and reporting strategy, and an information system framework, to maintain improvement gains and secure real-time response.

#### ENSURE ORGANIZATIONAL SUSTAINABILITY



Recognize that PAT will change organizational dynamics. Tunnell Consulting provides experts and tools to maximize and sustain the change.

## Our Pharmaceutical Clients Include:



Wyeth



Johnson & Johnson



NOVARTIS

Schering-Plough

## About Tunnell Consulting

Tunnell Consulting integrates technical, process and organizational skills to boost the operating performance of manufacturing and service firms with a focus in the pharmaceutical industry. We implement value-added, cost-effective solutions that fit the unique needs of each client we serve.

