

# New England Biopharma 2008, January 24, 2008

## Title:

**Process Analytical Technology (PAT) / Quality by Design in the biopharm area and their benefit for process development and product quality**

## Presenting Author

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## Biography / Professional experience:

**Ingrid** is responsible for innovative technologies, including Process Analytic Technology (PAT), within the Siemens Headquarter Competence Centre Pharma, located in Antwerp (Belgium). She obtained a Master degree in Chemical Engineering, and in biotechnology & medicinal chemistry, from the University of Brussels. She has worked for 15 years in Process Analytics and Multivariate Data Analysis as marketing & sales manager, and for developing new application fields for Process Analytics and control, in many industrial branches. She is author of many presentations at international conferences. She is also involved in various PAT related organisations, such as Executive Committee member of ASTM E55 (Pharmaceutical Manufacturing) and the ISPE PAT Interest groups (SIG). She has presented at the FDA inspectors and reviewers training in Washington.

## Abstract:

This presentation describes several applications of PAT and QbD approaches in bio process development and manufacturing for (1) monitoring, (2) controlling, (3) real-time release and (4) optimization. Examples from various cases will be presented.

### Presentation topics:

- *PAT is more than just monitoring*
- *PAT benefits and regulatory approaches*
- *Measuring what and how? Some examples on new process analytic (PAT) concepts for bioprocess monitoring, Design of experiments, multivariate data analysis*
- *Advanced Process Control and real-time product release*
- *PAT as part of the manufacturing and development architecture*
- *PAT and PLM as a continuous process understanding and improvement tool*
- *PAT implementation roadmap*

Participants will gain valuable insight and a useful roadmap for leading their organizations to make the necessary changes for PAT and QbD.