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## **Application of PAT in Pfizer Global Manufacturing**

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The Pfizer Global Manufacturing organized NIR team in 1998 and, from early 90's, started to apply NIR for the testing of raw materials, in-process materials and finished products, as the management team recognized that the application of NIR could provide many benefits, such as rapid analysis, accurate result and cost savings.

Furthermore, one of key business objectives of the company is "Premium Product Quality", and the management team realized and believes that the objectives could be achieved effectively through the application of NIR in the business.

Through the application of NIR, the tests and processes could be more robust and simple, data and documents become more organized and reliable, human error, such as sampling and testing error could be minimized, and continuous quality verification could be achieved effectively in a short time frame.

In early stage of the application, the company applied NIRs for the testing of raw materials, packaging materials, in-process materials and component analysis including supplier validation and material screening to replace wet conventional test up to early 90's. However, the application range of NIR became extended step by step, but very rapidly, up to in-line, at-line and on-line application, which could scope process control including process analysis technology (PAT) area.

At Pfizer, the management believes that PAT can improve process knowledge and this knowledge can be leveraged to identify and eliminate sources of variability and, thereby, enhance the reliability of product performance and product quality. At Pfizer, we define PAT as an enabling tool to accomplish the key strategic manufacturing objectives of Quality by Design and Right First Time. In company's terminology, right first time is largely synonymous with programs like six sigma and total quality management. To place Right First Time and PAT terminologies, PAT can be a key tool for reducing variation of the manufacturing process.

We use PAT to characterize, understand and control our incoming raw materials, the behavior of these materials during processing by monitoring in-process parameters as well as finished product parameters. Using this knowledge, we determine the attributes that are critical to quality (CTQ) in two ways: (1) establishing the correlation between critical process parameters and CTQ attributes, and (2) by design of experiments to establish a clear cause and effect matrix between process parameters and CTQ attributes.

Once the relationships and process understanding are established, PAT can be used to remove or control unwanted variation in CTQ parameters. In so doing, the risk of the process to product quality is mitigated and the specific information about process itself is provided.