Understanding PAT and QbD: with illustrations from major pharmaceutical companies

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A current trend among FDA (USA), EMA (Europe), and major pharmaceutical companies is transition from end-product oriented quality assurance to quality management of entire manufacturing processes. In this respect, Process Anslytical Technology (PAT) and Quality by Design (QbD) have been introduced and studied recently. According to FDA, PAT is a system for designing, analyzing, and controlling manufacturing processes through timely measurements (i.e. during processing) of critical process parameters and performance attributes of raw and in-process materials and processes with a goal of ensuring final product quality. In this presentation, concept and applications of PAT and QbD will be illustrated through industrial case studies in major pharmaceutical companies.