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QbD on the Menu at CPhI Mumbai: Industry Savings of $200 Billion Possible

Girish Malhotra, President & Founder, Epcot International

The air was full of three-letter acronyms at CPhI's recent conference on process analytical technology (PAT) and quality by design (QbD) in Mumbai. QbD even found its way to the dessert trays.

Malhotra was in Mumbai to lead a session and to present two papers on important topics: Using QbD to Improve API Manufacturing and API Process Simplification. His presentations included real-world data and examples of APIs and the processes used to make them. One major quality obstacle has been the fact that processes for new APIs must be shoehorned into manufacturing equipment that often is not optimized for them. This results in inefficiency, he said.

Some highlights from his papers: Pharma is still mired in a quality-by-analysis mindset, and it passes on the cost of inefficiency. Since the public is willing to pay a premium, and profits are still strong, many manufacturers ask why they should change the way they do things.

Unfortunately, this has resulted in lack of command over processes, as well as manufacturing and supply problems. The industry still suffers from low process capability, he said, citing figures from a 2001 (pre-PAT) FDA Science Board meeting.
Utilization levels are 15 percent or less. Scrap and rework are routinely planned at 5-10 percent, and the cost of quality is more than 20 percent. Savings from QbD could exceed $160-$200 billion a year for name-brand and generic drug manufacturing, Malhotra said.

In addition, lack of "first-pass" quality lowers overall industry profits by 20-25 percent. He cited the example of Nevirapine; the variability in its prices stems from the fact that it has too many plants and focuses on batch processes and quality by analysis.

In his presentation on API simplification efforts, Malhotra discussed the economic benefits of reducing process steps and taking such basic measures as minimizing solvent and reducing raw material requirements. He cited both Modafinil and diazo compounds. The industry continues to use low-temperature processes for these, he said, even though advanced heat exchange technology is available.

29150 Bryce Road
Pepper Pike, OH 44124
USA

girish@epcotint.com
216-223-8763;216-292-0626(W)
(216)-292-0626(F)