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## Quality is Key

CPhI experts make predictions on pharma trends for 2015.

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By PharmTech Editors

CPhI Worldwide has released its expert panel projections for the pharmaceutical industry in 2015. With quality constantly being the main emphasis in this highly regulated industry, it comes as no surprise that companies are widely adopting quality by design (QbD) and process analytical technology (PAT) in their processes. CMOs and generic drug companies, in particular, are actively implementing these approaches as a means of providing a competitive edge.

"Smart operation of multipurpose plants, continuous improvement of the current processes, permanent investments in technology, people, and cGMP compliance without compromise will guarantee the existence of the European API producers and key for their success," notes Hendrik Baumann, CEO of Arevipharma GmbH.

There is a strong move towards continuous manufacturing and FDA's role is evolving from being merely an "investigator" of products to an "enabler of better quality processes and cultures within pharma manufacturing. According Prabir Basu, consultant at Pharma Manufacturing, regulators will be expected to provide some guidance on the regulation of continuous manufacturing.

FDA will continue to emphasize on quality metrics. Girish Malhotra, president of EPCOT International, however, points out that the industry is still in its "regulation-centric" mode despite the benefits of "process-centric" methodology. API manufacturers, for example, will need to review its current model and practices and start embracing QbD and PAT. Brian Carlin, director, Open Innovation, FMC, adds that more attention should be given to the impact of raw material variability on the quality of finished pharmaceutical products.

Hedley Rees, managing consultant at PharmaFlow, commends FDA's launch of the new Office of Pharmaceutical Quality, "which will provide the much needed focus and integration in the US regulatory process and therefore drive drug developers and manufacturers to design quality into their products at a much earlier stage."

Source: CPhI Worldwide

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