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CPhI Annual Report 2019- FDA should withdraw ANDAs

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Pharma 4.0 will bring transformations from molecule to medicine, but how quickly they can be implemented depends on pharma's ability to pick the right objectives

CPhI Worldwide – the world's largest pharma event taking place in Frankfurt (5th-7th November 2019) – has released the first part of its eponymous 2019 Annual Report. Experts Bikash Chatterjee, President and Chief Science Officer at Pharmtech Associates and Girish Malhotra, President of EPCOT International discuss how manufacturing could be revolutionised by new technologies, but warn, that regulators must change to prevent hindering future innovation.

Bikash Chatterjee forecasts a positive outlook for the medium and long-term future of the industry, foreseeing that Pharma 4.0, the Internet of Things, and Artificial Intelligence could ultimately deliver huge shifts in how we discover and develop medicines – even if the short term applications may not bring the results people are striving for.

"There is no doubt we will see broader adoption of IoT on the shop floor and in the distribution portion of the supply chain in the short term. The biggest impact operationally, I believe, will be seen in the clinical trial management stage of the drug development lifecycle, over the next five years. However over the next decade, AI could have a transformational impact on molecular selection and design," commented Chatterjee.

Despite the call for these advances, Chatterjee emphasizes that such improvements within the industry will not come about unless they are used in the right way, and address the right questions. He forewarns,*"the focus on technology in the absence of understanding the basic question to be answered can derail a cross-functional initiative in the blink of an eye".*Chatterjee also calls for both AI and pharmaceutical companies to gain a better understanding of each other's fields in order to expedite the process of disruptive technology adoption.

"The challenge with anything new in our industry is that the organisations selling into life sciences don't know drug development, and the drug sponsors interested in AI don't really understand AI, so they cannot direct the solution provider very effectively. As this knowledge gap dissipates through experience on both sides, more effective pilot projects and solutions will be developed and brought to term" says Chatterjee.

Moving into the longer-term future, Chatterjee envisages AI being used to deliver significant changes in therapies by 2040, when 'it will be standard practice in the design of drug therapies, their processes and in the treatment of disease'. He predicts that ultimately this will mean personalizing dosing and drugs regimens designed around each patient's genetic markers and circumstances.

Malhotra explores the cost of manufacturing globally and the still high levels of regulatory infringements, postulating that regulators should use powers to remove ANDAs for repeat offenders. *"With USFDA being short staffed, even the use of 'risk-based inspections' may be insufficient to catch less than quality/cGMP producers"* speculated Malhotra. Adding *"repeated non-compliance to FDA's requirements and guidelines should be a cause to forbid shipments to the United States."*

Additionally, he suggests a 90-day approval process, which will necessitate that companies filing applications have complete command of every facet of manufacturing, product quality, and labeling.

Taking this a step further, he also advocates enforcing mandatory deposits (circa $200,000) for first deviation from FDA's expectations, with forfeiture of the deposit and, ultimately, being barred from importing into the United States should further problems occur.

Fundamental to Malhotra's regulatory proposals is the proposition that governing bodies should stick to enforcement - not preach to the market on how best to implement manufacturing processes. He added: *"Pharma has not explored increased profitability through continued process improvements and my conjecture is that the regulators are the obstacle to this. The FDA should refrain from suggesting to companies what types of manufacturing processes (batch or continuous) they need or practice, instead they should concentrate on helping ensure manufacturing processes are repeatable using continuous improvement principles."*

CPhI Brand Director Europe, Orhan Caglayan, commented: *"The CPhI Annual Report highlights the key issues and trends affecting the industry. Our experts explore the benefits of streamlined regulations and how technology could deliver tremendous improvements across the supply chain. Significantly, this year is also CPhI Worldwide's 30th anniversary, which provides us with an opportunity to reflect on both how far the industry has come during this time, as well as where it is heading in the years to follow. With over 45,000 executives attending, our event is designed to help meet new partners and drive forward innovation. By bringing the supply chain together - from APIs and FDF, to machinery, packaging, outsourcing and, biopharma,– we enhance the industry's ability to find new cost-effective solutions and learn about new developments that will sustain growth in the year ahead".*