Pharmatechs Chatterjee: Drug Manufacturing in the Future

It is an interesting proposition: define what drug manufacturing will look like 20 years from now. There has never been a time when the portent for change has been so imminent.

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While the U.S. market experiences unprecedented contraction in the marketplace to bolster its drug portfolios without taking up the risk of cost of development, emerging markets are already beginning to flex their muscles in a race to establish themselves as viable players in the global marketplace.

The status quo is in flux and the future of drug manufacturing has never been more unclear. As China braces for a bold step forward by rolling out their own new cGMP guidelines, based heavily on the European and ICH standards, it remains to be seen whether they can make the jump to a global quality mindset. Will the emerging markets make the adjustment to compete on a playing field where quality and cost are equally important?

So, what will the future of drug manufacturing look like? As an industry, we have always pursued new technologies to complement proven manufacturing principles. The emphasis on scientific-based product development in lieu of regulatory oversight has certainly given us incentive enough to explore the envelope and balance quality with productivity. If we start with the drug manufacturing supply chain, I believe Asia and Eastern Europe will become the primary suppliers of API to the industry. However, the risk of adulteration will not be mitigated through a newfound acknowledgement of the quality paradigm by the East; rather, technology will provide the basic assurance and the necessary control.

Information systems infrastructures will become the backbone for a global manufacturing strategy. API processes will utilize in-line control architecture to provide manufacturing process data, IR fingerprints and a full Bill of Material for each batch manufactured. This data will be available electronically as a digital certificate for each lot manufactured. Cost savings will be achieved through lower capital costs for automation: not cheap labor. All lots will be shipped in container systems that will monitor location, chain of custody and all interventions of each shipment. This data will be secured through state-of-the-art encryption technology. In terms of manufacturing, there will be a shift to intensive characterization of both API, excipient and primary packaging components to replace time-consuming and resource-intensive end-product testing.

Several technologies in particular will take the place of conventional analytical technology solutions used today. Raman Spectroscopy will become standard in lieu of HPLC for stability testing because of its ability to identify both primary API structures as well as their degradation products quickly and easily. Similarly, Raman Spec will be used to confirm laminate structure and integrity in laminate systems used for primary packaging or as a troubleshooting diagnostic aid.

The use of Near-Infrared Spectroscopy (NIR) will become routine for API material receipts as an incoming quality control verification for the API structure and its polymorphs. NIR has proved to be very accurate when compared to current UV and HPLC methods to measure overall drug potency and provide an instantaneous verification during the manufacturing process.

Inductively Coupled Plasma Mass Spectrometry (ICPMS) will be commonplace, both on the shop floor and in the laboratory, for its ability to detect minute quantities of non-metallic substances such as

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magnesium stearate. This technology will allow us to quickly and definitively identify differences in individual tablets that are having dissolution problems.

Sieve tests will become obsolete and will be replaced by CCD-based vision systems that allow rapid nondestructive measurement of the raw material and granulation samples.

Our industry has always been slow to adopt technology on a large scale. Even so, most brand pharmaceutical companies have PAT initiatives underway and many have taken advantage of the expedited regulatory review of PQAS that PAT offers. I believe this will only increase, not because we will suddenly change our thinking in terms of manufacturing, but because the marketplace will leave us with no other choice. To compete, brand and generic companies will have to manage the bottom line with a profound emphasis on Cost of Poor Quality. Leveraging low cost API manufacturers overseas, employing contract manufacturing organizations to minimize capital requirements and integrating automation as a part of well understood processes and well designed facilities will continue. They have become essential to viability.

In our time, the transformation to Quality by Design is nascent at best, but through the adoption of new technology, our industry will become more nimble and competitive without unnecessarily driving up the risk to consumers.

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