

The *Journal of Pharmaceutical Innovation*: an innovative, consensus-building tool for the 21st century

Ajaz S. Hussain

Vice President and Global Head of Biopharmaceutical Development, Sandoz, 506 Carnegie Center, Princeton, NJ 08540, USA, ajaz.hussain@sandoz.com.



It is an honor and a privilege to contribute a perspective on pharmaceutical innovation in the launch issue of the *Journal of Pharmaceutical Innovation* (JPI). This Journal is on the verge of becoming a unique forum for international scientific peer-reviewed publications of research and review articles and will emphasize new and innovative methods and techniques used by pharmaceutical professionals serving all aspects of the industry, including manufacturing, control, and applied pharmaceutical science and technology in process and product understanding.

In some aspects, JPI derives its inspiration from the FDA initiatives on Process Analytical Technology (PAT), current Good Manufacturing Practices (cGMPs) for the 21st Century, and the Critical Path Initiative. Through these initiatives, regulators have emphasized the need for innovation, identified some of the reasons why innovation is hampered in the pharmaceutical sector, proposed a framework for enhancing innovation, and recognized the challenge that the pharmaceutical community faces in the journey ahead toward the desired state of pharmaceutical manufacturing.

For example, [as stated in the FDA PAT Team and Manufacturing Science Working Group Report (<http://www.fda.gov/cder/gmp/gmp2004/manufSciWP.pdf>):

- “The health of our citizens depends on the availability of safe, effective and affordable medicines. In the future, pharmaceutical manufacturing will need to employ innovation, cutting-edge scientific and engineering knowledge, and the best principles of quality management to respond to the challenges of new discoveries (e.g., complex drug delivery systems and nanotechnology) and ways of doing business such as individualized therapies or genetically tailored treatments.”

Concludes on page 10.

- “Pharmaceutical manufacturing operations are inefficient and costly. The cost of low efficiency is generally not understood or appreciated (e.g., manufacturing costs far exceed those for research and development operations). Low efficiency is predominantly due to ‘self-imposed’ constraints in the system (e.g., static manufacturing processes, focus on testing as opposed to quality by design, approach to specifications based on discrete or the so-called ‘zero tolerance’ criteria, a less than optimal understanding of variability, etc.). These constraints keep the system in a corrective action mode.”
- “The combined work products of the cGMP Initiative are positioned well to provide a comprehensive set of regulatory tools to facilitate a move towards the desired state. Only companies that achieve a high level of process understanding will have the opportunity to use their information to justify a more flexible regulatory path towards continuous improvement.”
- “Although to a large degree consensus has been established on the ‘desired state’, it should be noted that there is often a tendency for a consensus on collective ends to attenuate when specifics are addressed. This is often due to divergent understanding of the problem being addressed and/or differences in interests and/or issues in representation of the problem being addressed.”

JPI has an opportunity to help with the implementation phase of these initiatives, mapping and guiding the journey of the pharmaceutical community toward the desired state. Among the various topics the Journal will choose to address, it is my humble request and hope that the Journal will strive to be the peer-reviewed source of high-quality scientific data, information and knowledge that promote common understanding among the various scientific disciplines that come together to become the pharmaceutical community. I also hope that it will help to articulate a clear, common representation of the problems faced by our community that need to be addressed. The public-health objectives and responsibilities that lie on our shoulders should be reiterated and emphasized as often as necessary. In doing so, JPI will challenge the notion that the established consensus on the ‘desired state’ might attenuate when the specifics of this consensus are addressed. [JPI](#)