Point of View: Gauging Regulatory Effectiveness

Bikash Chatterjee

That the pharmaceutical and biotech industry is in a state of flux is undeniable. Shifts within the U.S. marketplace have intensified the pressures on industry to perform, while the FDA has been struggling with its own charter. For both industry and regulatory, their raison d'être is clear. Each must find a way to make sure the drug therapies approved for the public are safe and efficacious, and they must do it efficiently. The FDA's effort to focus on scientific rigor rather than compliance overhead is well underway. Hiring and training new compliance inspectors armed with statistical tools to evaluate ICH Q8 and Q9 quality risk management approaches is off to a good start. Even so, it is difficult to say that change is coming fast enough, or that it is having the desired effect on industry. The proposed new Process Validation guidance is probably the most significant and tangible step to drive process design further upstream in the development process. However, as we sit here today, we find ourselves falling short.

The FDA first got industry's attention that things were going to change when it issued the 21 CFR Part 11 guidance. Industry backlash was so profound that the agency was forced to admit it had made a mistake, yet the guidance has not been formally replaced, and compliance officers are still inspecting against the original guidance. Now the agency has issued the new Process Validation guidance for comment, eliciting a huge response from industry. To date, there is no formal plan for integrating and reissuing a new guidance, once again leaving industry in limbo. In the meantime, consumer confidence in the safety of our drugs is waning, with a series of high profile product recalls and news about drug therapies that are being reexamined and found to be either ineffective or dangerous. For the FDA to be effective and industry to be successful, regulatory guidance and industry best practices must be aligned. Only then can we ensure the public safety both sides want, while catalyzing the business performance both sides sorely need. I believe the time of tolerance for silos of understanding has passed. If industry and the agency are to succeed, compliance assessments and Compliance and Regulatory practitioners must delve deeply into scientific understanding with the conscious recognition of its potential benefits to business performance. Compliance as a documentation exercise is no longer good enough, and the sooner the FDA embraces its own mantra through more comprehensive product development understanding amongst its inspectors, the sooner industry will move to begin its transformation in earnest.

Bikash Chatterjee is a regular columnist for Controlled Environments Magazine. To see his Regulatory Forum columns go to: cemag.us

A cleanroom is an environment, typically used in manufacturing or scientific research, that has a low level of environmental pollutants such as dust, airborne microbes, aerosol particles and chemical vapors.

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