The premise of Bill Gates’ 1999 book, “Business @ the Speed of Thought,” is that ever-evolving technology improves business practices today and will soon transform the very nature of business. The book offers a framework for how business leaders can think about and use technology to improve their practices and boost the growth and success of their companies. But the key message is speed. Speed in thought, speed in innovation, and speed in action.

In today’s pharmaceutical industry, we see speed increasing in production, packaging, and inspection. Increased production speed brings with it the need to increase quality and innovation, and quality improvements are driven by consumers and by regulations, either from government or from trade groups. A turning point in consumer-driven quality came in 1982 when lethal tampering led a Johnson & Johnson subsidiary to recall more than 30 million bottles of Tylenol, the company’s entire production. For Johnson & Johnson, which was not responsible for the tampering, the recall was the right thing to do, and it served the public good. We still have recalls today, some for mold in injectables and others for glass particles in capsules or for oversized (super-potent) tablets. Recalls are a public admission of problems and of the actions companies are taking to correct them. They heighten the public’s awareness, and that, in turn, leads to major increases in quality, safety, and innovation in all facets of pharmaceutical manufacturing. It also leads to government and self-regulation. Here are three examples.

1. At a July 2003 meeting, industry representatives and quality authorities from the International Conference on Harmonization (ICH) agreed on this goal: “A harmonized pharmaceutical quality system applicable across the lifecycle of the product emphasizing an integrated approach to risk management and science.” In order to develop a modern pharmaceutical quality system, the group focused on two topics: 1) Pharmaceutical Development (ICH Q8) and 2) Quality Risk Management (ICH Q9). Guidelines addressing those topics were published in 2006 in the three ICH regions.

2. The FDA is pursuing more Quality-by-Design initiatives. “In an effort to reduce public health issues due to poorly manufactured drugs, a change in mindset will take place to identify sources of risk in the process,” one FDA observer predicts.

3. The FDA and European organizations are sponsoring training on ICH Q10, which offers a comprehensive model of a pharmaceutical quality system.

Paramount to meeting these quality goals is innovation, something the pharmaceutical industry and its suppliers know well. At our company, innovations include novel concepts in capsules such as sustained-release delivery, dry powder inhalation, and gelatin that eliminates cross-linking. We’ve also adopted color inkjet printing and laser printing, which allows application of complex characters/symbols and QR/bar codes that prevent counterfeiting. In fact, today’s capsules accept printing on all surfaces: shoulders, domes, and sides.

Innovation in inspection includes machine vision so accurate that it can, in theory, reduce the error rate to zero. But inspection systems require more than just acute vision. They must also provide automatic feedback and integrate with capsule fillers. At our manufacturing sites, the technology enables us to operate in real time and check all capsules at various times as we make them.

Innovation and speed are also found during pre-commercialization and commercialization of drug products. By using capsules that contain multiple colorants during development, today’s formulators can advance their projects without having to select the capsule’s final trade dress until much later in the process. That means the heavy lifting of Phase I can start earlier.

One innovation—band-sealing—may have prevented tampering in 1982 and has become a requirement. The next requirements could very well entail color printing or printing complex characters and symbols, such as bar codes. And those requirements could come from regulators and/or consumers. Be ready.

[Editor’s note: To comment on the Back Page, visit www.tabletscapsules.com.]

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