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Janet Woodcock pushing industry to adopt quality mindset

Former FDA leader teaming up with industry veteran Anders Vinther to solicit CEO support, train operations staff

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For over two decades in FDA leadership positions Janet Woodcock exhorted biopharmaceutical executives to prioritize manufacturing quality. She persuaded many to open their ears, but few opened their companies' wallets.

"I feel like I failed to get things changed. Pharmaceutical manufacturing is still kind of lame," Woodcock told BioCentury. "Quality is not a high priority for pharmaceutical companies."

One reason quality hasn't captured the imaginations of industry leaders is that the value of investing in manufacturing hasn't been described in ways that shareholders and investors can understand.

Having retired from the agency, Woodcock is trying to change that. She has teamed up with pharma industry veteran Anders Vinther to preach the gospel of quality, solicit industry champions for the cause, and train a cohort of quality-minded leaders.

Woodcock is on the faculty of an online training program Vinther has established that will grant certificates in quality business leadership.

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In addition to the training program, which targets biopharma operational staff, they have drafted a quality business leadership manifesto and plan to solicit endorsements from industry leaders.

The goal, according to Vinther and Woodcock, is shifting from a compliance-oriented mentality which ensures that at best companies keep their heads above water to a continuous quality improvement stance that pursues manufacturing quality as a competitive advantage.

The widespread belief in the industry that manufacturing is a cost center rather than a driver of improved performance has led biopharmaceutical companies to outsource manufacturing to countries with low-cost labor, lax environmental regulations and, all too often, low quality manufacturing, Woodcock and Vinther told BioCentury.

"Companies outsource manufacturing to India and China because the labor is cheap," Vinther said. The tradeoff, he said, is a loss of control, and in some cases, costs associated with non-compliance with manufacturing standards or even falsified data.

The most obvious result is an increasing frequency of shortages of critical drugs, especially generics.

An analysis Vinther conducted of FDA warning letters shows that the most serious quality problems are concentrated in the generics industry, and especially in India.

Warning letters are a relevant measure because they report serious concerns stemming from inspections and often cause shortages as manufacturing or imports are halted while problems are mitigated.

Looking at the top 24 branded drug companies by revenue and the top 24 generics companies based on U.S. sales volume, Vinther found that from 2018 to 2023 that two branded companies received three warning letters. During the same period, nine generics companies received 15 warning letters, and that 14 of the warning letters "were given to manufacturers for GMP violations at facilities in India."

The burdens associated with inattention to manufacturing quality for branded drugs are less obvious but no less important, Vinther said.

In a career that has included serving as chief quality officer at Sanofi (Euronext:SAN; NASDAQ:SNY), VP for quality at the Genentech unit of Roche (SIX:ROG; OTCQX:RHHBY), and VP of quality at Novo Nordisk A/S (CSE:NOVO B; NYSE:NVO), he has seen the problem from the front line.

The consequences of failing to prioritize quality at innovative drug companies include high costs and loss of revenue from discarding products that don't meet specifications, supply chain vulnerability caused by reliance on manufacturers in India and China, and drug shortages, Woodcock said.

Vinther and Woodcock also make the case that creating a culture in which quality manufacturing is viewed as a driver of financial performance is critical to efforts to reduce supply chain vulnerabilities by bringing biopharmaceutical manufacturing back to the U.S. and Europe.

"For companies to bring business back to the U.S. or Europe, quality business leadership would be a good thing because you engage people, you look at what things cost to produce, and you probably find smarter ways of doing it," Vinther said.

This, in turn, will require investments in advanced manufacturing technologies — a hard sell for companies that don't see financial rewards or regulatory incentives that offset costs.

"Advanced manufacturing hasn't taken off," Woodcock acknowledged. "There are some examples, but it hasn't become the way drugs are manufactured, and I don't even see a trajectory toward a tipping point toward where more drugs are manufactured that way."

Pharmaceutical leaders are "dealing with so much risk, and to them derisking is doing it exactly the way we always have."