

# Mitigating Risk in Supply in an Era of Drug Shortages

As drug shortages become a growing global concern,<sup>1</sup> leading manufacturers of biologics, such as Amgen, have identified key practices to help mitigate risk in supply to patients.

Causes of drug shortages can include manufacturing difficulties, product quality issues, manufacturing delays, unexpected increased product demand, product discontinuations and recalls, and raw material sourcing issues.<sup>1</sup> Amgen has developed a multifaceted approach to help prevent drug shortages and employ risk management tactics that involve a continuous process of identifying, preventing, and responding to risks holistically.<sup>2</sup>

Beyond compliance with current good manufacturing practices (cGMP) and a robust quality management system, Amgen takes extra steps to help ensure a reliable supply to every patient, every time. As a first step, Amgen invests in inventory management at multiple points in the supply chain to mitigate potential risks of disruptions to supply (e.g., natural disasters). Additionally, Amgen maintains appropriate levels of raw materials by diversifying suppliers of sourced raw materials and storing high-risk raw materials in multiple geographical locations to safeguard their availability. By managing relationships with suppliers to ensure that raw materials requirements are understood and shared between both parties, Amgen is able to assure high-quality raw materials to minimize reprocessing and potential product manufacturing issues, and help ensure consistent product quality.<sup>2</sup>



Maintaining diverse manufacturing capabilities requires significant investment in internal manufacturing and contract manufacturing capabilities.<sup>2</sup> Amgen invested more than \$800 million in supply management from 2005-2011 and plans to invest an additional \$800 million through 2016. By maintaining eight manufacturing plants around the globe, Amgen is able to execute plans to implement back-up manufacturing capabilities (diversification), as well as enhance existing contract manufacturing capabilities.<sup>3</sup> Amgen is also able to ensure the active management of robust and secure distribution networks, by establishing well-controlled temperature (“cold chain”) distribution channels to maintain quality of each product and utilizing multiple approaches to mitigate distribution-related security risks to supply. These include controlled shipping lanes using temperature-validated shipping containers to maintain chain of custody, anti-theft and anti-counterfeiting measures to mitigate the risk of diversion and adulteration, and risk management programs to systematically address risks as they develop.<sup>2</sup>

## References:

<sup>1</sup>Woodcock J, Wosinska M. Clinical Pharmacology & Therapeutics, Vol. 93, No. 2, February 2012.

<sup>2</sup>Mica A, Green L, American Society of Health-System Pharmacists, 2012, poster

<sup>3</sup>Data on file. Amgen.