

# Amgen's Innovation: Efficiency Through Continuous Improvement

Manufacturing biologics, medicines produced by living cells,<sup>1</sup> is complicated, intricate and resource-intensive.<sup>2</sup> Biologics have changed the face of medicine<sup>1</sup> and will continue to do so;<sup>3</sup> however, it is clear that manufacturers need to ensure their processes are as flexible and efficient as possible to deliver a cost-effective and reliably available product.<sup>4</sup>

As a global leader in biologics manufacturing, Amgen evaluates all options to make its medicines with the highest quality manufacturing processes and continually evaluates those processes to find efficiencies in obvious and not so obvious ways. For example, Amgen has pioneered the combined use of new, single-use technologies with traditional stainless equipment to reduce the sole-reliance on expensive and inefficient apparatus. By using disposable equipment such as filters, tank liners and even bioreactors themselves, processes are more efficient and less prone to contamination.<sup>4</sup>

Single-use technology reduces the need to clean and sterilize equipment after use, thereby minimizing water consumption and consequent impact on the environment.<sup>5</sup> Importantly, these processes reduce the high energy required to sterilize large manufacturing equipment.<sup>4</sup>



Amgen scientists are transforming the biopharmaceutical landscape through combining innovative, single-use technologies, thereby improving productivity and efficiency in manufacturing biologics. This is achieved through stream-lining processes, reducing chances of contamination, and saving energy as repeated sterilization of older and more complicated equipment is no longer required. The combined use of disposable technologies will continue to shape the future of biopharmaceutical manufacturing.

Change-over times are shorter and this reduces production timelines with a resulting boost to productivity and ability to respond to demand. Single-use equipment is also designed to be more simple to operate and install, thereby reducing the potential risk of human error.<sup>4</sup> This results in a more efficient, streamlined manufacturing process.<sup>4,6</sup>

## References:

<sup>1</sup> Sekhon BS, Saluja V, Biosimilars 2011.

<sup>2</sup> Kuhlmann M, Covic A, Nephrol Dial Transplant (2006) 21 [Suppl 5]: v4-v8

<sup>3</sup> Bren L, FDA Consumer Magazine 2006. <http://www.fda.gov/AboutFDA/WhatWeDo/History/CentennialofFDA/CentennialEditionofFDAConsumer/ucm096141.htm>. Accessed 4/11/13.

<sup>4</sup> Zheng R, BioProcess International, Supplement April 2010.

<sup>5</sup> Rawlings B, Pora H, BioProcess International February 2009.

<sup>6</sup> Whitford W, BioProcess International, 10(5)s Supplement May 2012.