

## **GMP IMPLEMENTATION OF CONNECTED AND CONTINUOUS PROCESSING AT AMGEN**

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Amgen incorporated Integrated Continuous Biomanufacturing into the design of its Next Generation Biomanufacturing platform. Construction for the first Next Gen facility in Singapore occurred in June 2013 and in Sep 2018 for the second Next Gen facility in Rhode Island. At this point, the Singapore Next Gen facility is approved in major markets for multiple products, is operating at a high run rate, and has additional tech transfers underway. ICB lessons will be shared in the context of what has been executed in the GMP approved facility and processes. While Amgen's Next Generation Biomanufacturing platform extensively deploys single use technology, some lessons are also applicable to facilities of stainless steel design.

The presentation will review lessons of what went well from the start as well as lessons on what could be done better to implement integrated continuous technologies in GMP biological facilities and processes.