

Faster to Patient approach for significant benefit in cost, time, and product quality

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Amgen's large molecule pipeline is very rich in number and targets grievous illnesses. One of the modalities is the antibody molecule which has been well studied and proven amenable to a disciplined platform process development approach not only within Amgen but the biopharmaceutical industry. At candidate selection stage, Molecule assessment (MA) has been implemented to engineer and select molecules with optimum balance among key quality and manufacturing attributes to achieve the target product profile. To improve speed and cost of development, during MA the drug substance and drug product process platform is applied to choose the right cell line and process parameters for DS and DP. We have developed an integrated process development strategy that meets the needs of clinical entry and commercialization. In this talk we will present process and product quality data using high resolution analytical tools to profile attributes to ensure better product quality to meet patient safety. We will share the benefits of this accelerated path to cost, quality, and speed in bringing forward meaningful therapies to patients.