Integrated Strategy to Enable Rapid Delivery of Material for IND Enabling Toxicology Studies

Scott Estes, Cell Culture Development, Biogen Idec and Thomas Ryll, Cell Culture Development, Biogen Idec, Cambridge, MA

In an increasingly competitive business landscape, accelerating the ability to reach key decision points while minimizing the resources needed to do so has become a necessity for organizations to succeed. This has been evident in the biopharma industry with the major push over the years to achieve clinical proof of concept as rapidly as possible. Development of a manufacturing cell line and the production of representative material for toxicology is a key initial milestone in early clinical development and historically has represented a significant investment in time; frequently in excess of a year. In an effort to accelerate our IND readiness, we have reevaluated our approach to generating cell lines and producing Tox material. Through a holistic approach in which we have integrated strategic, operational and technical changes to our early clinical development work flow, we have created a new path in which it is possible to deliver representative material for IND enabling safety studies 7 months after selecting the final sequence for a candidate therapeutic. This has been enabled by the paradigm shift in which the material for Tox studies is generated prior to selection of the final cell line. To segue this approach from vision to reality, it was necessary to invest in improved expression systems and analytical capabilities necessary to rapidly and reliably produce sufficient quantities of well characterized drug substance.