Status and future developments for downstream processing of biological products Perspectives from the Recovery XIX yield roundtable discussions

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Abstract

Governments and biopharmaceutical organizations aggressively leveraged expeditious communication capabilities, decision models and global strategies to make a COVID-19 vaccine happen within a period of 12 months. This was an unusual effort and cannot be transferred to normal times. However, this focus on a single vaccine has also led to other treatments and drug developments being sidelined. Society expects the pharmaceutical industry to provide an uninterrupted supply of medicines. However, it is often overlooked how complex the manufacture of these compounds is and what logistics are required, not to mention the time needed to develop new drugs. The overarching theme, therefore, is patient access and how we can help ensure access and extend it to low- and middle-income countries. Despite unceasing efforts to make medications available to all patient populations, this must never be done at the expense of patient safety. A major fraction of the costs in biopharmaceutical manufacturing are for drug discovery, process development, and clinical studies. Infrastructure costs are very difficult to quantify because they often depend on whether a greenfield facility or an existing, depreciated facility is used or adapted for a new product. To accelerate process development concepts of platform process and prior knowledge are increasingly leveraged. While more traditional protein therapeutics continue to dominate the field, we are also experiencing the exciting emergence and evolution of other therapeutic formats (bispecifics, tetravalent mAbs, antibody-drug conjugates, enzymes, peptides, etc.) that offer unique treatment options for patients. Protein modalities are still dominant, but new modalities are being developed that can be learned from including advanced therapeutics like cell and gene therapies. The industry must develop a model-based strategy for process development and technologies such as continuous integrated biomanufacturing must be adopted. The overall conclusion is that the pandemic pace was unsustainable, focused on vaccine delivery at the expense of other modalities/disease targets, and had implications for professional and personal life (work-life balance). Routinely reducing development time from 10 years to 1 year is nearly impossible to achieve. Environmental aspects of sustainable downstream processing are also described.

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