Editorial

Pharmaceutical BIOPROCESSING

Bioproduction of Pharmaceuticals bioprocess and the Developing World

Irach B Taraporewala*

Department of Organic chemistry Southwest Foundation for Biomedical Research san Antonion, Sitara Pharmaceutical Group, USA

*Author for correspondence:

irachtaraporewala@ohrpharmaceutical.com

Abstract

Industrial animal cell culture is used to make many life-saving biopharmaceutical proteins, vaccines and cell therapies. Contamination of an industrial animal cell culture with a microorganism, such as a bacteria or virus, may occur through many means, for example, human error, inadequate aseptic protocols within biosafety level 2 (BSL-2) cabinets, failure of a processing step such as steam sterilization, loss of equipment integrity such as a crack in a disposable bioreactor, and/or introduction of a new adventitious agent not susceptible to current removal or inactivation procedures.The term microorganism is synonymous with the common term microbe (adjective microbial).

In response to such contamination crises, many firms simultaneously implemented a large number of changes, in emergency mode, without first identifying the source of the problem or thus understanding the likely effectiveness of any given change. Over time, one key change or two typically solved the problem. Sometimes the source of the problem, as well as the key change(s) that actually solved the problem, were identified. Other times, no such clear identifications were made. In nearly all cases, the whole slew of changes were carried forward, even though some were likely ineffective, as well as a waste of time, money and focus.

Yet many people in developing countries who could benefit from pharmaceuticals do not receive them. The failure of antiretroviral therapy to reach more than a tiny fraction of people with AIDS in developing countries has attracted widespread publicity, but even medicines that are far cheaper and easier to deliver are not reaching many of the people who need them. More than a quarter of children worldwide and over half of children in some countries do not receive the vaccines that are part of WHO's Expanded Program on Immunization, although these cost only pennies per dose and require no diagnosis. Three million lives are lost annually as a result (World Bank, 2001a). Only a small fraction of children in poor countries receive the newer hepatitis B and Haemophilus influenzae b (Hib) vaccines, which cost a dollar or two per dose. One in four people worldwide suffer from intestinal worms, although treatments only need to be taken once or twice per year, have virtually no side effects, and cost less than a dollar per year.

When asked which viral barriers proved impractical, company representatives had mixed responses. Filtration was characterized by some as expensive, having poor flux properties, or not suitable for use with bulk medium as some important media components were filtered out. Conversely, many interviewees stated that filtration was quite practical for small volumes, including heat-sensitive supplements, as well as hydrophobic additions. While certain respondents described HTST as quite practical and cost effective, others described it as ineffective due to cost, the large space it takes in the plant, and incompatibility with serum and hydrolysed.

Since the first public disclosure of a large-scale adventitious agent contamination by Genentech, the topic of viral barriers for upstream processes has become more mainstream. However, while many mid-size or large companies have investigated the implementation of barriers and their associated challenges, some companies remain uncertain about the difficulties they may face if they would like to implement a barrier in upstream cell culture processes.