Editorial

Pharmaceutical BIOPROCESSING

Biography of Pharmaceutical Bioprocesses

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Abstract

The use of spectroscopic sensors for bioprocess monitoring is a powerful tool within the process analytical technology (PAT) initiative of the US Food and Drug Administration. Spectroscopic sensors enable the simultaneous real-time bioprocess monitoring of various critical process parameters including biological, chemical, and physical variables during the entire biotechnological production process.

Approximately 30 ago, when modern biotechnology provided biological like Nobelmedaled monoclonal antibodies and more for the first time this innovative technology boosted pharm a's pipeline of drug candidates. However, the low-hanging fruits were early gathered and another disruptive innovation is not in sight. What is often described as the so-called innovation gap gets even worse when looking at the remaining patent terms of the drugs on the market. It becomes shorter and shorter and it is foreseeable that the pipeline of new NCE patents will not balance the loss. On the other hand, this development pushes the market for generics, which in the USA, is believed to exceed $81.5 billion with an impressive projected annual growth rate of approximately 10% for 2011–2013. Consequently, the valuation of big pharm companies is falling in an alarming way. According to Burrell& Company, the 17 most relevant players are valued at only $1 trillion today, compared with $1.6 trillion in 2000.

Single-use bioreactors are commonly used in the biopharmaceutical industry today; however, they are mostly limited to mammalian cell culture processes. For microbial processes, concepts including the CELL-tainer® technology provide comparable oxygen mass transfer such as in stirred tank reactors. this type of single-use bioreactor is applicable in biopharmaceutical processes, and also in a seed train for bulk chemicals production such as amino acid production. It is expected that single-use technologies will be applied ever more frequently in microbial-fed batch cultivation processes in combination with improved monitoring and control.

Bioprocess and biocatalyst IP developed for small-volume/high value pharmaceutical production will therefore find another even bigger market in bulk volume/ lower value processes. Therefore, today's financing climate for R&D targeting production processes is very different to the early days of biopharmaceuticals. For example, the development of genome sequencing has been financed at first by pharmaceutical industry investors and related industries. Later, such technologies were used by the chemical industry in their desire for modern biotechnological processes, without ever contributing to the basic cost of development. The controversy over intellectual property rights for pharmaceuticals and access to antiretroviral therapies in developing countries has been the subject of much public debate recently. This article provides a broader context for the debate. It first reviews characteristics of the developing country market for pharmaceuticals, including small markets, distinct disease environments and weak health care and regulatory systems.

Pharmaceutical use is sometimes suboptimal due to pricing above marginal cost and

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positive treatment externalities for infectious diseases; sometimes too great due to the failure of consumers to take into account externalities from drug resistance; and sometimes simply inappropriate due to information asymmetries between health care providers and their patients. Drug procurement is often inefficient and corrupt, and inappropriate regulation can hinder access. In addition, health care workers are politically powerful relative to patients.

Developed countries and international organizations could encourage differential pricing, allow more favourable tax treatment of appropriate drug donations, and encourage R&D and Pharmaceuticals and the Developing World 87 facilitate access to new products by committing in advance to purchase products needed in developing countries if and when they are developed.