

## **MAN.18 - Economic viability in the use of agitated single-use bioreactors as an alternative to rigid systems in a prokaryotic plant**

Miguel Angel de la O Herrera<sup>1\*</sup>; Wallace Fernandes Tavares da Silva<sup>2</sup>; Elezer Monte Blanco Lemes<sup>1</sup>.

<sup>1</sup>Fiocruz/Bio-Manguinhos;

<sup>2</sup>UERJ - Universidade Estadual do Rio de Janeiro.

**Introduction:** Nowadays, agitated single-use bioreactors are prominent in the pharmaceutical industry as potential alternatives to conventional rigid systems. This is due to the advantages associated with this technology. For example, it reduces operating costs due to the lack of cleaning and sterilization. However, in an economic evaluation, it is necessary to emphasize the associated costs of bags, the impact of disposal, the volumetric production capacity and the operational limits of the technology when compared with conventional systems.

**Objective:** The objective of this work was to perform an economic evaluation of agitated single-use bioreactors as alternative to stainless steel, considering the same production compatibility, aiming to establish the cost benefit between both technologies, thus allowing to select the best option to be used in a prokaryotic Bioreaction plant in Bio-Manguinhos.

**Methodology:** First, the information of the installed equipment was analyzed from the P&ID's of the bioreaction line, in addition, internal meetings were organized in order to obtain an estimate of the flows and the time spent in the CIP/SIP process. Afterwards, providers of agitated single-use bioreactors were consulted to obtain technical and economic information of equipment. A simulation was performed using the SuperPro Designer software, in which inputs were defined from internal documents for the production of proteins expressed in *E. coli*. Finally, the investment and the operational cost between both technologies were estimated, being a system composed of two stainless steel bioreactors (100L and 600L) and a single harvest tank (600 L), and four agitated single-use bioreactors, in simultaneous configuration, each of them consisting of 30 L and 300 L of working volume, respectively.

**Results:** After performing the simulation using both technologies, it was observed that the single use system has a cost of USD 16,50 per batch. Added to this, the management of waste (used bags) was an important point of attention. However, even when the initial cost was 13% higher than the cost of the CIP/SIP process, the single-use technology promoted an operating cost savings of 45 %. This covers the cost of the bags and promotes the reduction of 4 hours between batches, because there is no need for CIP/SIP, allowing the increase of batches in 30% per year and flexibility for being a compact system.

**Conclusion:** Despite the limitation of the single-use technology in relation to the size of bags, it was necessary the use four agitated single-use bioreactors versus two stainless steel for productive compatibility. Another issue was the dependence of a single provider of bags, and an investment over conventional. Nevertheless, according to the obtained results, it was perceived the economic advantage and the gains of increase the production capacity when the single use technology is applied in the line of prokaryotic bioreaction in Bio-Manguinhos.

**Keywords:** agitated single-use bioreactor; stainless steel bioreactor; economic feasibility