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Abstract

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Research review paper

Upstream processes in antibody production: Evaluation of critical parameters

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Abstract

The demand for monoclonal antibody for therapeutic and diagnostic applications is rising constantly which puts up a need to bring down the cost of its production. In this context it becomes a prerequisite to improve the efficiency of the existing processes used for monoclonal antibody production. This review describes various upstream processes used for monoclonal antibody production and evaluates critical parameters and efforts which are being made to enhance the efficiency of the process. The upstream technology has tremendously been upgraded from host cells used for manufacturing to bioreactors type and capacity. The host cells used range from microbial, mammalian to plant cells with mammalian cells dominating the scenario. Disposable bioreactors are being promoted for small scale production due to easy adaptation to process validation and flexibility, though they are limited by the scale of production. In this respect Wave bioreactors for suspension culture have been introduced recently. A novel bioreactor for immobilized cells is described which permits an economical and easy alternative to hollow fiber bioreactor at lab scale production. Modification of the cellular machinery to alter their metabolic characteristics has further added to robustness of cells and perks up cell specific productivity. The process parameters including feeding strategies and environmental parameters are being improved and efforts to validate them to get reproducible results are becoming a trend. Online monitoring of


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
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the process and product characterization is increasingly gaining importance. In total the advancement of upstream processes have led to the increase in volumetric productivity by 100-fold over last decade and make the monoclonal antibody production more economical and realistic option for therapeutic applications.

Keywords: Monoclonal antibody production; Wave bioreactors; Cryogels as bioreactors; Disposable bioreactors; Process monitoring and control; Cell engineering

Abbreviations: HFBR; Hollow Fiber Bioreactor; mAbs; Monoclonal antibody; IgG1; Immunoglobulin gamma 1; ECS; Extracapillary Space; MWCO; Molecular weight cut off; CHO; Chinese hamster Ovary; DOT; Dissolved oxygen Tension; DO; Dissolved oxygen; OUR; oxygen uptake rate; q_{Mab} ; specific antibody productivity; GS; Glutamine Synthetase; DHFR; Dihydro folate reductase; Q_p ; Specific production rates; LDH; Lactate Dehydrogenase; CPS I; Carbamoyl phosphate synthetase I; HSP 70; Heat Shock protein 70



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