low-dose and short shelf-life therapeutics, it is not feasible to wait 28 days for test results. Thus, the need for rapid mycoplasma test results has also increased. Real-time PCR based assays provide a viable alternative to the culture based method and provide results in hours while meeting the required sensitivity. Following validation, regulatory filing and review, users across multiple therapeutic modalities have received regulatory acceptance for use of a rapid, real-time PCR based mycoplasma detection assay.

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Scalability strategies for cell manufacturing

E Aguilar [1] G Carmona [1] R Sanchez-Pernaute [1]

1: Andalusian Network for Design and Traslation on Advanced Therapies - Junta de Andalucía - Sevilla

Cell-based therapeutic products are being consolidated as a conventional treatment, as highlighted by the recent rise of phase I-III clinical trials, its incorporation into healthcare systems and the increase in commercialization. The AND&TAT coordinates a network of GMP laboratories, belonging to the Andalusian Public Health System, which make it possible to offer these innovative therapies to the population. Currently, most ATMPs used are being manufactured using manual methods (flasks or cell-factories). These time-consuming methodologies, require highly-qualified human resources, imply a scalability bottleneck and will not be able to accommodate future needs. We have evaluated the different available technologies to prepare the System for the expected increase in cell production demand. Automated 2D planar technologies, comparable to 2D-manual methods, could be design with limited surface, appropriate to autologous treatment, or in multiple size modules, being the easier transferring option. Packed-bed system represents the most optimized space alternative due to 3D cell distribution, favoring niche environment but, affecting harvesting efficiency and cell potency. Microcarrier suspension culture platforms require a thorough process of optimization in each scale-up step; moreover, aggregation, shear stress and detachment are critical in those devices. In conclusion, given the heterogeneity of cell types, doses, and disease indications, there is not a “one-size-fits-all” standardized manufacturing platform which could be viewed as a solution. Any platform scale will require an exhaustive transfer process from manual manufacturing protocol to automation, and should be chosen according to the specific medicinal product requirements and individual needs.

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Nontrivial properties of small heat shock protein IbpA from Acholeplasma laidlawii

L S Chernova [1 2] A R Kayumov [1 2] I E Vishnyakov [2]

1: Kazan Federal University, Kazan, Russia 2: Institute of Cytology RAS, Sankt-Peterburg, Russia

Small heat shock proteins (sHSP) are ubiquitous molecular chaperones preventing the irreversible denaturation of proteins. In the genome of only one free-living Mycoplasma Acholeplasma laidlawii only one gene encoding the protein α-sHSP AIIbpA is present. This work is devoted to the study of the role of N - and C-termini of AIIbpA in oligomerization and chaperone-like activity of protein. We show that, regardless of temperature, AIIbpA forms a heterogeneous mixture of 24-dimensional globules, fibrils and huge protein aggregates. Removal of either 12 or 25 N-terminal amino acids leads to the formation of fibrils and increases the protein's ability to prevent temperature aggregation of insulin, indicating that the N- termini is not involved in chaperone activity, while responsible for the formation of globules. Since E. coli IbpB inhibits the formation of fibrils by IbpA, we assume that the N-terminus AIIbpA behaves as an autoinhibitor and the regulator activity of C-terminus, which complements the lack of IbpB. In turn, the removal of the C- terminus or replacing its LEL motif by SEP disrupts the temperature stability of AIIbpA and completely eliminates chaperone function, while the protein still remains predominantly in the globular state and is able to bind to insulin. Taken together, the data demonstrate nontrivial properties of AIIbpA, where competition between the N - and C-termini for interaction with the α-crystalline domain regulates the transition to a fibrillar or globular forms representing the molecular mechanism of regulation of AIIbpA activity. Research was funded by the Russian Science Foundation (project No. 17-74-20065).