Extended Abstract | Journal of Biology & Medicine Case Reports | 2020 | Vol.4 No.2

INTENSIFIED CELL-BASED VACCINE MANUFACTURING

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Statement of the Problem: Interest in process intensification for cell culturebased vaccine manufacturing is growing. Many new facilities, equipment and processes supporting the factory-of-the-future are included in this intensification initiative. Some consider intensification technologies as limited to those that directly improve the productivity or economy of the process and distinct from those providing other improvements. Many diverse technologies, including those described in the Industry 4.0 initiative, are being incorporated into newer vaccine manufacturing platforms, modes, equipment, materials and facilities. Factory-of-the-future initiatives include flexible and modular facilities, ballroom and dancefloor layouts, real-time PAT monitoring, integrated and enterprise control, prefabricated and factory-in-a-box facilities, closed and connected operations, real-time product release testing, enterprise centralized control, single-use equipment, real-time MAM product release, as well as AI and automaton-driven processes. Conclusion & Significance: Intensified manufacturing might specifically refer to higher volumetric and reduced footprint productivity, heightened cellspecific productivity, shortened/simpler process trains, integrated continuous processes, continuous but un-joined operations, perfusion intensified seed train/reactors, straight-through processing and in-line fluids conditioning. Such developments are occurring in mammalian, avian, yeast, and bacterialbased platforms. A survey of these initiatives, definitions of their composition, and examples of their application in vaccine platforms and facilities will be presented. accine manufacturing processes are designed to meet present and upcoming challenges associated with a growing vaccine market and to include multi-use facilities offering a broad portfolio and faster reaction times in case of pandemics and emerging diseases. The final products, from whole viruses to recombinant viral proteins, are very diverse, making standard process strategies hardly universally applicable. Numerous factors such as cell substrate, virus strain or expression system, medium, cultivation system, cultivation method, and scale need consideration. Reviewing options for efficient and economical production of human vaccines, this paper discusses basic factors relevant for viral antigen production in mammalian cells, avian cells and insect cells. In addition, bioreactor concepts, including static systems, single-use systems, stirred tanks and packed-beds are addressed. On this basis, methods towards process intensification, in particular operational strategies, the use of perfusion systems for high product yields, and steps to establish continuous processes are introduced.

This work is partly presented at EuroSciCon Conference on Virology and Infectious Diseases, April 22-23, 2019 | Athens, Greece