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INTENSIFIED CELL-BASED VACCINE MANUFACTURING William Whitford

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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 cell-specific 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 bacterial-based platforms. A survey of these initiatives, definitions of their composition, and examples of their application in vaccine platforms and facilities will be presented.

Biography

Bill Whitford is Strategic Solutions Leader, BioProcess, GE Healthcare in Logan, UT with over 20 years' experience in biotechnology product and process development. He joined the company 16 years ago as a Team Leader in R&D developing products supporting biomass expansion, protein expression and virus secretion in mammalian and invertebrate cell lines. Products he has commercialized include defined and animal product-free hybridoma media, fed-batch supplements, and aqueous lipid dispersions. He is an invited Lecturer at international conferences. He has published over 250 articles, book chapters and patents in several areas of bioproduction and vaccine manufacturing. He now enjoys such industry activities as serving on the Editorial Advisory Board for BioProcess International.

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