



PARTS 1&2- SYMPOSIUM MAIN PROGRAM

IMMUNOTHERAPIES

CHALLENGES AND OPPORTUNITIES IN THE CHEMISTRY, MANUFACTURING & CONTROL OF GENE AND CELL THERAPIES.



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Dr. David Y. H. Chang is currently CEO at WuXi AppTec Advanced Therapies Business Unit. Dr. Chang has more than 30 years' experience in the biotechnology industry, experienced in bioprocess R&D, manufacturing operations, facility engineering, global strategy, and CMC regulatory. Prior to current role, he was Corporate VP and Head of Cell Therapy Global Manufacturing, of Celgene Corporation; the Global Head of Engineering and Strategy at Roche based in Basel, Switzerland; the VP/Site Head of Roche Shanghai Technical Operations in China. Earlier in his career, Dr. David Chang worked at Genentech as the Senior Director of Global Manufacturing Science and Technology, and as the Director of Process Development in its Oceanside, CA site. He was also formerly at Biogen Idec as Director of cell culture R&D, at BASF Bioresearch as a cell culture group leader, and Schering-Plough Research Institute as a process development engineer.

Dr. Chang obtained his Bachelor's degree in Chemical Engineering from National Taiwan University and Master's and Ph. D. degrees in Biochemical Engineering from Massachusetts Institute of Technology.



ABSTRACT

Cell and gene therapies (CGT) have evolved to become mainstream modality owing to recent breakthrough success in treating genetic disorders and blood cancers. However, the CMC (Chemistry, Manufacturing and Control) efforts have encountered significant challenges, limiting patients' access to these life-saving therapies. Dr. David Chang will provide the overview of current challenges and opportunities in the CMC development effort to ensure the effective control of critical quality attributes, manufacturability, and reduced cost of goods.