Development of modern biologics and cell therapy products through globalCMOs

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Introduction: Fast growth in the Cell and Gene Therapy (CGT) industry is driving increased demand for process development and manufacturing services. Contract Development andManufacturing Organizations (CDMOs) remain crucial to CGT process development, manufacturing and commercialization providing multi-stage services. Controlled temperature supply chain adds additional level of complexity to the successful CGT project implementation

AIM:

To provide the project framework for CGT outsourcing to CDMOs, which includes required business documentation, quality/GMP due diligence process, providing examples of the company and site overview, analysis of org chart and communication process, analytical development and qualification, process development strategy, timeline and budget challenges and final criteria for CDMO selection.

CONCLUSIONS:

Based on our experience we recommend the implementation of following principles:

- Development of detailed project roadmap prior to signing the contract
- Signing separate sections of the contract to mitigate the risks: tech transfer and process biochemistry, scale up and demo batches, followed by GMP manufacturing & stability studies
- Development of alternative scenarios to address changes

KEYWORDS:

CDMO selection criteria, outsourcing, process development, manufacturing, quality due diligence, controlled temperaturesupply chain

Biography: Dr. Klyushnichenko has over 20 years of experience in Bio/ Pharmaceutical Development and Manufacturing. Vadimis responsible for the development of biologics, gene, and cell therapy products as well as their supply chain, which involves multiple CDMOs in the US, EU, India, and China. Vadim has developed his growing managerial and scientific responsibilities serving as VP of Drug Development at Paragon,Terapio, and Coldstream Laboratories, Sr/Principal Scientist atPfizer, Baxter, Aventis and Altus. Vadim has received his B.S. in Physics from Moscow Institute of Physics and Technology (FizTech), Ph.D. in Chemistry from the Russian Academy of Sciences, and continued his postdoctoral research in Germanyand Canada.