UNIVERSITY OF GEORGIA
Center for Continuing Education & Hotel

QUALITY BASICS FOR CELL AND GENE THERAPY PRODUCTS • Learning Objectives

Module 1: Overview of FDA and the Regulatory Framework

- Identify the different centers within FDA and their regulatory scope
- Recall the regulations and guidance's applicable to GQR
- Recognize and appreciate tools (inspections and enforcement) in FDA to maintain compliance to regulations

Module 2: GMP and Quality Systems

- Summarize the GMP principles
- Summarize the Quality Systems approach
- Describe how the GMP principles and Quality Systems approach work together to consistently produce a high quality product that is safe and efficacious

Module 3: Standards

- Summarize the role of Pharmacopeias, ICH guidelines, ISO and ASTM standards in GQR
- Describe and develop the standard (s) that will be appropriate for use in cell and gene therapy product manufacturing

Module 4: Controls

- Understand and explain the importance of control on sourcing for raw materials, cell banks, cell-line etc. and qualification of suppliers and CRO's
- Learn about production and process controls, critical quality attributes, SOPs, batch records and validation protocols
- Develop an appreciation for the sterilization and aseptic process validation methodologies
- Describe Quality Control and Quality Assurance process

Module 5: Risk Management

- Recognize the components of the Risk Management paradigm
- Understand and describe the strategies used in Risk Management
- Delineate the Risk Management Strategies applicable to cell and gene therapy product manufacturing

Module 6: Emerging Technology (e.g., MSC manufacturing)

- Describe the Challenges in cell and gene therapy product manufacturing under GMP
- Explain how GQR principles can facilitate the emerging technology development