Training Course Agenda

PDA EU00167 Practical Application of Risk-Based GMP & Quality Principles to Clinical Development of ATMPs
CEST

DAY 1 – Monday 04 July 2022	
15:00	**Welcome and Introduction**
15:30	**Overview of the ATMP Landscape (90 min)** • Defining the critical terminology: CGTP, ATMP, CAT, OTAT, RMAT, etc. • How the diversity of ATMPs challenge the application of GMP and quality
17:00	***Break (15 min)***
17:15	**ATMP GMP and Quality Risk Consequences (90 min)** • Major differences between gene/cell-based medicines and protein-based medicines • Necessity of a risk-based approach
18:45	***End of Day 1***
DAY 2 – Tuesday 05 July 2022	
15:00	**Regulatory Authority Expectations During Clinical Development (90 min)** • FDA guidances and risk-based considerations for ATMPs • EMA guidelines and comparison to FDA
16:30	***Break (15 min)***
16:45	**Industry Practice in Applying Risk-Based Considerations to ATMPs (90 min)** • PDA Technical Report No. 81 • Lessons learned from industry practice
18:15	***End of Course***