Training Course Agenda

611 - Practical Application of Risk-Based GMP and Quality Principles
to Clinical Development of Cell and Gene Therapy Products - Advanced Therapies

DAY 1	
8:30	**Welcome and Introductions**
9:00	**Overview of the Cell & Gene Therapy Product Landscape** • Defining the critical terminology: CGTP, ATMP, CAT, OTAT, RMAT, etc. • How the diversity of the Advanced Therapy products challenge the application of GMP and Quality
10:30	**Coffee/Tea Break**
10:45	**Advanced Therapy Product GMP and Quality Risk Consequences** • Major differences between gene / cell-based medicines and protein-based medicines • Necessity of a risk-based approach
12:00	**Lunch**
13:00	**Regulatory Authority Expectations During Clinical Development** • FDA guidances, and risk-based considerations, for Cell & Gene Therapy products • EMA guidelines, comparison to FDA
14:30	**Coffee/Tea Break**
14:45	**Industry Practice in Applying Risk-Based Considerations to Advanced Therapy Products** • PDA Technical Report 81 • Lessons learned from industry practice
16:00	**End of Training Course**