Training Course Agenda

281 - Economical Design of Lyophilization Experiments Workshop

DAY 1	
8:30	**Welcome and Introductions**
9:00	**Confounding?** How to get more out of a DoE with the same or less work and the very minimum investment of time, materials, and human resources.
10:30	**Coffee/Tea Break**
10:45	**Picturing the Process** All too often we launch into a Risk Assessment by focusing on the details without any expectation that they will be used. This session will be conducted in a lab with hands on experiments to identify critical quality attributes, create a mental model of the system, and capture failure modes to prioritize parameters in our experiment.
12:00	**Lunch**
13:00	**Getting Excited about Nothing** Pharma's statistically unlike other Industries. In a business where there are large volumes, low costs, and low risk, experimenters are searching for the smallest of changes because they mean increased profits and competitive advantage. Pharma, however, has relatively small volumes, high cost, and high risk. In our case we are proving that there is no change in the product. Several drivers may be at play in the exorbitant costs of CMO DOE's but one of them is certainly a sponsor's statistical inexperience causing a fear of building a case upon process knowledge versus the relative anonymity of the p-value.
14:30	**Coffee/Tea Break**
14:45	**From the Lab to Manufacturing Floor to the Executive Suite and Back Again** Applying the knowledge gained to streamline regulatory interactions, to handle process deviations, to handle complex post-market approval changes, and to train new people, to communicate to the executives and to take that message back to the organization.
16:00	**End of Training Course**