



Challenges and Successes in Technology Transfer

Course Leaders: Frank Kohn, Ph.D., FSK Associates

AGENDA

Wednesday, February 8

7:30 a.m. Registration & continental Breakfast

8:30a.m. Introduction to the World of Technology Transfer

A discussion on various issues concerning the subject of technology transfer including a review of survey data from industry.

10:30a.m. Refreshment Break

11:00a.m. Review of Regulatory Requirements & Expectations

Review of the various regulations and governmental view of critical items noted during technology transfer projects.

12:30p.m. Lunch

1:30p.m. Technology Transfer Tools

A review of ICH Q-9 guidance on risk management and how to use risk management for improvement of your technology transfer projects

3:00p.m. Refreshment Break

3:30p.m. Industrial Case Studies

A discussion using actual industry case studies to pin point problems that have occurred during technology transfer projects.
Discussion plus Q & A.

5:30 p.m. Networking reception



AGENDA

Thursday, February 9

7:30a.m. Continental Breakfast

8:30a.m. Drug Process Defined

Critical process validation parameters will be identified and reviewed in context of ICH Q-8, Q-9 and Q10.

10:30a.m. Refreshment Break

11:00 a.m. Models for Technology Transfer

What works and what does not work concerning technology transfer

12:30p.m. Lunch

1:30p.m. Process Strategies

How the use of Project management and other Quality systems strategies can improve your project timelines to market.

3:00p.m. Refreshment Break

3:30p.m. Case Studies

Several case studies will be reviewed and a "hands on" case study project will be assigned to the class.

5:00 p.m. Adjourn