

UNIVERSAL TECHNOLOGY TRANSFER METHODOLOGIES FOR BIOPHARMACEUTICALS

NORTH CAROLINA STATE UNIVERSITY'S BTEC

<http://www.btec.ncsu.edu/contact>

Course Information

Room 123 at BTEC:
+Session 1: 2-3 NOV 2009
+Session 2: 15-16 MAR 2010



Course Cost: \$990

Early Registration Discount: Save \$100 for registration prior to Oct 19, 2009 for Session 1 and prior to Mar 2, 2010 for Session 2

Multi-Attendee Discount (from same company):
Save \$200 on each additional registration

An extensive two-day program for professionals in pharmaceutical, biologics, vaccine and combination drug-device industries.

- Learn what technology transfer is all about
- Learn what steps to take and in what order
- Learn what tools to create and how to use them effectively
- Receive a package of procedures and editable templates to assist in your technology transfer projects

Why You Should Attend

Every time your organization contemplates moving a process or product from one location (e.g. lab, manufacturing facility, country) to another, you enter the domain of technology transfer.

The technology transfer process is complex with multiple steps performed in a specific order, requiring a significant resource commitment from many different groups in the organization for activities spanning from a few weeks to many months. All of this calls for comprehensive planning, effective coordination and first-time-right execution, often on very aggressive timelines.

By following the procedures and using the tools and templates provided, this course will allow you to avoid costly and often irreversible errors and to be successful, while being in control of schedule and budget.

Who Should Attend

Anyone involved in moving analytical assays and/or manufacturing processes internally or externally, in early development, for clinical or commercial manufacturing, including but not limited to professionals from the following functional areas:

- Process Development
- Manufacturing Sciences
- Quality Assurance and Regulatory
- Quality Control
- Manufacturing
- Validation
- Process Engineering
- Business Development
- Project Management

How To Register

Email: stephen.perry@kymanox.com

Web: www.kymanox.com/services/TechTransferCourse.php

<http://store.kymanox.com/trco.html>

Kymanox
2220 Sedwick Road
Suite 201
Durham, NC 27713 USA



+1-919-246-4896

Course Outline

Day 1

Lecture 1:

Introduction to Tech Transfer

Definition of and rationale for technology transfer as it applies to biopharmaceuticals.

Tech Transfer Initiation

Define the need, formulate key goals and set timelines. Assign the Project Manager and assemble the team on both sites.

Lecture 2:

Information exchange

Sender provides the most up-to-date information on the process and assays. Receiver provides information on the facility and team capabilities.

Feasibility and Risk Assessment

Match the process to the receiver's capabilities and evaluate and justify any potential changes. Perform risk assessment.

Planning for Tech Transfer

Key tools for planning Assay and Process Transfer.

After this course you will be able to...

- Set-up a team of professionals essential for the success of technology transfer
- Assess feasibility, business and regulatory impact
- Identify necessary actions and create detailed assay and process transfer plans
- Monitor, evaluate progress and manage proactively the ongoing technology transfer
- Define criteria and document the success of the technology transfer
- Defend the rationale for and the outcome of the transfer in front of US and international regulatory bodies

Day 2

Lecture 3:

Tech Transfer Execution

Transfer of materials, assay transfer/qualification and process transfer. Process verification at bench scale (non-GMP).

Process Scale-up

Perform a scale-up to the final production scale to be used for the actual cGMP campaign.

Lecture 4:

Process Verification (Engineering Run)

Perform in a GMP facility with released materials and documents in draft form at a minimum. Go/No-Go decision for a cGMP campaign.

Tech Transfer Reports

Assay Qualification report, Process Transfer report, and Process Specification document.

cGMP Campaign and Project Closure

Preparation to and execution of the campaign. Collecting and trending batch data, data analysis and confirmation of consistent control.

Attend and you will receive...

- Four in-depth lectures on the specifics and mechanics of technology transfer
- Examples of real-life industry cases
- Detailed list of documents and tools required for successful technology transfer with samples and editable templates based on best industry practices
- Access to instructors with first-hand technology transfer experience
- Support of Kymanox capable staff for all of your technology transfer and technical project management needs

About Your Instructors

Stephen M. Perry, PMP – President, Kymanox

Vladimir Kostyukovsky, Ph.D. – Sr. Technical Manager, RTP Operations, Kymanox

About Kymanox

**Kymanox is dedicated to assisting companies and individuals
with knowledge transfer on a project-by-project basis.**

**Serving the biotechnology, pharmaceutical, and medical device
communities, we help get projects**

