Reduce Tech Transfer Failure Rates by Implementing Proven Team Communication Strategies and Aligning Priorities and Goals
Presenters:

♦ Suketu Desai, Ph.D. – Johnson & Johnson
♦ Kelly Tate, MA, MBA – Translational Drug Development (TD2)
♦ Rob Duncan, MBA, CMC – Great Capes Consulting
Workshop - Goals

- Tech Team Members and priority differences
- Developing Interpersonal Relationships
- Motivation
- Communication breakdown
- Alignment of goals
- Managing expectations
Importance – FDA 483 Statements

♦ In sum, your labeled “retest by” date is unsupported by adequate data.

♦ Product complaints are to be investigated thoroughly and with respect to their relevance to related batches and material.

♦ Failure of the Quality Control Unit to reject drug products which may have been contaminated with metal.

♦ Failure to Investigate unexplained discrepancies prior to releasing a batch.

♦ Failure to develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications as required by 21 CFR 820.70 (a).
Goals of a successful transfer

♦ Robust Process
  – Scaled to commercial manufacturing
♦ Successful project
  – On time
  – On budget
♦ Regulatory Approval
♦ Continued good working relationship
Critical Factors

Team Members
Tech-Trans Team Members

♦ Leadership
  – Overall project manager (suggest this person be at the accepting site)
  – Project coordinator at each of the contributing sites

♦ Members
  – API development, Product development, Manufacturing Tech Svcs
  – Engineering, Manufacturing
  – Quality Control, Regulatory
  – Etc.
How do groups form? – Tuckman

♦ Forming – uncertainty, rules and procedures, determine their place
♦ Storming – differences confronted, conflict, resistance
♦ Norming – discover ways to work together, cohesiveness, commitment
♦ Performing – goal achievement, proficiency, flexibility in working together
♦ Adjourning – group disbands

Exercise

- Name
- Education
- One bit of personal information
- Current organization
- What is one thing you want to learn by attending this conference?
Determination of Priorities

♦ Better quality group decisions come from
  – Cooperative motivational orientation
    • Superordinate group goals
  – Simultaneous consideration of issues
    • Issue map

Interpersonal Relationships

♦ Group Identification – how is your tech transfer group different from other groups in the organization?
  – Internalization of membership
  – How are “we” different from “them” – is that important
  – How important are “they”

Group Identity – A tale of two functions.
  – Deductive – set of properties (e.g., color, politics, goal)
  – Inductive – based on communication and interaction
Johari Window

Known by self | Ask | Not known by self
---|---|---
Known by others

Open | Blind

Tell

Hidden | Unknown

Not known by others
Johari Window - Exercise

♦ Disclose one thing that no one in the room knows about you.
Johari Window

Known by self

Ask

Not known by self

Known by others

Tell

Not known by others

Open

Shared discovery

Feedback

Self-disclosure

Others’ observation

Hidden

Self-discovery

Unknown
Goal Alignment

♦ Project statement
♦ Development of sub goals
♦ Characteristics
  – Quality
  – Quantity
  – Time
Motivation

♦ Extrinsic
  – Pay, time off, bonuses, prizes

♦ Intrinsic
  – Competence, self-worth
Motivation - continued

♦ Intrinsic reward characteristics – contingent tangible rewards undermine intrinsic motivation
  – Context – how much social pressure is there to behave in a certain way?
  – Cue value – how much information is associated with a performance reward?
  – Verbal reward – how much “control” is in the praise?

Communication – Following directions exercise
Communication

♦ Sender
  – Own your message – “I”
  – Use appropriate vocabulary
  – Ask for feedback on the message
♦ Receiver
  – Clarification questions
  – Restatement (in your own words)
♦ Active listening behaviors
Communication – Active listening exercise
Expectation Management

Project Team

Internal

External

Stated

Technology
Overtime
Training

Requirements
Budget
Schedule

Perceived

Stagnation
Process
Skills

Manpower
Money
Goals