

Change Management for Virtual Pharmaceutical Firms

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Opening Considerations

Managing the kinds of changes encountered by and instituted between two organizations requires an unusually broad and finely honed set of skills, including:

- Empathy
- Clarity
- Communication
- Responsiveness
- Detailed planning and analysis

The Perspective of a Virtual Firm



Purpose

- Meaning of Change Management for Virtual Firms
- Unique Challenges
- Quality and Manufacturing Agreements
- Document Systems
- Outcomes of Effective Change Management

Meaning of Change Management

- Task of Managing Change and the RELATIONSHIP
- Process of Risk Evaluation/Assessment
- Definition of the level and detail and information
- Procedures and mechanisms for effectively managing change

Meaning of Change Management

- Defining the Systems at both firms
- Focusing on relationship building
- Enabling change in a risk-based manner
- Managing the change process
- Allowing for Innovation, Process Improvement and Optimization
- Assuring Quality by Design

What are unique challenges to Virtual Firms?

- Need to manage at least two Quality Systems
- Changes to be managed lie within and are NOT controlled by your organization
- Identify the interfaces
- Identify differences
- Impact on CMC sections
- Each firm sees risk in a different way

Manage the Interface

- Clearly understand the interface
- Prepare a Process Map for processes, inputs and outputs, meet and discuss
- Early on, focus on the point at which both organizations truly interact
- Encourage performance
- Identify and eliminate obstacles

What are unique challenges to Virtual Firms?

- Determine if anticipative and proactive or knee jerk and reactive
- Different processes for regulatory interpretations
- Master Parallel Review Cycles
- Encourage and motivate supplier to improve and optimize

Is your firm proactive or reactive

- How you approach depends on -
 - Examine capabilities of your firm from a process, production, technical, quality, regulatory knowledge-based perspective
 - What is your style
 - Can you rely on the CMO/CRO to make major decisions about your product

Parallel Review Cycles

- Try to achieve efficient parallel reviews at both firms
- Attempt to incorporate this parallel review in one process
- Try to achieve equivalent risk assessment mechanisms

Encourage and motivate supplier to improve and optimize

- Change Control systems should be **DYNAMIC ENABLERS** for optimization
- Find ways and establish relationships with operators and analysts to encourage understanding and participation with the Change Control Process
- Identify and avoid the potential for disincentives for change

Different processes for regulatory interpretations

- Examine carefully the philosophy and process for the CMO/CRO interpretations
- Ensure that you have agreement on how changes are interpreted
- Ask specific questions regarding process, method and procedural changes and how they are processed
- Agreeing on the defined set of Controlled Documents subject to your review can help

Quality Agreements – The Basics

- AT THE EARLIEST STAGE - Start with a comprehensive Quality Agreement
- Basis of information, who provides what
- Identify points of control
- Identify responsibilities
- Documentation Change Control and Risk Management
- Discuss Deviations and OOS situations
- Use to tightly bind your suppliers to you

Quality Agreements – Key Elements

- Maintain involvement and understanding
- Define changes the manufacturer may make, using Risk Management Processes, to improve or implement changes
- Identify raw material, component, process and product controls within the design space to create requirements or guideline against which change management, risk assessment, and audits may be performed
- Periodic on-site reviews to evaluate deviations, CAPA, outcomes of joint actions
- Provisions for assessment of manufacturing issues related to Adverse Experiences

Quality Agreements – What If?

- Regardless of the details in the Quality Agreement, the culture of the organizations and the relationship you have developed will make a difference when problems arise

Manufacturing and Supply Agreements

- Build in flexibility and provide accommodations for improvements
- Understand variability in raw materials and processing
- Regional Regulatory Approaches
- Constantly assess changes in interactions for improvement
- Agreements should be DYNAMIC

Integrate Document Change Control as part of Regulatory Process

- Choose team members with relevant skills and high energy levels
- Ensure that provisions are in place for evaluation of changes for regulatory impact for both parties
- Agree on timelines and expectations for evaluation and risk assessment
- Be prepared to Get to Know Your PARTNER

Document Systems

- Determine in which documentation system the CMC will reside
- Transfer the CMC in its entirety
- Provide Summary Document
- Transfer Manufacturing, Quality Control Methods, Specifications in your document format

Documents to Consider

- Full CMC
- Amendments
- Annual Reports
- Product, In-Process, Drug Substance Specifications
- Analytical Methods
- Master Batch Records
- Inspection Procedures
- Sampling Procedures and Requirements
- Certificates of Analysis and/or Compliance

Document Systems

- Establish distribution system
- List of documents maintained per Quality Agreement
- Maintain jointly a list revisions currently in effect
- Insist on formal acknowledgement of distributed documents

Document Systems

- Determine if philosophies for “change evaluation” are compatible
- Ensure and commit to a rapid review process for all proposed changes
- Seek compatible approach in level and detail of information

Outcomes of Effective Change Management for Virtual Firms

- Vision and plan for achieving change
- Implementation of an communications plan
- Established standard for performance (from meeting times for participants to turnaround for change)
- Built an effective team
- Awards and incentives

Outcomes of Effective Change Management for Virtual Firms

- CMOs/CROs will prefer to work with you
- Reduce time to approval and market
- An additional team will be helping you solve your problems
- Effective Change Management SHOWS and gives FDA confidence in the team during the PAI process

Outcomes of Effective Change Management for Virtual Firms

- Demand and Nurture Progress
 - Able to maintain aggressive schedules
 - Maintain momentum
 - Identify interdependencies
 - Facilitate enterprise wide involvement
 - Continue to realign competencies in the groups to support the model

Connecting the Dots

- Seek to understand
- Be clear
- Adapt, control and effect change
- “Make it look easy”

Change as a “What” Problem

- What are we trying to accomplish?
- What changes are necessary?
- What are measures of success?
- What standards apply?
- What are the periodic measures of performance?
- Ask “Why” questions to get at the heart of improving interactions.

Selected Sources

1. *Strategic Organizational Change* - Michael Beitler
1. *The Planning of Change* - Warren Bettis
2. *Organizations in Action* - James D. Thompson

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