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CONSIDERATIONS FOR SUPPORTING A GXP COMMERCIAL LAUNCH

Clinical companies face significant challenges as they approach regulatory approval and commercialization of their first product(s). Behind many of these challenges is the reality that being successful in clinical operations is quite different from being successful in manufacturing operations. At a strategic level, major differences include required skillsets of personnel, regulatory environment, operating culture, and facility requirements. At a tactical level, the differences explode into a complex array of challenges often intensified by the looming reality of the scheduled Pre-Approval Inspection (PAI) date. These challenges arise whether the clinical company plans to produce the commercial product itself or employ a Contract Manufacturing Organization (CMO) for production.

One common situation faced by emerging pharmaceutical or biotech companies transitioning from clinical to commercial is successfully completing all of the necessary activities in the required timeframe. **This challenge is often exacerbated by the reality that:**

- All of the required processes across the entire quality and supply chain systems need to be defined, developed, and instituted.
- All of the supporting documents (*Policies, SOPs, Work Instructions, Forms, etc.*) need to be authored, edited, approved, and made effective.
- Applicable training for all processes, procedures, and practices needs to be developed and delivered.
- Managing substantial culture change needs to occur and be complete and effective.
- Supporting software (*e.g., QMS, document management, LIMS, MES, etc.*) requirements need to be defined, the software vendors selected, and the software purchased, configured, and implemented.
- Suppliers need to be identified and qualified, and corresponding contracts need to be negotiated and finalized.
- Ongoing selection and hiring of required personnel to support the quality and supply chain functions needs to occur. Once hired, their assimilation and learning curves consume additional time.

Many of these activities require a large initial investment of time, resources, and expertise followed by much smaller resource requirements for ongoing operations. All too often, emerging companies underestimate the full scope of activities and the time required for successful development and execution of all necessary systems. Coupled with the fact that these companies are simultaneously hiring the staff needed to develop and implement all of the elements needed for the PAI, the result is often a chaotic attempt to meet what becomes an impossible deadline. PAI postponement and/or PAI failure become inevitable. Both of these undesirable outcomes can be avoided.

At Clarkston, our consultants have the expertise and experience to assist in developing and implementing efficient, compliant processes; overcoming the mountain of initial work; training new and existing staff; and managing the changes and timelines necessary to successfully navigate the PAI and transition into commercial manufacturing. In this download, we break down the various areas often requiring attention and corresponding considerations for a successful GxP commercial launch.

MOVING FROM CLINICAL TO COMMERCIAL OPERATIONS

Life sciences companies in the process of transitioning from strictly clinical operations to commercial operations often find themselves asking questions such as:

- Are all needed quality processes in place, compliant, and right-sized for our company, and are they fully developed and sustainable?
- Do we have all the quality processes we need in place or identified as needed?
- Do we (and will we) have adequate qualified staff to design and implement needed quality policies in time for the PAI?
- Are we fully capable of performing all our regulatory filings, or would we benefit from some professional assistance?
- Are we fully capable of performing all our upcoming scale-up, technology transfer, and validation activities?
- Do we have a plan to prepare for our PAI, and will we be ready and able to be approved?
- Do we have a plan for commercial launch once approved?
- Do we have adequate processes to ensure robust Quality Agreements with our Suppliers and CMOs?

These are just a few examples of the questions that companies moving toward commercial operations need to resolve. These companies are entering into a new arena and typically aren't properly staffed to do so effectively and efficiently.

On a positive note, companies facing these challenges are not in a unique situation. Although it can be complex, the path to a successful PAI is remarkably similar for emerging GxP companies, regardless of the specific drug or device pending regulatory approval.

The following are common functional areas needing attention and corresponding remediating steps, and how they can be effectively supported.

MOVING FROM CLINICAL TO COMMERCIAL OPERATIONS

Strategic support for quality systems and processes that will be assessed during the PAI begins with an assessment of existing quality systems and processes to determine the gap between what is in place and what is needed. As applicable, any missing systems or processes are developed, any substandard systems or processes are remediated, and required process flows and documents (*Policies, Standard Operating Procedures, Work Instructions, Forms, etc.*) are authored and marshaled through the review and approval process. Corresponding training materials are then developed, and the training is delivered.

The below table is an overview of the quality systems and processes included in the scope of the document:

Quality Standard Creation and Administration	Document Architecture, Format, and Content	Document and Record Control / Retention	Personnel Qualification	Training System	Deviations & Investigations
CAPA	Change Control	Risk Management	Specifications	Production Label Control	Lot Disposition
Certificates of Analysis	Stability Monitoring	Master Batch Record	Batch Record Review	Validation Program	Process Validation
Cold Chain Validation	Computer System Validation	Method Development and Validation	Facilities, Utilities, & Equipment	Cleaning Validation	Design Control

Materials Control	Storage and Distribution	Supplier Inspection / Audits	Internal Inspection / Audits	Regulatory Inspections	Supplier Assessment / Qualification
Quality Technical Agreements	Supplier and Purchasing Control	Trending & Statistics	Periodic Product Review	Quality Planning & Objectives	Quality Management Review
Governance and Management Notification	Rework / Reprocess	Environmental Monitoring	Contamination Control	Calibration	Laboratory Controls
Product Recall Management	Terminal Sterilization	Technology Transfer	Complaint Management	Hygiene and Gowning	Aseptic Production Control

In addition to the comprehensive quality system development and implementation process described above, companies may also find themselves needing temporary support with (or staffing) of critical, time-sensitive roles, including for:

Staff Augmentation: Filling key roles from entry level through executive on a short-term as well as long-term basis, focusing on the areas of Quality, Manufacturing, Technical Services, Supply Chain, and Regulatory.

Inspection Support: An inspection imposes a considerable burden and disruption to an organization. Given the criticality of the outcome, comprehensive preparation and strategic management of the inspection – both before and after – are essential. *Inspection types benefitting from additional support include:*

- Pre-Approval Inspection (PAI)
- General GxP
- Supplier / Vendor
- Internal
- For Cause

Training: As a company transitions toward commercial operations, training is a critical component. Training programs are very resource-intensive during initial development but require fewer resources for ongoing operation. A proven methodology and trusted partner, however, can greatly enhance the efficiency and efficacy of a training program.

Organizational Change Management: Ultimately, the success or failure of any change is a result of people and their adoption of the changes being implemented, whether a change in company strategy, departmental process, or a global system implementation. As companies prepare to move to commercial launch, here are some key elements to keep in mind:

Organizational Change Management Objectives

- Prepare the organization for changes to the business environment in preparation for commercial launch
- Transition employees to accept new ways of working by defining and instilling new values, attitudes, norms, and behaviors that support commercial launch
- Ensure that the organization is prepared to pass Pre-Approval Inspection

Key Organizational Change Management Activities

- Assess the breadth and depth of the change on the organization
- Plan the most effective way to drive the needed organizational and individual behavioral changes needed to transition to the new ways of operation
- Plan and manage the effort of communicating and training the organization so that everyone is ready for commercial launch

Organizational Change Management Variables

Listed below are a few variables to consider as a company defines their overall OCM strategy in pursuit of their commercial launch:

1. Who is impacted by the changes?
2. What will the business stop doing as a result of the changes?
3. What will the business start doing as a result of the changes?
4. What will the business continue but do differently based on the changes?
5. How will the roles and responsibilities and the organization overall change?
6. How has the organization reacted to change thus far?

OCM needs to have a central role in the transition, so starting early is crucial. Organizations should approach OCM with a holistic methodology that addresses all elements in the cycle of change tailored to the unique culture, situation, scope of transformation, user groups, and job impacts of the organization.

ENSURING A SUCCESSFUL GXP COMMERCIAL LAUNCH

Clarkston Consulting provides the full spectrum of GxP support from a comprehensive development and implementation of all GxP processes to simple assistance through the authoring of a few SOPs to help prepare for the PAI and commercial success beyond. For assistance in developing or remediating GxP processes, reach out to our GxP compliance experts.

ABOUT CLARKSTON CONSULTING

Businesses across life sciences industries partner with Clarkston Consulting to enhance strategic decision-making, improve operational efficiencies, implement new technologies, and promote business growth and market diversification. Leveraging deep functional and industry expertise, our people discover, design, and deliver solutions that fit your business, your goals, and your future. At Clarkston, your purpose is our purpose.

For more information about how we can help your company, please contact us.