Six Steps Pharmaceutical Manufacturers Should Follow For Successful CMO Projects

The relationship between pharmaceutical manufacturers and their contract manufacturing organizations is a key factor determining successful outcomes.

Several important areas should be considered during project negotiations between manufacturers and their CMO partners to maintain productive relationships that maximize positive results. These categories include dispute resolution, division of responsibilities, changes requested outside the agreement terms, regulatory compliance filing requirements, logistics capabilities and business practices.

DISPUTE RESOLUTION

Complex scientific, regulatory, manufacturing, testing, packaging, labeling and administrative procedures require frequent collaboration. Expectations are documented in a Quality Agreement And Scope of Work that details the responsibilities of all parties before work begins. The document outlines specific steps to investigate and resolve issues that may arise.

The Quality Agreement benefits the manufacturer and the CMO because it assigns responsibility for specific program elements to avoid misunderstanding or confusion for the duration of the working relationship.

DIVISION OF RESPONSIBILITIES

When duties between manufacturers and CMO partners are not clearly defined, trust may erode if any problems arise during the project. The project manager at the manufacturer and the CMO team must continue to communicate without any clear process to correct issues or resolve problems.

CHANGES TO AGREEMENT

Manufacturers paying for services from CMO partners may sometimes assume that project scheduling can be modified based on the manufacturer requirements. The CMO manages schedules according to availability of resources based on work required by multiple clients. Therefore, a change requested by the manufacturer to reschedule production for another time may create a conflict with other work for other manufacturers.

REGULATORY FILINGS

Generating, compiling, maintaining and submitting documentation to regulatory authorities including the Food and Drug Adminisration , states and other organizations is necessary to prepare a pharmaceutical drug product for market. Information provided by the manufacturer and by the CMO are combined on

various production reports, license submissions and other requests. Without comprehensive and accurate paperwork, projects may be halted or products not approved for sale.

Successful collaboration between pharmaceutical manufacrturers and their CMO partners requires detailed negotiation prior to project start. Photo credit: WDPrx

LOGISTICS CAPABILITIES

Manufacturers that focus on production and pharmaceutical manufacturing at the expense of supply chain and distribution capabilities often experience delays when marketing their products. Although manufacturers may have arrangements with their own Third Party Logistics (3PL) providers, full-service CMO partners have the capability to label, package and ship orders to various locations according to manufacturer demand. Since November 2018 the FDA requires 2D barcodes to appear on labels for certain pharmaceutical drug products to conform to requirements of the Drug Supply Chain Security Act. Some full-service CMOs have relationships with 3PL firms authorized to receive, store and fulfill orders, providing an efficient and cost-effective option for manufacturers to produce, manufacture and ship medications.

BUSINESS CONTINGENCIES

A comprehensive agreement between a pharmaceutical manufacturer and a CMO may also consider factors including intellectual property issues and corporate ownership changes. Although these and similar situations may be infrequent, agreements that consider every potential area that may affect the ownership or production of the medication can put both parties at ease.

For example, the way in which proprietary formulas or information is handled by the pharmaceutical contract manufacturer should be known in advance and steps taken to modify internal policies to meet client

expectations. As business consolidations increase in the pharmaceutical industry , there may be the need of an understanding about how projects may continue if and when ownership changes at the CMO or at the manufacturer.

SUCCESS IS DETERMINED BEFORE WORK BEGINS

Pharmaceutical manufacturers rely on excellent communication with their CMO partners to help assure projects proceed on schedule and reach successful completion. Creating a framework where each party clearly understands their responsibilities in different scenarios generates trust and builds confidence that guides each project from start to finish. Thorough discussions about dispute resolution, division of responsibilities, changes requested outside the agreement terms, regulatory compliance filing requirements, logistics capabilities and business contingencies serve manufacturers, contract manufacturing organizations and patients.