Can’t Ignore cGMPs

“Unfortunately the biologics industry has not gotten the message about the FDA’s increased focus on GMP compliance.”

Deborah D. Ralston, Director, Office of Regional Operations for the FDA Office of Regulatory Affairs (ORA), speech to Food and Drug Law Institute, December 1999

1. NOT OPTIONAL

Chemistry, Manufacturing and Controls (CMC) is the body of information that includes the manufacturing, testing, and release of product. Good manufacturing practices are the actual requirements that need to be followed to ensure that the product meets its intended characteristics. One cannot be CMC regulatory compliant if one is not following good manufacturing practices.

1.1 What are ‘cGMPs’?

Regulatory agencies around the world have issued performance requirements that drug manufacturers are expected to follow. These regulations are referred to as either good manufacturing practices (GMPs) or current good manufacturing practices (cGMPs).

The two main underlying concepts of all GMPs are:

1. A recognition that quality cannot be inspected or tested into a drug product
2. An acceptance that each step of a manufacturing process must be controlled to maximize the likelihood that the drug product will be acceptable and safe for its intended use

Few would disagree with these two fundamental concepts; after all, they also make good business sense.

In the U.S., GMPs for drug manufacturing are requirements found in legislation and FDA regulations. In Europe, GMPs are considered part of the overall quality assurance system for drug manufacturing.

GMPs weren't formed in a vacuum as regulatory requirements. They are based on quality principles and practices that have evolved over time. Through the 1950's, the quality and safety of a product was determined mainly by testing it to determine whether it met pre-defined specifications. One wasn't really sure that the product was acceptable until all the test results were completed. From 1960's to the 1970's, the idea of building quality into the product began to take hold. By designing quality in from the very beginning, manufacturing processes can produce products that meet predetermined requirements. This philosophy is formalized in current GMPs.

GMPs can be summarized into seven elements:

- Protect the product from contamination and cross-contamination
- Prevent product mix-ups
- Know what is being done before doing it
- Document what really occurred
- Strive for consistency and control
- Have an independent group make the final decisions ("Quality Unit")
- Solve problems, learn from mistakes, monitor and continually improve

These seven elements of GMPs also make good business sense.

1.2 Three main GMP questions

Each biopharmaceutical company needs to determine what GMPs mean to their specific operations, and then make a determination of how they will meet those requirements. Most companies readily admit the need to follow GMPs, but many times they get hung up on the 'but' portion of three main questions: