Raising the bar for quality

Complying with cGMP standards can help pharmaceutical and nutraceutical companies meet basic quality requirements, but to really cultivate a reputation for quality, a company needs to challenge itself to go beyond compliance. Here are three practices that can help companies raise the bar for quality and efficient production.

Exceed expectations

Identify your customers’ expectations and then work within the quality-by-design (QbD) model to exceed them. Determine your product’s critical-to-quality (CTQ) attributes and design your processes and equipment to achieve them. Leverage innovation and process controls to reduce negative variations and use ongoing internal and customer feedback to continuously improve.

For capsules, print quality is critical for consumer compliance and confidence. Capsule printing machines can perform well at high production speeds but only if the process is tightly controlled. Capsule weight is also critical, as weight variations can influence drug delivery and produce dented or poorly fitting capsules. Variations in capsule dimensions can require frequent adjustments to encapsulation equipment, increasing downtime and reducing efficiency.

With these CTQ attributes in mind, Lonza used a QbD approach to identify and implement material, process, and equipment changes for its pharmaceutical Coni-Snap Sigma Series gelatin and HPMC capsules. The company now uses redesigned high-precision manufacturing and printing lines that have greatly improved visual and print quality, reduced variations, and eliminated excess handling steps. Inline process technology allows continuous feedback of product attributes, reducing defect rates from industry-standard AQLs (percentages) to parts per million (PPM). Besides improving product quality and consistency, these changes have increased security of supply, reduced stock levels, decreased downtime and manufacturing costs, and minimized risk from inspections and recalls.

Communicate value

Product transparency communicates value to customers and gives them peace of mind about a product’s quality, especially when the product exceeds customer criteria. It can also help reduce your customers’ manufacturing and market-release times by providing assurance that the product will surpass regulatory requirements.

Upgraded product specification sheets offer such transparency and provide customers with a single, easy-to-access information source, eliminating the need to search multiple documents such as technical reference files or certificates of analysis. Product specification sheets should clearly identify the product type, testing requirements, customer-specific specifications, regulatory standards, and lifestyle and religious certifications with visual reference to recognized market accreditations. For products manufactured to sigma quality levels, include a sigma designation and outline improvements in defect levels in PPM compared to AQLs.

Develop relationships

Synergy between the customer and the vendor is critical for product quality and efficient production. Inefficient supply-chain delivery can cause errors, increase costs, result in product deterioration and waste, and limit a company’s ability to meet last-minute production demands.

With vendor-managed inventory (VMI), the vendor is responsible for replenishing the customer’s inventory and is active in the purchasing process. The vendor may review the customer’s inventory levels onsite and restock either immediately or at a later date; the customer may periodically provide the vendor with inventory levels for creating orders, or the customer may provide a forecast for the vendor to use as a production guide. VMI simplifies inventory management, production schedules, and administration, reducing costs, lead times, and risks related to demand spikes and process disruptions.

Electronic data interchange (EDI) streamlines inventory administration by integrating product orders and delivery into a quick and flexible automated system. The customer can place orders automatically on a set calendar. The vendor reads the orders as they come in and acts on them based on the customer’s timing and delivery specifications. If an emergency or last-minute opportunity arises, the customer can quickly communicate the need for faster delivery electronically. Lonza has found that EDI can reduce transaction costs by more than 30 percent, decrease administration errors by more than 40 percent, and speed up the supply-chain cycle by around 60 percent.

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