PALL Biotech

Change Management

What are the Main Elements of an Effective Biotechnology Supplier Change Management Process?

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In a global manufacturing and business environment, change management requires close coordination between technical, business, quality, and regulatory functions across geographies. In designing effective change management processes, suppliers also need to consider end user applications, as well as regulatory requirements to help minimize risk to customer's operations, drug product or ultimately patient safety.

A well-designed change management system follows a holistic approach which aims to provide an uninterrupted and consistent supply of critical qualified products to the industry. This is achieved through, and may not be limited to:

- business continuity planning,
- negotiation of long-term supply agreements,
- quality agreements for critical materials, and
- product life cycle management.

Within the context of change management specific to filtration and single-use systems, risk can be defined as any unintended consequence resulting from a change in product form, fit, or function. Changes in form are those that alter product physical appearance or the chemical composition of the materials of construction. Changes in fit are those affecting product interface with mating components. Changes in function are those that affect product performance, including quality attributes. It should be mentioned that changes in labeling, packaging, certification, manufacturing site, process and equipment must all be included within the scope of change management.

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Pall Biotech supports the industry standard approaches jointly proposed by the Biophorum Operations Group (BPOG) and the Bio-Process Systems Alliance (BPSA) [1] and is implementing aligned standard work practices to manage changes in a manner leading to timely, transparent communication to customers. Changes are typically categorized not only by type but also by potential impact based on risk assessments, including an internal Application Risk Assessment (ARA). Although it is expected a final assessment will be conducted by the end user, the ARA is intended to assess the impact of the change on end users beyond the simple aspects of form, fit and function. The determined change category represents the criticality of the change and hence drives the issuance and timing of a Change Notification. Customers must be notified, with sufficient lead time, when there is a need to provide information on the nature of a change, so they can fully assess (and eventually verify) the (absence of) impact of that change with respect to use of product, patient safety, regulatory filings, or any other concerns.

Pall Biotech's change management and notification processes follow BPOG / BPSA recommendations for all products and provide:

- Controlled and categorized changes
- Defined work flow and deliverables
- Pre-notification of the most critical changes to inform customers of the intent to initiate a change so that they may begin to plan qualification activities, determine the need for samples, and manage stock levels or other issues
- High quality Change Notification document to allow customers to fully understand the nature, scope, and impact of change
- Robust Data Packages for the most critical/impactful changes
- Consideration of customer needs and risk
- Standard documentation
- Single point of contact for formal customer communication(s)

References:

1. BioPhorum Operations Group / Bio-Process Systems Alliance, An Industry Proposal for Change Notification Practices for Single-Use Biomanufacturing Systems. https://www.biophorum.com/resource/change-notification/overview/

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