



PERRY JOHNSON REGISTRARS, INC.

Change Control Procedures: How? & Why?

Change is inevitable in any industry, but it is of particular importance in the medical device and pharmaceutical industry. With myriad regulatory agencies inspecting every modification, the time and work necessary to complete changes are not insignificant. Of course, any and all scrutiny should be welcome to avoid putting end-users at risk due to a failure of a product's safety, reliability, or performance. Change control guidelines aim to moderate the risk posed to products' users from the start, and adherence is critical.

The initial identification of attributes should start early on in the development cycle, from the manufacture of products for both pre-clinical and clinical testing and continuing on through the rest of the product life cycle. Each change in design or manufacture of the product must be documented according to the applicable change control processes and regulatory guidelines. While some aspects of change control may be challenging, there are some strategies that may be undertaken to simplify and streamline the process.

But first things first – what *is* change control, really? “Change” in a manufacturing environment refers to the modification of equipment, materials, facilities, designs, formulations, utilities, processes, computer systems, packaging/labeling, and any documentation associated with the product being made. (Note: This may include documents such as quality manuals, SOPs, etc.) Something as slight as an equipment change, a manufacturing site change, a document update, etc. falls under the umbrella of “change” in this context. Changes may be seemingly insignificant or game-changing, permanent or even temporary; but all must be controlled and carefully monitored.

Regulatory agencies take on change control to help ensure the highest standards of quality in health care products, requiring ongoing compliance from manufacturers to ensure existing products as well as new ones remain on the market. Any changes requiring change control procedures must be reported appropriately to applicable regulatory agencies.

The control of changes made is typically overseen by a change control committee or a designated individual, usually depending on the size or complexity of an organization's operations. All discussions, meeting minutes, emails, notes, and ephemera associated with changes that occur must be included in change documentation regardless of the number of



persons involved. The establishment of all documents, approvals, and supporting data is what constitutes a *controlled* change versus an uncontrolled one. Uncontrolled changes – without the proper review and approval of quality control units and other relevant departments – can result in compliance violations.

Change processes can vary based upon the specific circumstances of a given organization, but all of them should contain at least the minimum:

- A change request form is completed and submitted. These forms include information such as:
 - Identification and description of the change.
 - Specification of other documents that may be affected by the change.
 - Dates of approval and efficacy.
 - Signatures of change control staff in approval.
- Change control staff reviews the request form to assess the significance of the change.
 - Staff should evaluate the details of the request and its implications against the CGMP (current good manufacturing practices).
- Once reviewed and approved, change control staff should deliver submissions to the appropriate regulatory authorities.

The thoroughness and completeness of change controls used is crucial, given the potential reach and impact of changes made. Should an incident occur following a change that requires corrective or preventive action, having records easily accessible for those involved in resolving the issue can greatly help streamline the resolution and save time.

At face value, change control may seem straightforward – at least for smaller-scale businesses. But with scale comes complexity, and additional processes and products being handled in a facility can quickly multiply the amount of documentation required. Especially where controlled processes cross the boundaries between different departments, communication problems and differing systems or databases can pose a challenge when it comes to collaboration between sides. Uniting and streamlining document collaboration, however, is easier than ever in the modern age with enhanced document sharing and meeting software widely available. Storing documents in a centralized digital location (such as Sharepoint, for instance) with proper permissions granted to the right people and a clear revision/change history available can reduce the need for in-person meetings and reviews.

When developing or optimizing your organization's change control procedures, it can help to keep in mind the regulatory perspective. While some regional differences may exist (for instance, between the FDA, ISO, and the EU), there are a number of broad points that are well-covered by CGMP guidelines:

- Written procedures describing the necessary actions of a proposed change to starting material, product component, process equipment, process environment/site, method of production, or any change that may affect quality or reproducibility should be in place.
- Sufficient supporting data to demonstrate that revised processes will result in the level of quality allowed by approved specifications must be included in change control procedures.
- All changes must be controlled: documented at the time of performance, reviewed, and approved by the quality control unit and other relevant personnel.
- Change control is part of CGMP focused on managing change to prevent unintentional consequences and must be completed within the guidelines detailed in CGMP regulations.
- Any deviations from written control procedures must be recorded and justified.

For more information on change control procedures as a part of ISO 13485 certification for medical devices, reach out to PJR – call **(248) 358-3388** or email pjr@pjr.com.

