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🔄 Technical 🔄 Regulatory 💢 Quality 🦳 Management

QUALITY SYSTEM IMPROVEMENTS

Here are four steps to help you organize, define, simplify and improve your quality system. These steps apply whether you are developing a new system or just going through the process of review and revision.

Organize by Department (Level-3):

- 1. Break your system down into logical departments/ locations. This makes locating information easy and it avoids complicating a function with requirements outside of their responsibility.
- 2. Create a standard set of abbreviations for departments.
- 3. Create an organizational chart for each department.
- 4. Identify job titles on documentation (never names).

Define Responsibilities and Authorities for Personnel:

- 1. Determine the management-level personnel responsible to "own" the documentation for their department or area of responsibility.
- 2. Define the responsibilities and authorities for each function listed on the department's organizational chart.
- 3. Review each responsibility and determine if it lends itself to a work instruction.
- 4. Use the responsibilities and authorities document as a mechanism for driving your training program.
- 5. Do not repeatedly identify "responsibility" boilerplate information on every document.

Simplify Work Instructions:

- 1. Be sure there is only one sentence per action verb.
- 2. Stay away from writing paragraphs (nobody will read it and it does not allow for easy reference).
- 3. Focus the writing on "how" things are done.
- Do not describe "why" things are done. "Why" detail is best to be left for the training process.
- 5. Work instructions are not written to the level of detail that could help someone off the street. They are the guiding instructions to facilitate the training process that are made available for reference.
- 6. Do not write interdepartmental work instructions. No one should write what another department or area outside of their responsibility should be doing. Those responsible for the work must be the ones involved with the definition of the instructions.

7. Before you create a new document, ask yourself "can we modify our existing documentation?"

Improve Control:

- Avoid duplication documents that reside in multiple locations increase the possibility of confusion and are difficult to control.
- Do not require a signature or initials on work instructions. Approval can be shown by identifying the owner of the documentation as the person authorized to make changes.
- Make documentation available electronically. Have the "Table of Contents" for the particular department on the desktop and "hyperlink" to each procedure from this table of contents.
- Make the electronic version the "controlled" copy. Everything printed is considered to be uncontrolled (and identified as such in the footer).



Level 1: A document that describes the policies of the organization to address the requirements of a quality system. It contains no confidential information and controlled internally and uncontrolled externally.

Level 2: Documents (identifying who does what, when) that describe responsibilities or methods for achieving the policies as stated in Level 1. These are the guidelines that define the processes in support of policies and are normally interdepartmental.

Level 3: Documents that describe the necessary detail on how to perform a task within a process. They are normally intradepartmental and required where the absence could adversely affect quality.

Level 4: Forms and reports used to communicate and distribute information or data throughout the organization. They are the objective evidence that supports claims of the quality system.

All Craftsman's Cribsheets are available for viewing and download at pmpa.org/knowledge-tools/craftsmans-cribsheets