COMBINATION PRODUCTS
DEVICE SPECIALISTS®

Lean GMP Process Management

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CPDS Workshop / Training

Streamline and optimize GMP systems (US/EU GMP + ISO 13485:2016) without compromising compliance and product quality

Lean GMP: Be the Best and Save Big

CPDS has crafted a comprehensive series of trainings and services/workshops tailored to the diverse needs of lean Pharma combination product manufacturers and their suppliers. With 30 years of proven and mature methods, CPDS ensures that when these are followed and applied, Quality Management will become:

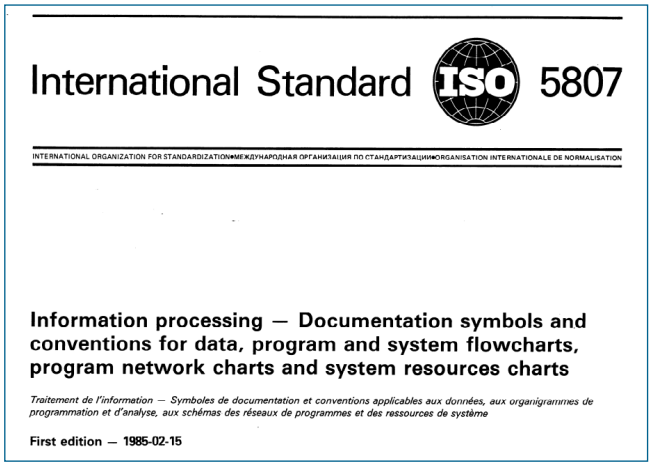
- Lean
- Robust
- Efficient
- Mature
- Globally harmonized

Introduction to the CPDS Process Approach Workshop/Training:

Implementing a process approach is essential for an effective lean Quality Management System. This means viewing every operation within the company as a process, with clearly identified inputs, resources, documents, activities and outputs for each. By adopting LEAN principles and structuring your system around processes, you can monitor and measure their efficiency and effectiveness, allowing for continuous improvement.

During the workshop you will learn this new complete model from A to Z, with practical and pragmatic examples. For instance, when we explain the role of a process owner, we will show you a sample job description covering all aspects.

By integrating LEAN thinking, you ensure that each step is value-adding, efficient and aligned with business objectives. This systematic approach not only enhances operational efficiency but also drives ongoing improvements, making your Quality Management System more robust and reliable, ultimately leading to a high maturity level.



International Standard ISO 5807

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION•МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ•ORGANISATION INTERNATIONALE DE NORMALISATION

Information processing — Documentation symbols and conventions for data, program and system flowcharts, program network charts and system resources charts

Traitement de l'information — Symboles de documentation et conventions applicables aux données, aux organigrammes de programmation et d'analyse, aux schémas des réseaux de programmes et des ressources de système

First edition — 1985-02-15

In simple terms, the process approach involves viewing all operations within a company as processes. This entails breaking down the company into its processes, determining their sequence and interactions, identifying inputs and outputs and recognizing which processes can begin before others are completed. Additionally, it involves determining the necessary resources and information to start each process and identifying the expected results.

By adopting LEAN principles, you can further streamline this process approach. Begin by creating a comprehensive process map that includes all the processes in your company and their interconnections. This process map serves as a visual representation of how different processes interact and depend on each other, helping to identify and eliminate inefficiencies and waste.

Once you have developed this company process map and identified all the processes and their interrelations, you can begin to define each process more specifically. This includes:

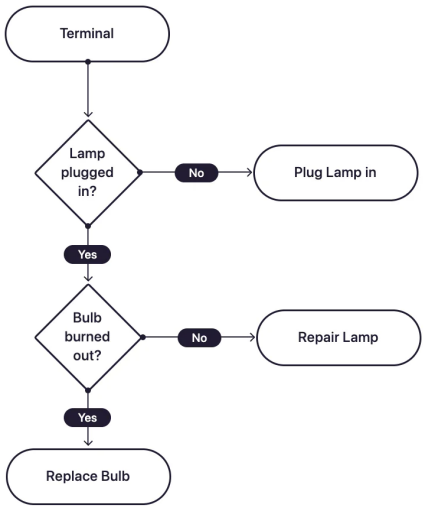
- Identifying Inputs: Determine what resources, information and materials are necessary to start each process
- Applying Controls: Establish what controls need to be applied to ensure the process is carried out correctly and efficiently
- Defining Outputs: Identify the expected results or outputs of each process

It's important to note that this detailed definition of processes should be done progressively throughout the implementation. You do not need to finalize every detail all at once. By taking a systematic and step-by-step approach, you can ensure that each process is thoroughly understood and properly integrated into the overall Quality Management System.

To effectively implement the process approach with LEAN thinking, ensure that:

- Frequently interacting processes such as Document Control, Control of Records, Management Review, Internal Audit, NCP, Event Deviation Management and CAPA are streamlined and optimized
- The process map clearly illustrates the interactions of any related support functions (both internal and external) and specifies who is responsible for each process
- Processes are continuously monitored and improved to enhance efficiency and effectiveness, ensuring that they are value-adding and aligned with business objectives

This LEAN process approach not only enhances operational efficiency but also drives ongoing improvements, making your Quality Management System more robust and reliable.



What you will Learn:

During the workshop we will create the following elements for a sample (sub) process (e.g., pH measuring):

A) Assign a unique identification to each (sub) process. Assign a process owner for each process. This owner is accountable for the entire process and is responsible for ensuring high-quality training of process employees and managing their curriculum.

B) Process flow.
Process mapping is a technique used to visualize workflows and processes. This involves creating a process map, also known as a flowchart, process flow diagram or workflow diagram. The aim of process mapping is to communicate how a process works in a concise and clear manner. This allows team members to easily understand how a specific process should be carried out, without the need for lengthy explanations (ideally using few words, images and videos). By mapping a process from start to finish, you can gain a better understanding of the entire process, identify inefficiencies. and make improvements.

C) Applying RACI to this process flow is an unbeatable method for precisely assigning roles to each process step. For example, it determines when (product impact or not) to involve QA, when to involve the QP and how they should be involved (informed or consulted).

D) Identify the need for and create all process specifications:

1. Identify the Need for Process Specifications

Determine which processes require detailed specifications to ensure consistent and high-quality outputs. This may involve identifying critical processes that significantly impact product quality, compliance or efficiency.

2. Develop Process Specifications

Document the required inputs, resources, methods. and expected outputs for each process. Clearly define the criteria and standards that must be met to ensure process consistency and effectiveness.

3. Determine Validation or Verification Requirements

Decide if process validation is necessary to provide documented evidence that a process consistently produces the desired outcomes. Alternatively, evaluate if 100% verification (inspection of each product) is required to ensure that specifications are met.

4. Monitor Compliance with Specifications

Establish monitoring mechanisms to regularly check if processes are adhering to the defined specifications. This could involve regular audits, inspections or using statistical methods to measure process performance.

5. List all supporting processes that can be called upon if needed

For example, Non-Conforming Product, event management and calibration. These processes should be part of the process training program (curriculum).

By following these steps, organizations can ensure that their processes are well-defined, monitored and continuously improved, leading to higher quality and compliance with regulatory requirements.

E) Establish process risk management with the process team and other SMEs as part of the company-wide risk management program.

By following steps of forming the process team, engaging SMEs, identification and assessing process risks, developing and implementing risk mitigation strategies, monitoring and reviewing risks and documenting risk management activities, organizations can establish a robust process risk management framework that enhances the overall effectiveness and reliability of their processes. The process risks should be part of the (visual) training program.

F) Determine which quality records. need to be created during the execution of each process step. Quality records are essential documents that provide evidence of compliance with your quality management system and meeting regulatory requirements.

These quality records should be identified and linked to the process from which they are created.

G) Develop comprehensive training curriculum for each employee,covering all the aforementioned topics, including risk management. Ensure the training is delivered effectively, incorporating high visual content for better engagement and understanding.

H) Continuously monitor and report on process performance over time through management reviews.

There is no need to alter any external QMS process software packages; however, it is strongly encouraged to automate certain processes!

Before considering whether the CPDS approach is compatible with all your process support software, we strongly advise against altering any of your significant existing implementations. Instead, utilize these packages as they are, ensuring their complete and well-documented implementation.

Packages such as Veeva Systems, Scilife and TrackWise are:

- Process-based: Designed to streamline and optimize specific processes
- Process flow supported: Facilitating smooth and efficient workflows
- Responsibility and authority assigned: Clearly defining roles and responsibilities
- Performance monitored and reported: Enabling continuous performance tracking and reporting

These packages/modules primarily focus on system processes and supporting processes, such as training. We recommend assessing the quality of your QMS implementation and ensuring the availability of detailed process flows. The CPDS process approach can easily serve as the benchmark for evaluating your existing QMS documentation.

For instance, we highly recommend visualizing most of your training modules. Excellent packages like Veeva support "movie-based" training, which is far more engaging and effective compared to the traditional "read and understood" method. Transitioning to visual instructions can result in significant improvements.

Our process approach extends company-wide, with the most significant impact and change occurring in primary processes. With a well-crafted quality plan (which we can assist you with) and a carefully planned implementation, your state of control will continuously improve.

The main area for improvement we observe concerning these external modules is the quality of the implementation. One common issue is deviation and CAPA (Corrective and Preventive Actions) management. The quality of investigations documented in these modules often lacks completeness, thoroughness, and timely resolution. Many companies face a backlog of open cases with new cases inflowing faster than they can be closed.

By adopting CPDS modules and focusing on identifying and addressing root causes, you can significantly reduce this unacceptable condition of non-compliance.

Target Workshop attendees:

- Ideally, all process owners and their delegates
- Representatives from the leadership team

Custom

This workshop can be tailored to your specific needs and preferences, including the option to incorporate one of your processes.

Contact us to discuss the possibilities.

Availability and Costs:

This workshop is performed on-site and the number of participants is flexible. Contact us for availability and pricing details.

Languages:

The training material is available in English.

The training can be delivered in:

- English
- German
- Dutch

Duration:
One day on-site.

Benefits for the hosting Company:
Our inhouse workshop will teach the participants:

- **State-of-art Lean GMP** process mapping, analysis and documentation
- **Most effective process training methods:** visual instead of words
- **Risk management applied:** see how risk management fits in this part of the life cycle
- **Apply RACI and process ownership**

Lean GMP workshop: preceding CPDS modules:

1. Initial introduction meeting (2 days):
   An in-depth session to understand your company's current status and specific needs. This forms the basis for designing the future state based on well-informed decisions.
2. Gap assessment starting with 2 days:
   This comprehensive assessment will result in a broad review of the Pharma cGMP QMS and the creation of the necessary "process interaction map".

Workshop leader
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