

5 steps to master continuous improvement in API DEVELOPMENT with Lean methodology: PDCA and A3-report



In today's fast-paced pharmaceutical industry, optimizing your API (Active Pharmaceutical Ingredient) development process is essential to staying competitive. Continuous improvement methodologies like A3-report and PDCA (Plan Do Check Act) offer proven, systematic approaches to problem-solving that drive efficiency, enhance quality, and reduce costs.

This guide will walk you through 5 key steps to implement these powerful tools, helping you streamline operations, overcome challenges, and achieve continuous improvements in API development.

Whether you're looking to improve product quality, reduce operational waste, or enhance cross-functional collaboration, mastering A3-report and PDCA will empower your team to deliver superior results.



What is the use of A3-report tool and what are the benefits for your company?

The A3 method has proven to be versatile and effective in a wide range of problem types. For a better understanding, we will take the example of CARBOGEN AMCIS on how this method helped us.

- **Improving product quality and chemistry process robustness:**

A3 thinking is commonly employed for analyzing deviations. When faced with an issue, we utilize the A3 format to document the understanding of the situation, investigate root causes, and propose effective countermeasures to tend to a most robust process with the lessons learned.

- This structured approach saves valuable time and enables teams to address issues more efficiently. The A3 report provides a structured framework that ensures all relevant factors are considered and the problem is thoroughly analyzed. Once the root cause is identified, the problem can be solved with accountability, the new standards are defined (Standardization), to prevent the recurrence of the same issue. Documenting the problem-solving process can also be useful for training and/or future improvement(s) (Sustainability).

- **Improving internal Standard Operation Processes:**

The A3 method has helped us to streamline and enhance standard operation processes, leading to increased efficiency and productivity from our internal company processes, such as processes with multiple departments interfaces.

- The A3 report serves as an effective communication tool that allows the problem, analysis, and proposed solutions to be easily shared with others. This can facilitate collaboration and consensus-building. For instance, the A3 report encourages communication between different teams, for improving an internal

process at the interface(s) with greater transparency, enhancing teamwork.

- **Reducing energy expenses:**

By identifying wasteful practices and proposing energy-efficient solutions, the A3 method has contributed to significant energy savings in our company. For instance, at the Vionnaz site, an A3 sheet was used to focus on each major energy consumption area. The project team collaboratively worked through the A3 format, identifying opportunities for optimization and implementing changes.

- This approach introduces structure and efficiency, fostering the development of critical thinking skills within the team. It requires the problem-solver to deeply analyze the problem, identify root causes, and develop effective countermeasures, which may sometimes challenge the status quo.

- **Improving document management:**

The A3 method has been used to improve the archiving system, making it more organized and easily accessible.

- The A3 report promotes a culture of continuous improvement by encouraging a systematic approach to problem-solving for all employees who would like to improve their workspace. It helps to turn employees' daily issues into potential for improvement by analyzing the problem deeper.

These examples demonstrate the broad applicability, effectiveness, and benefits of the A3 method in addressing several types of problems in our business context.

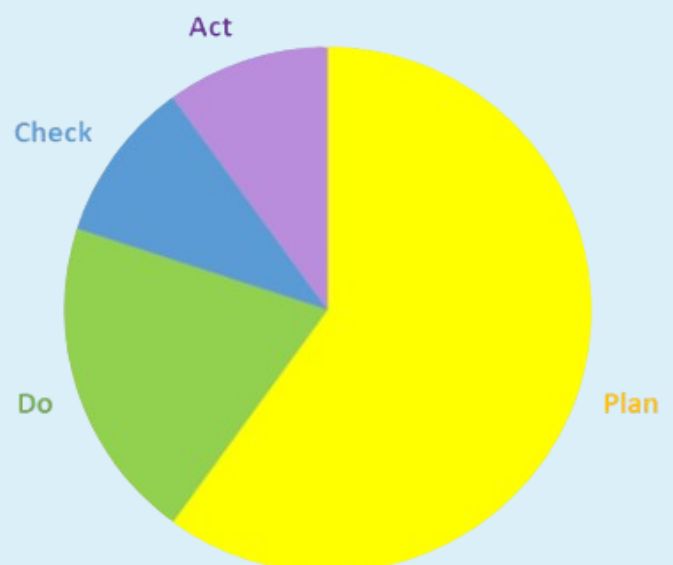
2 What about the time to be invested in the A3 report tool?

The time required to complete an A3 report can vary depending on the complexity of the problem and the level of detail required. However, it is important to note that the A3 method is not just about filling out a form, but about fostering a systematic, fact-based approach to problem-solving in team collaboration.

While the process might seem time-consuming at first, especially during the problem analysis phase ("Plan" from PDCA), the long-term benefits can far outweigh the initial time investment. As shown on the previous graph, the planning phase is the most time-intensive. Once this phase is complete, the solution is typically clear, making the subsequent phases much easier—like reaching a summit before descending.

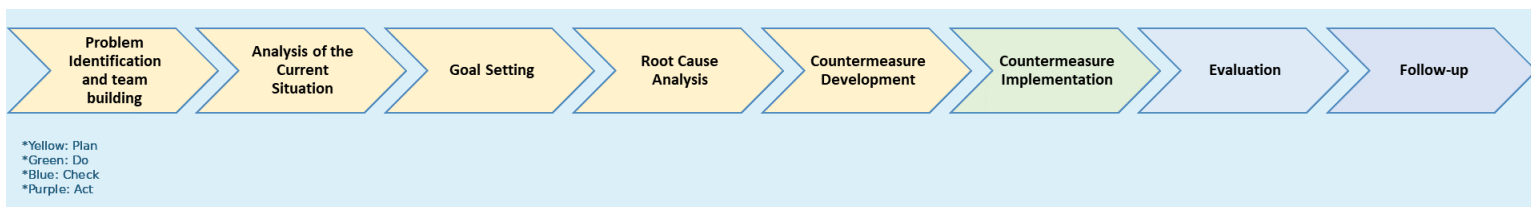
The A3 method is a powerful tool for solving problems in business. It encourages a systematic and collaborative approach to problem-solving, while promoting a culture of continuous improvement. Though it may require an initial time investment, its benefits (in terms of improved problem-solving, communication, and continuous improvement) can make it a valuable tool for any organization. Keep improvement going!

***"A problem well stated
is a problem half-
solved."*** Charles Kettering



3 What is the A3-report methodology?

The A3 method is a management tool that guides the problem-solving process in seven steps, on a single sheet of A3 format paper.



The 9 Steps of the A3-report:

- 1** Problem description and team building: Clearly define the problem and understand its impact on the business.
- 2** Analysis of the Current Situation: Collect data and analyze the current process to understand where and how the problem occurs.
- 3** Goal Setting: Define what you hope to achieve by solving the problem.
- 4** Immediate actions (if needed): Take any necessary immediate actions to mitigate urgent issues.
- 5** Root Cause Analysis: Identify the fundamental causes using tools like the Ishikawa diagram and the 5 'Why' questions.
- 6** Countermeasure Development: Propose and evaluate solutions to address the identified root causes.
- 7** Countermeasure Implementation: Implement the proposed solutions by following a plan.
- 8** Evaluation of results: Track the outcomes and evaluate the effectiveness of the countermeasures.
- 9** Follow up and Standardization: Define a new standard or plan new countermeasures if the target is not reached.

3 continued

Relation between PDCA and A3-report

There is indeed a strong parallel between the A3 method and the Plan-Do-Check-Act (PDCA) cycle, another key tool in the Lean methodology.

The A3-report below shows how they align in their structure:

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Measure with date and person responsible



Measure in implementation



Measure implemented



Effectiveness of the measure proven

The A3 report is a document that embodies the PDCA process. It provides a structured template for undertaking each phase of the PDCA cycle

and for communicating the results in a clear, concise manner. This makes it an invaluable tool for problem-solving and continuous improvement.

4 A3 Report Template and Instructions

•• Plan Phase

- Problem Description and Team Definition: Clearly define the problem.
- Current Situation Analysis: Collect data and analyze the existing process.
- SMART Goals: Set Specific, Measurable, Achievable, Relevant, and Time-bound goals.
- Immediate Actions: Take necessary immediate actions.
- Root Cause Analysis: Use the Ishikawa fishbone diagram and the 5 Whys.

•• Do Phase

- Implementation: Execute the countermeasures according to the plan.
- Track progress and assign responsibilities.

•• Check Phase

- Evaluation: Assess the results of the implemented changes.
- Evaluate the effectiveness of the countermeasures.

•• Act Phase

- Follow-Up and Standardization: Define new standards for continuous improvement.
- Plan additional countermeasures if the target isn't met.

5

Download the template

**Download the full template A3 Report
and complete the details with your own
company challenges!**

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