# Effectiveness Checks in the World of Software Technology Providers

An effectiveness check is a systematic evaluation conducted to determine the degree to which a corrective action or preventive action (CAPA) has been successful. It assesses whether the CAPA has addressed and resolved the root cause or underlying issue it was implemented to correct or prevent.

In various industries, including pharmaceuticals, biotechnology, and manufacturing, effectiveness checks are essential components of Quality management systems. These checks ensure that the implemented corrective or preventive actions are indeed effective in preventing recurrence of the problem or similar issues. A corrective action on a manufacturing process line may have an Independent Quality Assurance Team monitor the process over time or perform some level of "sampling" to ensure the correction addressed the issue and the original problem has been solved. You select the time frame, the sample size, the data to monitor. Efficient and straightforward.

> *In any proficient quality system, effectiveness checks are part of the overall process, and not a task that needs to be checked off after the issues are addressed.*

But how do effectiveness checks work with software and technology providers? This answer is not quite so straight forward as many techniques traditionally used in manufacturing may not work, but there are alternative methods that make sense in the world of software development.

According to *GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems, 2nd edition*, effectiveness checks in software "ensure the implemented actions have addressed the risk and minimized the risk of recurrence".

Verification and validation are tools that are outlined in software development life cycle guidance documents, such as GAMP5, that are used to ensure software issues and risk are addressed both in the product- product requirements (verification) and the process in which the product is used- process requirements (validation). GAMP5 recommends the use of verification and validation in software to ensure additional risks are minimized and managed resulting from corrective actions.

Other organizations in the pharmaceutical or healthcare industries agree. According to Pharmaceutical Online, verification of *corrective actions and preventive actions* is, in itself, an effectiveness check. The IMDRF Global Harmonization Task Force, in their guidance document, *Quality Management System – Medical Devices – Guidance on corrective action and preventive action and related QMS processes* also highlights verification and validation as critical components in CAPA systems, along with escalation to management and independent review of issues identified as all part of the effectiveness of the CAPA system.

In the world of software development, fixing a bug is just that. Fixing the issue. There is no need to observe the software over time to see if indeed the bug is fixed. That is the whole nature of verification and validation in software development life cycles. Instead, it is important to understand where the bug originated from, and to track over time if similar issues originate from the same code or if the issues arise in another part of the software or system with similar root causes. This analysis of trends over time and looking for repeat similar issues in other areas of code, for example, is one way to truly understand the effectiveness of technology fixes and minimize the risk of making similar software design choices through effective risk planning.

To ensure the effectiveness of corrective actions for software or technology issues, companies should embrace an effectiveness program that contains the following:

1. Ensuring identification of an appropriate root cause, and the actions needed for correction of the root cause.
2. Verification and validation that the corrective action (issue or bug) has been addressed with evidence so that independent third parties can verify the correction (typically quality organizations).
3. Management awareness program to report CAPAs on a regular basis (particularly those of a critical nature) and discuss significant issues and root causes over time (trend analysis).
4. Understanding the risk that CAPAs might introduce to the software code base or processes in order to improve the risk based planning process over time.
5. Establishing an independent group responsible for ensuring the CAPA is correctly worked, root cause identified, corrective actions taken, preventive measures (if any) identified and ultimately be the ones to close the issue. This is typically a Quality task. Ensuring that ONLY a single group has access for this oversight and ultimately closing out the CAPA, is the most effective way to ensure CAPAs have been addressed.

Corrective and preventive actions are a key component of any quality system implementation. In any proficient quality system, effectiveness checks are part of the overall process, and not just a task that needs to be checked off after the issues are addressed. The effectiveness of the system and corrective actions may look different based on the type of process, industry or systems you are working with. In technology companies, the key is ensuring there is evidence of corrective actions taken to address the root cause, and there is both management awareness of the issues, and independent oversight of every issue to ensure they are appropriately addressed. It is important to ask what risk this issue might introduce if something similar were to arise in other areas of code or configurations. Combining that with reviewing trends over time to look for repeat or similar issues is essentially the best effectiveness check for technology providers.

If this is all built into your quality system, you can rest assured that you have effectiveness of your CAPA system addressed and under control.

## *Meet the author*

**Laura Araujo** Laura Araujo is the Senior Vice President of Quality and Regulatory. With over 30 years of experience in Quality Assurance and Technology, she has held various positions in Software Development, Quality Assurance, Software Auditing, Regulatory Compliance, Organizational Development / Change and Technology Management. She has vast experience dealing with regulated authorities and processes from the DoD to Pharma/Biotech industries.

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