White Paper

4 Benefits of Adopting an Integrated Approach to CA/PA Management

Introduction

Within regulated industries, managing quality effectively is imperative in being able to deliver products and services that are fit-for-purpose and brought to market on time.

Fundamental to the success of any quality management system (QMS) is an integrated approach to CA/PA management that ensures non-conformances can be corrected and prevented efficiently and effectively.

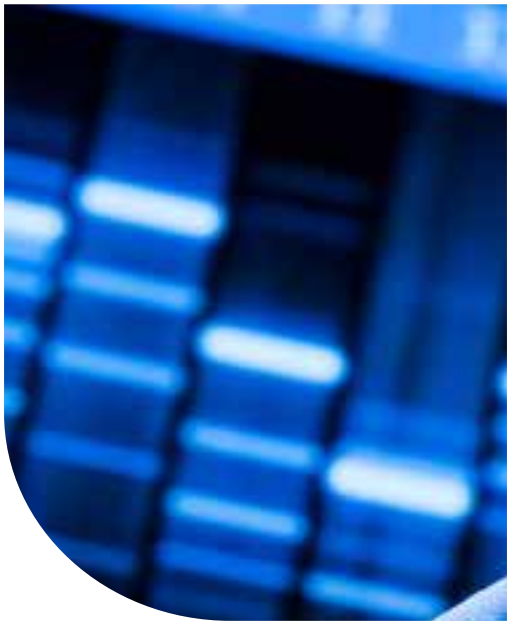
An integrated approach to managing CA/PA delivers company-wide benefits that include:

- Management commitment
- Staff competency
- Integrated root cause analysis
- Continual learning

In this way, non-conformances can be quickly and consistently corrected in the short term, and in the long term prevented from recurring, with processes improved to achieve increased quality and reduced costs.

Together with document and audit management, CA/PA management is the driving force in improving the QMS to achieve increased productivity and reduced expenditure. Where these processes can be integrated, companies can achieve greater efficiencies and effectiveness.

Maintaining separate systems to manage documents, audits and CA/PA requires increasing time, effort and cost in their day-to-day operation. As a result of managing these processes separately, companies in heavily regulated industries can often face:



- Reduced commitment to compliance activities from management and staff as a result of the lack of integration between manual systems
- Restricted ability to demonstrate staff competency at the point of need to customers, regulatory authorities or certification bodies
- Increased time to completion for CA/PA as a result of the lack of ability either to identify, or to analyse root causes
- Decreased efficiency and effectiveness of the management system as a result of the inability to continually improve compliance-related activities

In gaining company-wide commitment, ensuring staff competency, integrating root cause analysis and reinforcing learning, adopting an integrated approach can help to establish and maintain an efficient and effective CA/PA management process.

For companies operating in regulated industries, managing CA/PA efficiently and effectively as a key component of an integrated approach assures that compliance goals and objectives can be achieved, and makes a significant contribution to the continual improvement of safety and quality.

An integrated approach enables regulated companies to manage CA/PA efficiently and effectively, by:

- Encouraging all appropriate personnel to report events that require further analysis and investigation
- Capturing events from all areas and at all levels of the business quickly and easily, including throughout the supply chain
- Reporting issues both individually and collectively to avoid connections missed in maintaining multiple systems
- Notifying all appropriate personnel of issues specific and relevant to them to reduce repeat occurrences of mistakes
- Reducing organisational risk by preventing problems from occurring, to increase customer satisfaction and improved financial performance

In an effective quality management system, CA/PA can be integrated with audit in order to trigger corrective and preventive actions from audit findings, as well as with documents. This ensures that processes and procedures can be documented and controlled documents can be made available that describe the requirements of CA/PA procedures.

In addition, an efficient and effective reporting system ensures that staff can raise issues at the point of occurrence, and where this can be integrated with the quality management system, CA/PA can be automatically triggered in response to issues raised in order to reduce time to completion for CA/PA and to ultimately encourage a reporting culture throughout the organisation.

A staged approach to CA/PA management enables non-conformances to be broken down into stages, eg corrective action, preventive action, follow up and approval, which must be performed in a defined order.

In addition, this can align with the necessary actions to achieve the organisational culture that supports such a system and ensures its effectiveness.

The benefits of adopting an integrated approach to CA/PA management include:

1. Gain company-wide commitment

Extending reporting systems throughout the supply chain can ensure that management and staff can report compliance-related issues, non-conformances and complaints through a standardised framework that improves subsequent investigation and analysis.

Centrally managing all corrective action plans enables the automatic notification of all appropriate personnel of upcoming and overdue compliance-related actions. This ensures compliance with legal and regulatory requirements, accelerating time to completion and preventing recurrence.

Extending quality systems throughout the supply chain can ensure that management and staff understand their role in maintaining legal and regulatory compliance, actively participating in controlling and minimising risk.

Automatically notifying appropriate personnel of overdue or upcoming compliance actions can significantly increase the visibility and control of your quality systems and achieve greater ownership and transparency of compliance-related information.

In an effective quality management system, CA/PA can be integrated with audit in order to trigger corrective and preventive actions from audit findings, as well as with documents. This ensures that processes and procedures can be documented and that controlled documents can be made available that describe the requirements of CA/PA procedures.

2. Ensure competency of appropriate staff

Automating the document control process can secure greater buy-in from all appropriate personnel to radically reduce approval cycle times, and ensure that all compliance-related documents and records can be accurate, reliable and continuously updated.

Secure, centralised access to the policies and procedures that support your quality systems can ensure that management and staff can be aware of and acknowledge their responsibilities in complying with multiple legal and regulatory requirements.

Reviewing training needs against policy requirements and person specifications can make sure that all staff have the relevant expertise and experience to contribute to an understanding of operations, and to actively participate in controlling and minimising risk.

Automatically identifying all management and staff impacted by changes to compliance-related documents enables the scheduling of relevant procedure-based training, to develop and encourage adherence to best practice that is consistent with your organisational culture.

3. Integrate root cause analysis into quality systems

Analysing all compliance-related information across the enterprise can identify root causes and trends to ensure that compliance-related policies and procedures meet and exceed legal and regulatory requirements through regular internal and external evaluation.

Learning from issues, non-conformances and complaints throughout the supply chain can identify opportunities to improve quality systems, in order to contribute to the continuous improvement of compliance, to control and minimise key risks and to create greater business value.

Integrating all audit programmes within a streamlined, standardised framework enables the tracking and continuously monitoring of all compliance-related information across the enterprise to reduce audit cycle times and to dramatically drive down compliance costs.

Centrally managing all external, internal and third-party audits enables the measurement of ongoing compliance-related performance to deliver assurance over key risks and demonstrate legal and regulatory compliance to customers, regulatory authorities and certification bodies.

4. Reinforce learning

Improving the visibility and control of compliance-related information and systems can encourage all management and staff to contribute to a shared understanding of operations, in order to reduce business risk and take advantage of growth opportunities.

Putting a foundation in place for stability and growth drives an organisational culture that encourages adherence to internationally-recognised best practice, and which contributes significantly to the continual improvement of legal and regulatory compliance throughout the supply chain.

Conclusion

An integrated approach enables companies operating in heavily regulated industries to manage CA/PA efficiently and effectively, ensuring management and staff can capture events from all areas and at all levels of the business quickly and easily, including throughout the supply chain. This should encourage all relevant personnel to report events that require further analysis and investigation.

Managing CA/PA as a key component of an integrated approach should also notify all appropriate personnel of issues specific and relevant to them, in order to reduce repeat occurrences of mistakes and to enable the reporting of individual and collective issues, in order to avoid connections missed in maintaining multiple systems.

In adopting an integrated approach to managing documents, audits and CA/PA, companies in regulated industries can reduce risk throughout the organisation by preventing problems from occurring, in order to increase customer satisfaction and achieve improved financial performance.

Such an approach can provide regulated companies with benefits that include:

- Company-wide commitment
- Competency of all appropriate staff
- Root cause analysis integrated with quality systems
- Continual company-wide learning

About Gael Ltd

Gael helps organisations manage quality, safety and risk more effectively and more efficiently. Our flagship solution, Q-Pulse, is widely used in heavily regulated industries, and helps companies worldwide to successfully meet and maintain their regulatory requirements.

Companies including AstraZeneca and Reckitt Benckiser use Q-Pulse to improve the effectiveness of processes and systems, increase overall business efficiency, and transform the management of compliance activities from a costly overhead into a business benefit.

For more information about Q-Pulse, visit **www.q-pulse.com** or contact us at **info@q-pulse.com**.

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To find out more about how to manage your CA/PA processes more effectively, contact Gael today at **info@gaelquality.com**.

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