Quality Assurance in the Pharmaceuticals Industry

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100% HIGH QUALITY!

Optimizing Processes and Organization

In many industries, particularly the pharmaceuticals sector, the strict regulatory requirements and the challenges of staying competitive in a fast-changing environment are not only increasing the pressure on sales, production and administrative functions, but also on quality assurance departments. The QA team is now expected to keep control of quality, costs, reliability and speed, while also complying with regulations.

If this is to be achieved, quality assurance must become a proactive process which ensures that product manufacture adheres to specific standards and strives to continuously improve results and eliminate errors. In a nutshell, products should be "fit for purpose" and "right first time". By optimizing process reliability and efficiency, quality assurance can bring about speedy and effective operational performance which still observes all statutory requirements. To ensure the sustainability of this success over the medium to long term, quality assurance also needs to lead quality enhancement initiatives, eliminate activities which do not add value, reduce the cycle time required to handle and resolve quality issues, and lessen reoccurrence of deviations.

Achieving this is no mean easy and it is crucial that the right control system is clearly defined and closely enforced for meeting the required standards and attaining quality improvements along the way. In reality, many companies are experiencing troubles with this challenge, finding that support functions, such as quality assurance, are increasingly tied up with administrative activities, reducing the time

they can spend on the shop floor preventing issues and directly adding value to the end customer.

However, any trend such as this also provides us with many opportunities for optimizing and better organizing QA activities. We urge pharmaceutical companies to acknowledge the need to streamline their operations, improve flow and operational speed, while minimizing unnecessary tasks in which time and money is wasted. Now is the time for them to structure their organizations around the key processes that add value to patients and users.

This article presents Tefen's holistic approach as a method of QA process optimization, aiming to help organizations pursue business growth by becoming more proactive when dealing with failures and/or risks, reducing fire fighting situations and attaining higher levels of customer satisfaction. Moreover, with the use of lean methodologies and techniques, Tefen can help companies to significantly increase resource efficiency and successfully manage high and fluctuating workloads.

Implementing process optimization

The holistic approach from Tefen starts with a diagnostic benchmarking stage, which assesses three key factors: a site's strategic priorities, performance and practices. This then allows us to formulate customized recommendations for the specific objectives and constraints of each company,

giving valuable insight into what other organizations with the same issues have done to improve their areas of low performance.

1. Strategic priorities

Before any structural changes are made, it is crucial to specify the priorities of each site. Conducting specially designed interviews gives us an understanding of the drivers, constraints and overall philosophy, with its principles and trade-offs. This then enables us to define high-level targets for cost, quality and delivery metrics. Once site priorities have been set, a process/function matrix is used to prioritize the key business processes within the scope. Processes are prioritized according to their impact on quality and drivers, such as workload per department, cost, lead-time, customer value etc.

2. Current state: Performance and practices

An analysis of current practices at the site and their impact on performance forms the foundation for any change and is crucial to the success of the program. Workshops are used to identify the process steps, inputs and outputs, and to clarify accountabilities. These processes are mapped, focusing on the most critical 10-20 QA processes. Customers, outputs, suppliers and inputs are specified for each of the processes and subsequently, each of the process steps is categorized as either value adding, non-value adding or required for sustainable business. In addition to process mapping, working practices should

be observed and analyzed. The aim of all this is to establish the impact of practices on quality and to quantify the performance in terms of lead-time, FTEs or other costs, before benchmarking performance levels with other sites in the industry. At this stage it is essential to invest time on site to develop root causes and agree action plans with the teams.

3. Future state

For an organization to be successful it should have a clear vision and processes designed to maximize value to the customer. At this stage, each of the mapped processes is analyzed, in close cooperation with the teams performing these activities, to determine the optimum measures for process streamlining and removal of any waste and NVA activities. Benchmarks and best practices are brought in, assessed and incorporated where suitable to improve QA activities. Once the processes have been streamlined, the structure can be designed to enhance their output. Roles, responsibilities, accountability and interfaces are re-designed whilst taking into account existing knowledge and skill levels. Roles and structures may also be bench-marked, to provide a view of how other similar companies are organised (see summary of Tefen's 2012 QA organi-sation benchmark, below). A training plan is designed to enable speedy and effective transition. When the projec-ted benefits of the improved processes have been quantified, new performance targets are set and KPIs introduced to monitor and promote the effectiveness and reliability of each process.
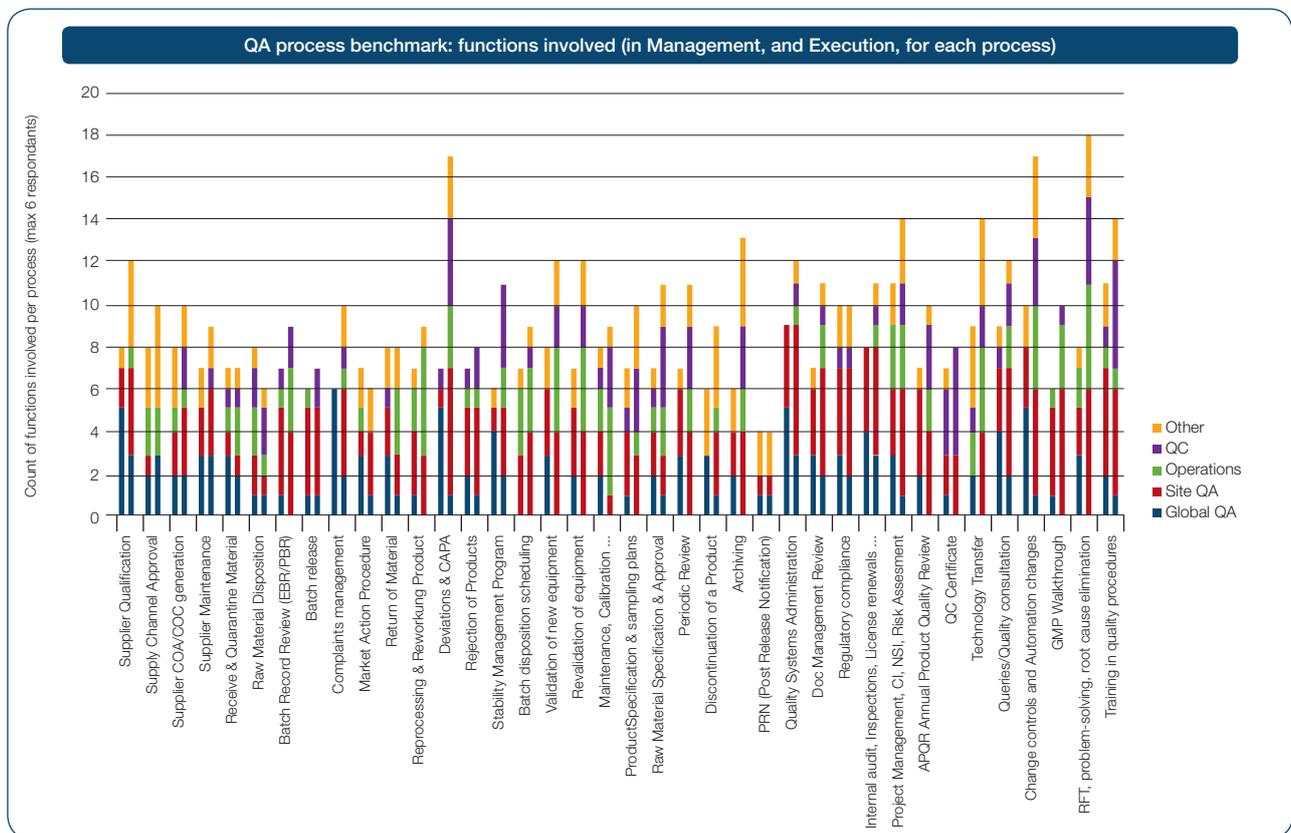

Figure 01: Benchmark of life sciences QA organisations, highlighting the functions involved in each QA process (management on the left, execution on the right)

4. Roadmap

The roadmap should translate all these recommendations into a tangible and explicit work plan to enable a complete, timely and successful implementation. This includes detailed work streams, responsibilities, timescales, and resource requirements. The roadmap should clearly illustrate the exact route to be followed by the organization, in order to achieve the desired future state, while also assessing the benefits of each work stream and prioritizing them accordingly. It is imperative that the quality leadership and management teams agree and sign off on the roadmap to guarantee a successful implementation phase.
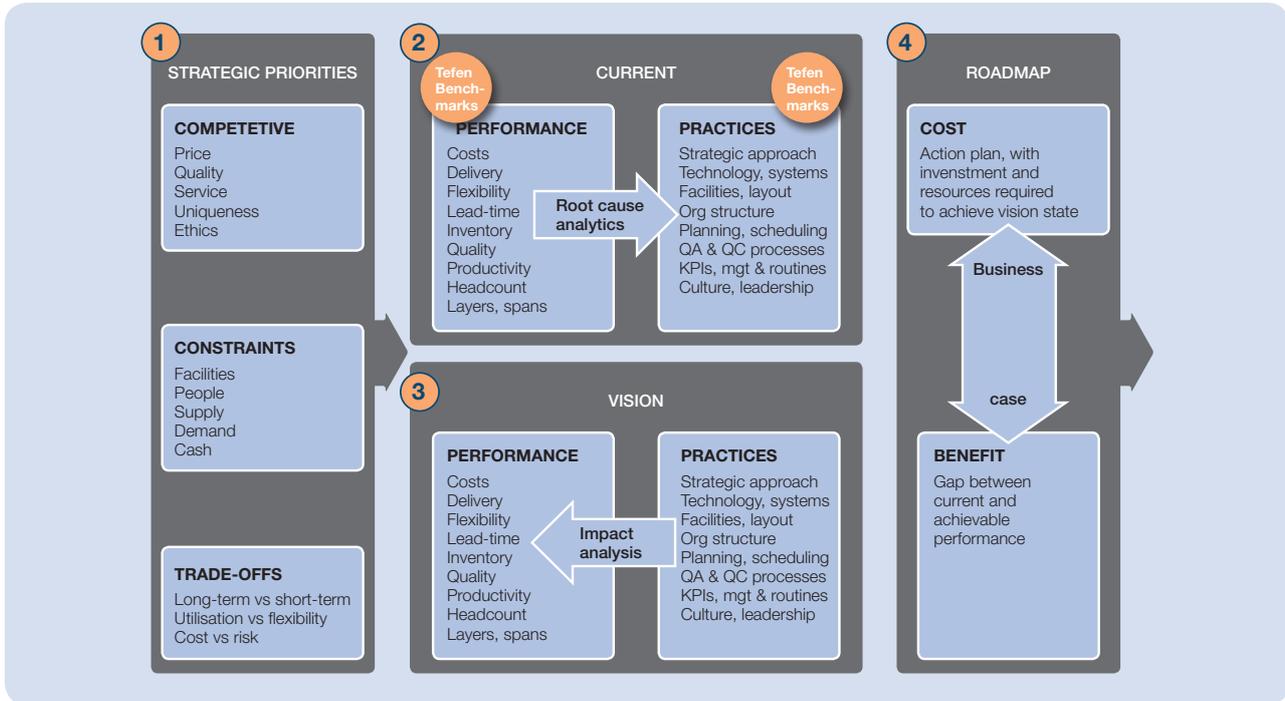
Case study

Introduction

A global pharmaceutical company had experienced increased deviations and claims over the past year, which alerted them to deterioration in product quality. Overloaded with administrative tasks, the support functions had a low presence on the shop floor and were unable to prevent quality issues. The company needed to focus more on pursuing quality enhancement and strive to anticipate issues in advance instead of just reacting to "unexpected" events. In addition to the long term objective of corporate growth within the network through major cost reductions, the company had an initial target to reduce overall QA administrative workload and decrease the workforce from 30 to 25 FTEs by optimizing 14 QA processes.

Tefen was asked to apply the above problem-solving methodology and design a lean QA operation in order to improve quality performance and reduce administrative costs.

Strategic Priorities

The priority ranking approach revealed that the key site drivers were quality (non-negotiable and a top priority for the site, especially bearing in mind recent quality issues) and cost (playing a key role in bringing new products to the site and satisfying clients). Meanwhile, the major constraint was perceived to be infrastructural management (the overwhelming QA workload and the organizational structure - sub-optimal knowledge, skills, roles and responsibilities of personnel).

In light of the above, the strategic project objectives were agreed to be:

- Enabling anticipation of issues instead of "fire-fighting" (quality)
- Decreasing admin. activities to allow time for walkthroughs on the shop floor to identify issues, confirm SOP etc. and hence increase quality performance (quality)
- Reducing overall QA workload and workforce from 30 to 25 FTEs (cost)
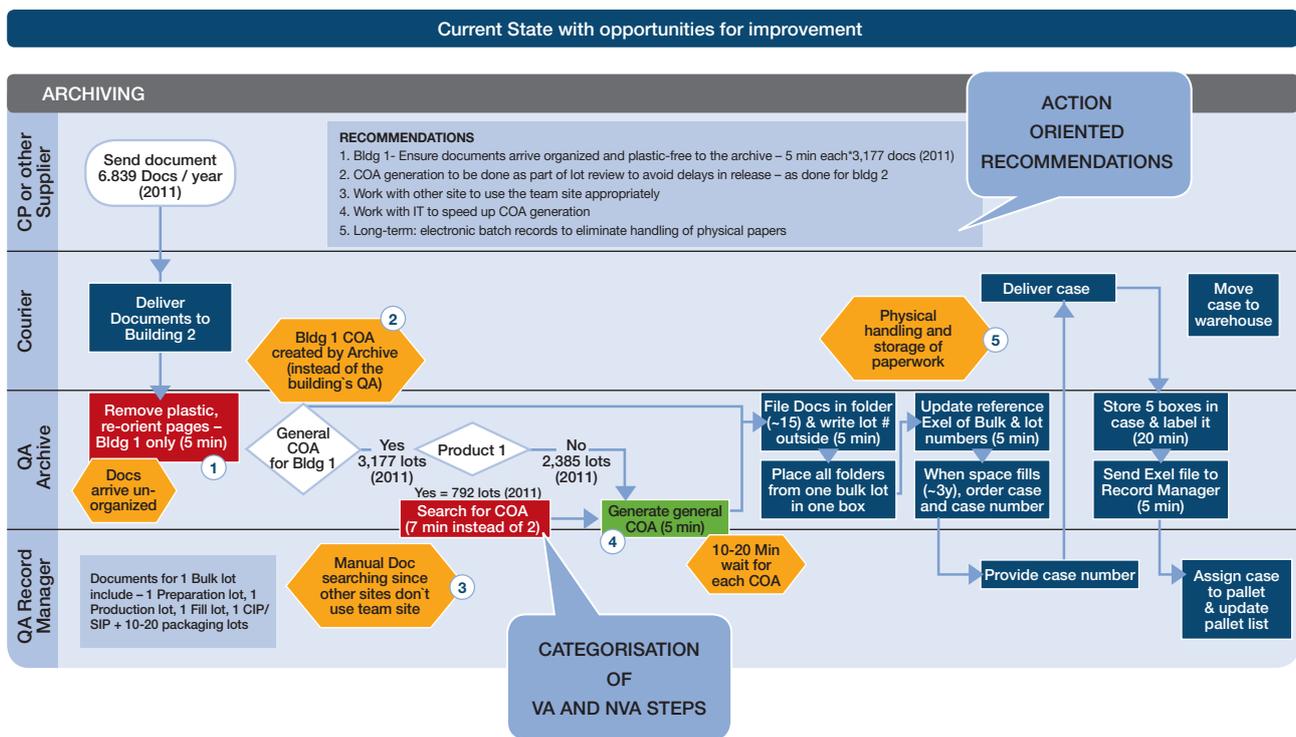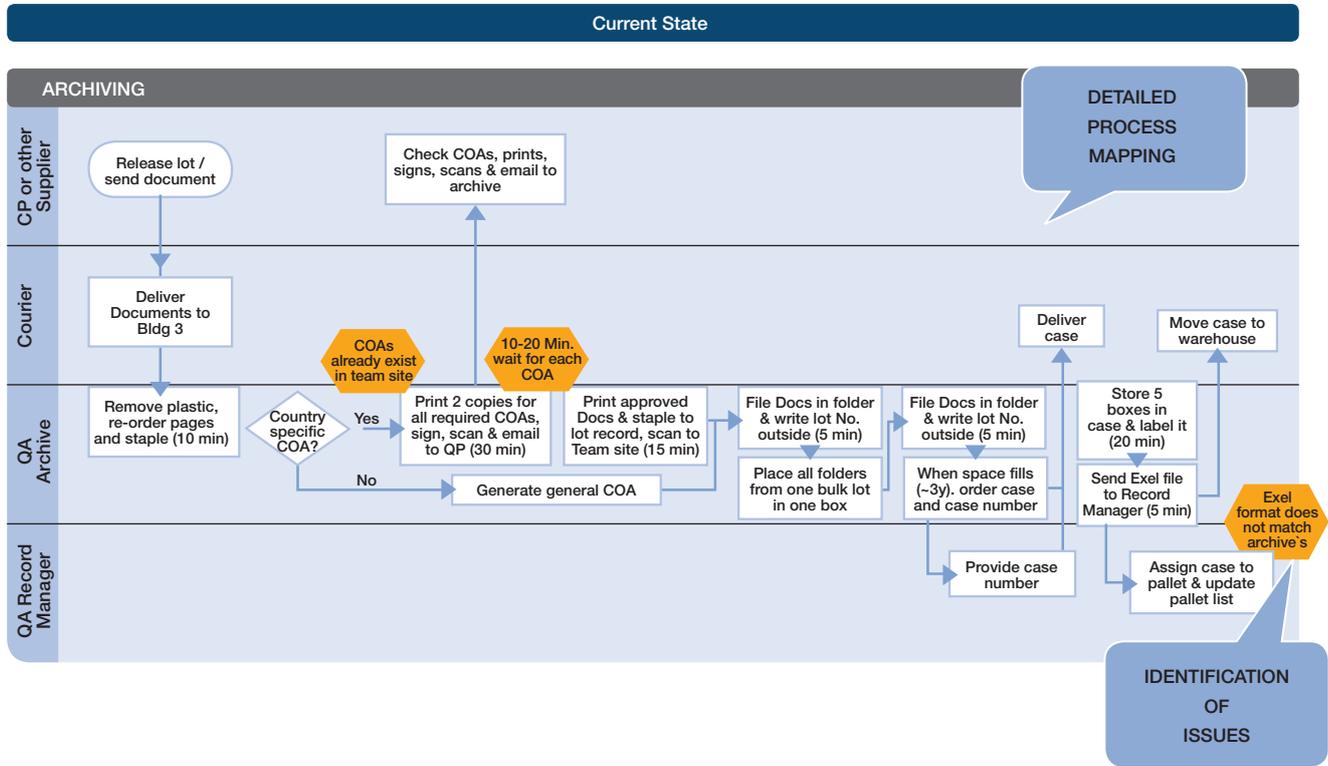
Current State: Performance

Focusing on the priority areas, key performance data was collected from the site and assessed against relevant QA departments at similar pharmaceutical sites, using Tefen's benchmarks, to identify areas for improvement.

Current State: Practices

The next step in the site analysis was a review of current QA support practices. Detailed process mapping sessions were used to identify areas of low performance and high cost, establishing major root causes and classifying each action as either value adding, non-value adding or sustaining activity.

Current State

ARCHIVING

DETAILED PROCESS MAPPING

CP or other Supplier
- Release lot / send document
- Check COAs, prints, signs, scans & email to archive

Courier
- Deliver Documents to Bldg 3
- Deliver case
- Move case to warehouse

QA Archive
- Remove plastic, re-order pages and staple (10 min)
- Country specific COA?
  - Yes → COAs already exist in team site → Print 2 copies for all required COAs, sign, scan & email to QP (30 min) → 10-20 Min. wait for each COA → Print approved Docs & staple to lot record, scan to Team site (15 min)
  - No → Generate general COA
- File Docs in folder & write lot No. outside (5 min)
- Place all folders from one bulk lot in one box
- File Docs in folder & write lot No. outside (5 min)
- When space fills (~3y). order case and case number
- Store 5 boxes in case & label it (20 min)
- Send Exel file to Record Manager (5 min)
- Exel format does not match archive's

QA Record Manager
- Provide case number
- Assign case to pallet & update pallet list

IDENTIFICATION OF ISSUES

Current State with opportunities for improvement

ARCHIVING

ACTION ORIENTED RECOMMENDATIONS

CP or other Supplier
- Send document 6.839 Docs / year (2011)

RECOMMENDATIONS
1. Bldg 1- Ensure documents arrive organized and plastic-free to the archive – 5 min each*3,177 docs (2011)
2. COA generation to be done as part of lot review to avoid delays in release – as done for bldg 2
3. Work with other site to use the team site appropriately
4. Work with IT to speed up COA generation
5. Long-term: electronic batch records to eliminate handling of physical papers

Courier
- Deliver Documents to Building 2
- Deliver case
- Move case to warehouse

QA Archive
- Remove plastic, re-orient pages – Bldg 1 only (5 min) ①
- Docs arrive un-organized
- ② Bldg 1 COA created by Archive (instead of the building's QA)
- General COA for Bldg 1
  - Product 1
    - Yes 3,177 lots (2011)
    - No 2,385 lots (2011)
  - Yes = 792 lots (2011) → Search for COA (7 min instead of 2) ④ → Generate general COA (5 min)
- ⑤ Physical handling and storage of paperwork
- File Docs in folder (~15) & write lot # outside (5 min)
- Place all folders from one bulk lot in one box
- Update reference Exel of Bulk & lot numbers (5 min)
- When space fills (~3y), order case and case number
- 10-20 Min wait for each COA
- Store 5 boxes in case & label it (20 min)
- Send Exel file to Record Manager (5 min)

QA Record Manager
- Documents for 1 Bulk lot include – 1 Preparation lot, 1 Production lot, 1 Fill lot, 1 CIP/SIP + 10-20 packaging lots
- ③ Manual Doc searching since other sites don't use team site
- Provide case number
- Assign case to pallet & update pallet list

CATEGORISATION OF VA AND NVA STEPS

Future State

Tefen designed the future state in collaboration with the client. All this stage, waste was eliminated from all steps within each of the 14 QA processes that were chosen for analysis and new streamlined processes specified that would enable a more timely and efficient result for the internal / external process customers. The benefits from each of the quality improvements were quantified in terms of lead-time, FTEs or other costs so that individual initiatives could be prioritized accordingly.

Roadmap

An action plan was compiled with all recommendations and process owners were assigned to be responsible for the successful implementation. The roadmap was comprehensive, including tasks for all 14 processes, and distinguishing between quick wins, short, medium and long term benefits.

Results

Direct process efficiencies

Potential for improvement through the reduction of waste and elimination of non-value adding activities was found in each and every one of the 14 process analyzed. The total workload reduced by these improvements can be translated into 4.32 FTEs savings which can be deployed elsewhere.

Task-level efficiencies (reorganization of process/people distribution)

Having mapped each of the 14 QA processes, a comparison was done between the workload shown from these maps and the actual time being spent on these activities in the current situation. This comparison revealed a significant discrepancy between the two workloads, especially regarding processes that were performed on a full or part time basis by a large number of individuals. In the most extreme situations, processes were spread across 13-14 QA associates, despite the workload requiring no more than 2-3 FTEs (according to process maps), leading to significant losses of efficiency, and time and effort being wasted communicating and coordinating amongst this large group of participants. By reassigning roles and responsibilities and achieving a more balanced spread of the workload amongst associates, an extra saving of 2.3 FTEs was achieved.

Error reduction benefits (quality improvement)

The high administrative workload of QA, together with its misplaced focus and removal from the shop floor was to a large extent responsible for the deterioration of product quality. Further to the efficiencies attained above, processes were redesigned to bring QA closer to the shop floor and prevent future quality issues from occurring. Some of the FTE savings above were reinvested in new processes, including the introduction of Gemba walks in order to optimize the quality system, ensure SOP compliance, identify further improvement potential, and prevent quality issues (by using risk assessment tools and monitoring). In addition, the knowledge obtained during the Gemba walks was beneficial in ensuring that the SOPs reflected the latest internal and external guidelines and regulations.

Conclusion

A holistic approach of QA process optimization and organization can generate a quality culture across a pharmaceutical organization and help to overcome the challenges faced. The purpose of process optimization is to focus on value adding activities so that value and responsiveness to the customer are maximized and waste and delays are eliminated. Tefen shows how lean practices should be applied in an organization's structure and processes to encourage continuous improvement.

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