

OPTIMIZING QUALITY SYSTEMS THROUGH A PARADIGM SHIFT

Placing the operator at the center of the systems



Table of contents

- 03... Executive summary
- 05... Life sciences: a challenging environment
- 06... Quality systems: ensuring product compliance
- 07... Documentation: a first lever for mastering daily operator activities
- 09... Training: a logical extension of the documentary system
- 11... Major challenges in the context of cost reductions

Executive Summary

The ever-challenging environment of the Life Sciences industry requires absolute control over product quality and compliance. Optimizing quality systems is essential today to reduce the overall cost of quality, which represents almost 30% of the industry's total revenue. Meanwhile, the impact of non-quality is increasingly significant, having doubled in 5 years.

This article offers thoughts on the performance of quality systems and, more particularly, the key role of documentation and training in achieving this objective. Why are these systems not effective today? How can they be redesigned to gain efficiency and restore the quality systems to their former glory?

Documentary system

- Today: documents are regarded as tools to meet regulatory requirements. User comprehension has become increasingly strained – they no longer know what needs to be done. Maintaining large documentary systems has become increasingly complicated and costly. Errors persist, even increase – performance decreases and the costs of non-quality go through the roof
- Tomorrow: the end-user is placed at the heart of the system and documents become the operator's third working tool. Operators access the critical information they require easily and rapidly with complete and ergonomic documents. At the same time, the overall document efficiency⁽¹⁾ rate is implemented and optimized, the number of human errors decline, and costs stabilize and fall



Training system

- Today: long, costly, and relatively ineffective. Companies spend far too much time and energy training their personnel, with mixed results – most of the time, operators fail to gain true autonomy
- Tomorrow: training is targeted and prioritized for better operator autonomy. The content, approach, and timing must be designed with the end-user in mind. Redesigning training, introducing the overall training efficiency^[2] indicator, and structuring the training process are necessary and complementary steps to gain autonomy more rapidly

Optimizing the quality system entails a paradigm shift – placing the operator at the center of the systems to guarantee the quality, effectiveness, and reproducibility of everyday operations, thereby reducing errors. The stakes are high for the company – reduction of non-quality costs, reduction of costs associated with documentary and training systems, and inspections – reduced risk of comments.

About the author: Camille Marcel is a senior consultant of the Capgemini Engineering life sciences process excellence world-class center, specializing in compliance and business process improvement. She has worked on diagnostic redesign and quality process optimization projects – documentary management and training management for a large number of pharmaceutical industry clients in France and internationally.

1. O.D.E. – Overall Document Efficiency rate, is an innovative metric developed by Capgemini Engineering life sciences WCC and is the likelihood of finding the critical information required, in a reliable and understandable format, directly at the workstation

2. O.T.E. – Overall Training Efficiency rate, is an innovative metric developed by Capgemini Engineering life sciences WCC to quantify the percentage of people who perform their activities properly at the end of the training process

Life sciences: a challenging environment

The life sciences environment has changed considerably in recent years. Major technological developments have been site specialization, the rapid growth of generics, and the development of biotechnology. The last 25 years have seen a number of increasingly rapid transformations that have changed the face of production-based activities.

The regulatory requirements have changed too

Conscious of their obligations with regard to the public, pharmaceutical companies hold themselves to ever-stricter ethical standards in order to guarantee the safety and quality of drugs throughout their lifetime, from research to commercialization.

Pharmaceutical market: key figures

- Pharmaceutical market revenues in 2014: €981 billion
- Total pharmaceutical R&D spend in 2014: €127 billion
- CAGR in the industry between 2014-2018: 4.8%

The pharmaceutical industry employs over 4.3 million people worldwide, with 8,10,000 employees in the United States and 700,000 in Europe, 25% of whom work in production. The number of production-focused jobs has increased 22% in the last 10 years. Employees working in quality account for 20% to 25% on sterile sites and 10% to 15% on non-sterile sites and contract manufacturers.

Sources: Statista, EvaluatePharma, IFPMA, and IMS



Quality systems: ensuring product compliance

Patient safety and compliance with regulations are major challenges. Over the last 25 years, quality systems have been constantly changing – frequent modifications to regulations and the growing internationalization of medications. Pharmaceutical quality systems must be increasingly effective to ensure risk management at all stages of the drug value chain.

These systems become more and more complex and are thus ever more costly, as well as increasingly ineffective – increased sorting, deviations, and stock shortages. The overall cost of quality including personnel and non-quality costs accounts for 20% - 30% of the industry's total revenue – greater than R&D investments in the sector.

This figure is rising

- The number of product recalls has doubled since 2010
- The collaboration with consulting and service companies is constantly growing – compliance consulting income is estimated at €7.5 billion in 2014

Sources: FDA, McKinsey

It is important to rethink quality systems, process mastery, skill development, and team involvement in quality and document system optimization.

Complex, costly, ineffective – why do companies struggle so much to get it right the first time?

Quality Assurance (QA) concerns not only the product but the operator as well, by giving operators access to a comprehensive system that enables them to carry out their everyday tasks correctly and without error. This QA system thus includes documentation and training – applying good practices for documentary drafting, structuring, and compilation, accelerating employee integration, and offering more targeted and effective training are major challenges for companies.

Quality assurance systems focus

- Definition: implementation of an appropriate set of pre-established rules to increase users' confidence that the required level of quality will be obtained
- Components: deviation, CAPA, record management, documentation, and training
- Objective: guarantee quality and compliance, control risks, and reduce the number of errors at every level of the drug value chain

Quality assurance key figures

- Three-quarters of deviations may be linked to human error, and at least 1 to 2 deviations per batch are due to human error
- Most companies currently have a 'right-first-time' rate at the operator level close to 0% – linked to the documentary system, batch record, release workflow, and culture. But how can documentation and training contribute to managing the operator's risk and reducing errors at the shop-floor level?

Documentation: the first lever for mastering daily operator activities

Because of audit comments, incorporation of corporate demands, and a failure to manage document creation, documentary systems sprawl. A single document may cost up to €3,500/year. As detailed in the good manufacturing practices – good documents are an essential part of the quality assurance system. Clear texts prevent errors inherent in verbal communication. The legibility of the documents is of paramount importance. But what is the purpose of the documentary system? How are all these documents used?

Documentation today: low added value?

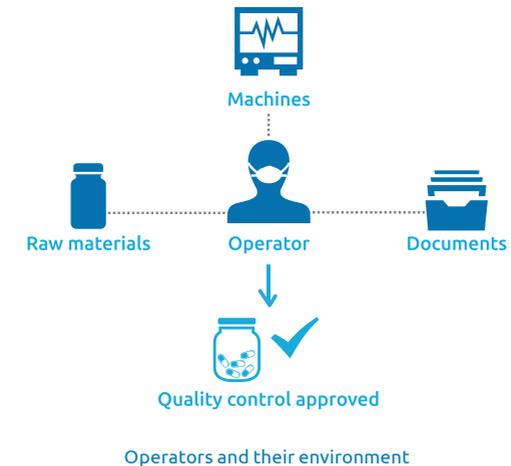
Traditionally, documents were considered tools to meet regulatory requirements and were intended for inspectors. This vision had consequences in the field, including:

- Content ill-suited to the reality at the shop-floor level – dense, visually poor documents

- Documents consulted rarely or not at all by production-based employees
- Pirate documents were created in parallel to the documentary system
- A verbal culture to train teams, based on people and not on systems.

A new vision: considering documentation as a working tool

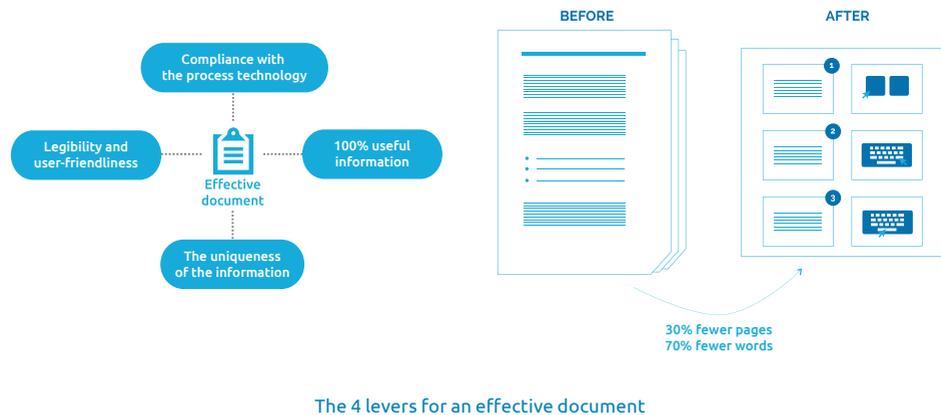
With an innovative vision, documentation is seen as the operator's third working tool – after machines and raw materials. It is time to design our documentation in a more efficient way, to increase its value, and avoid human error and QA costs. SOPs are not only documents but information to be provided to doers, to help them do their daily work.



Placing the operator at the center of the quality system

Users become central – they must have quick and easy access to the critical information they need. To this end:

- The information is structured based on the process map, identification of the critical stages, and the document pyramid



- Documents comply with the basic rules of ergonomics, legibility, and innovative media are employed – IKEA-like instructions, touchscreen tablets, and video.

When working to redesign documentation so as to make documents accessible, complete, valid, user-friendly, and attractive for the operator, the objective is of course to enhance documentary efficiency. The O.D.E. (Overall Document Efficiency) indicator was developed with this in mind – you can only manage what you can measure. Although the O.D.E. is currently close to 12% in companies – i.e. operators have approximately one in 10 chances of finding the information they need at the time they need it, this new approach makes it possible to achieve an ODE greater than 70%.

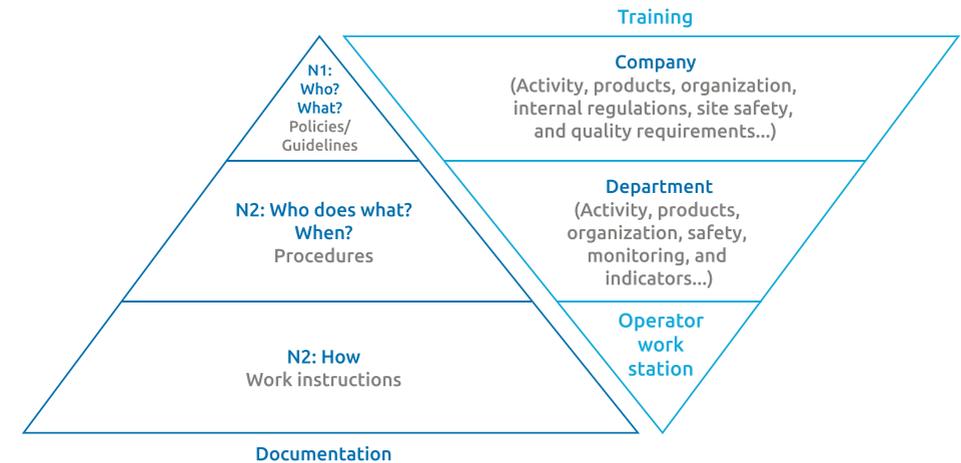
Taking control of document creation

In parallel, the creation of documents must be placed under control:

- By working on the link with CAPAs, deviations, and change control
- By avoiding inopportune document modifications and creations, and instead analyzing the criticality and relevance of requests
- By defining and implementing the necessary skills within the company – for e.g., by training document writers

Training: a logical extension of the documentary system

There is just a small step from documentary architecture to operator training. The documentary and training processes are closely linked – formalizing the company's know-how to facilitate transmission.



Documentation and training: as the basis for autonomy on the job

Training today: long and costly

Training initiatives observed in companies today are not very effective

All companies aim to increase the quality culture of their employees. Some deploy training or education programs in the hope of enhancing employees' knowledge.

However, the results are often the same:

- The content and pedagogical approach are inappropriate
- The training is often too theoretical
- Training is not performed at the right time
- The trainers are not always the right ones

And from a performance point of view:

- Many hours are spent in training
- Staff do not gain autonomy quickly and the objectives of the training are rarely achieved

Training in the future: targeted, offering rapid autonomy

Placing the operator at the center of the system

As with documentation, the user becomes central. The content, approach, and timing, must be designed with the end-user in mind. To do this, the right questions must be asked:

- Content: Who needs to be trained? For what scope? What is the relevant content according to trainees' profiles and skills?
- Approach: What is the best pedagogical approach depending on the training objective? Does this approach suit trainees? At the end of the training process, do trainees feel confident to perform their work alone?
- Timing: Is it performed at the right time, not too late, not too early? Do trainees implement the tasks for which they have been trained within a short timeframe?

The objective is to focus on the ability to perform the work alone after training. As with documentation, work must be done to redesign training with the aim of increasing training efficiency for the operator. The O.T.E. (Overall Training Efficiency) indicator makes it possible to measure training efficiency. The average O.T.E. currently observed is around 10% – i.e. an operator has approximately 1 chance in 10 of carrying out the task at the end of the training process correctly and without error. This new approach would increase training efficiency to 60%.

Taking control of the training process

Structuring the training process is an indispensable step for managing training within the company:

- Identify a process owner for the training
- Optimize (or define) the training management process itself: identify needs, determine the training strategies, design the training modules, implement training and track progress
- Set out the guiding frequencies: frequency of re-training? Training of trainers? What impact does prior experience have on training?

Major challenges in the context of cost reductions

A company's documentary structure may be seen as the reflection of its organization. This information structure must be perfectly in line with the scope of knowledge to be transmitted. Users see the benefits of having user-friendly documents suited for immediate use to make it possible to transmit know-how to new arrivals within a company.

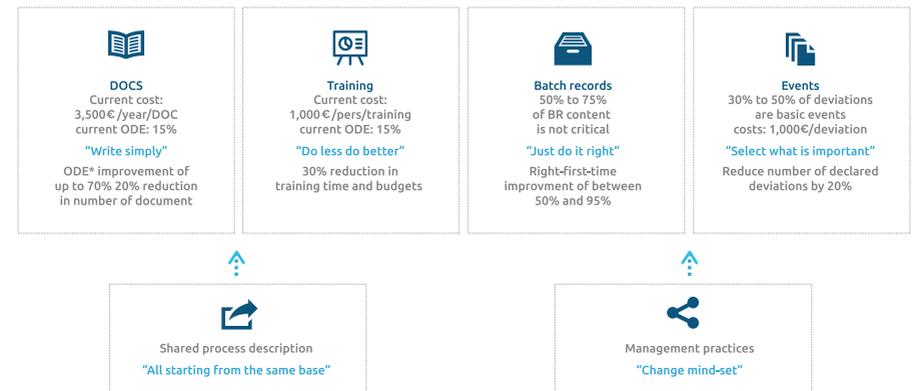
In conclusion, thought must be given to everything users need to get it right the first time:

- Training that must enable users to acquire the knowledge and know-how they need
- Easy and immediate access to necessary information

The purpose of both documentation and training is, after all, to ensure the quality, effectiveness, and reproducibility of everyday work:

- Fewer human errors and thus deviations, batch rejections, or stock shortages
- A reduction in documentary volume and the cost of documentation and training maintenance
- A process appreciated by regulatory compliance inspectors (some pharmaceutical companies present the changes in their ODE during inspections)

Documentation and training are pillars of on-the-job autonomy, but this approach must be extended to all systems surrounding users such as non-compliance management, simplification of batch records, and process control. Furthermore, guidance must be provided to ensure that these changes are fully understood and accepted.

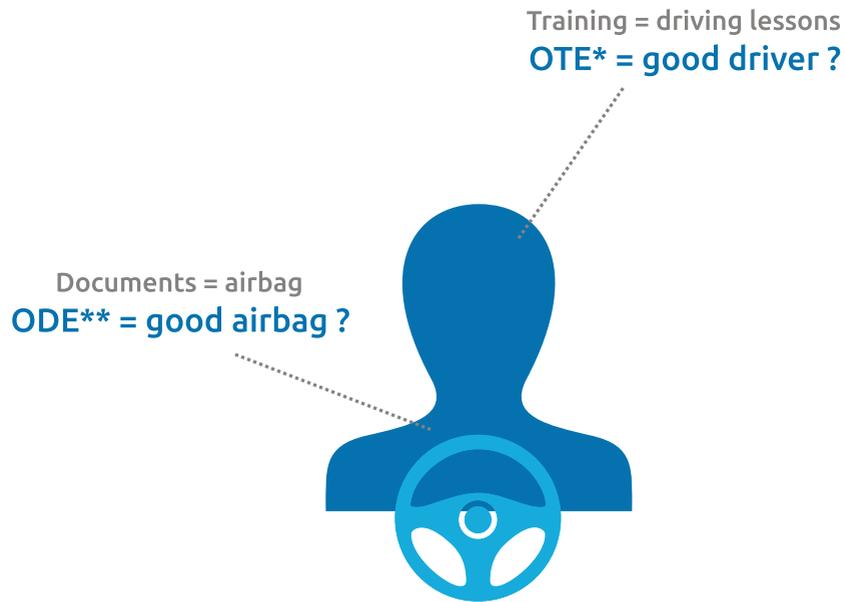


A holistic approach to reducing the number of human errors in your company by 50%



The analogy between on-the-job-autonomy and driving a vehicle

Documents can be seen as an automobile airbag – to be used only rarely, but in the event of a problem, it must work immediately! Training can be compared to driving lessons. Do you have confidence in your documents and training? Do you have confidence in your airbag and driving lessons? Would you get into the vehicle?



OTE = confidence rate in the driver

*OTE: overall training efficiency rate
**ODE: overall document efficiency rate

About Capgemini Engineering

Capgemini Engineering combines, under one brand, a unique set of strengths from across the Capgemini Group: the world leading engineering and R&D services of Altran – acquired by Capgemini in 2020 – and Capgemini's digital manufacturing expertise. With broad industry knowledge and cutting-edge technologies in digital and software, Capgemini Engineering supports the convergence of the physical and digital worlds. Combined with the capabilities of the rest of the Group, it helps clients to accelerate their journey towards Intelligent Industry. Capgemini Engineering has more than 52,000 engineer and scientist team members in over 30 countries across sectors including aeronautics, automotive, railways, communications, energy, life sciences, semiconductors, software & internet, space & defence, and consumer products.

For more information please visit:
www.capgemini-engineering.com

Contact us at:
engineering@capgemini.com