Optimizing Quality systems through a paradigm shift: Placing the Operator at the center of the systems
Summary

The ever more 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 in efficiency and restore the quality system to its former glory?

Documentary System:

→ TODAY: documents are regarded as tools to meet regulatory requirements. User comprehension becomes increasingly stained, they no longer know what needs to be done. Maintaining sprawling documentary systems is 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 declines and costs stabilize and fall.

Training System:

→ TODAY: long, costly and relatively ineffective training... 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, timing, etc. must be designed with 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 for inspections (reduced risk of comments).

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[1] O.D.E., Overall Document Efficiency rate, is an innovative metric developed by Altran 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 Altran Life Sciences WCC to quantify the percent of people who perform their activities properly at the end of training process.
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Life Sciences: a challenging environment

The Life Sciences environment has changed considerably in recent years...

Major technological developments, site specialization, rapid growth of generics, development of biotechnologies, etc. The last 25 years have seen a number of increasingly rapid transformations that have changed the face of production-based activities.

...as have regulatory requirements

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 2014-2018 : 4.8%

The pharmaceutical industry employs over 4.3 million people worldwide, with 810,000 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; IMS
Patient safety and compliance with regulations are major challenges. Over the last 25 years, Quality Systems have been constantly changing: frequent modifications to regulations, growing internationalization of medications, etc. 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, stock shortages, etc.). 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).

And 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 for 2014

**Sources:** FDA, McKinsey

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

**Complex, costly, ineffective... Why do companies struggle so much to get it ‘right 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 & Training.

→ **OBJECTIVE:** Guarantee quality and compliance, control risks, 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 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?
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 communications. [...] The legibility of the documents is of paramount importance.”

But what is the purpose of the documentary system? How are all these documents used?

3.1. DOCUMENTATION TODAY: LOW ADDED VALUE?

Traditionally, documents were considered as tools to meet regulatory requirements and “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/not at all by production-based employees;
→ “pirate” documents created in parallel to the documentary system;
→ a verbal culture to train teams, based on people and not on systems.

In conclusion:

→ Documentation is considered a necessary evil by operational staff; it does not allow for autonomy; meanwhile, training and standardization of practices is difficult. A verbal culture predominates, often leading to non-uniform practices, deviations, human error and rejected batches!
→ The documentary system becomes increasingly costly to maintain: declining efficiency despite major efforts, continuous improvement difficult or even impossible to achieve.
→ Errors persist and performance declines in the field (rejections, deviations, human error, etc.).

3.2. 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 becomes 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, etc. and innovative media are employed ("IKEA"-like instructions, touchscreen tablet, video, etc.).

When working to redesign documentation so as to make documents accessible, complete, valid, as well as 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 chance in 10 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, 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 (e.g. by training document writers).
Training: a logical extension of the documentary system

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

4.1. 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/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.
4.2. 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, timing, etc. 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, etc.;

→ Set out the GUIDING PRINCIPLES: frequency of re-training? Training of trainers? What impact does prior experience have on training, etc....?
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, etc.;
→ 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).

In conclusion, thought must be given to everything users need to get it right first time:
→ training that must enable users to acquire the knowledge and know-how they need;
→ easy and immediate access to necessary information.

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, process control, etc. Furthermore, guidance must be provided to ensure that these changes are fully understood and accepted.

A HOLISTIC APPROACH TO REDUCE THE NUMBER OF “HUMAN” ERRORS IN YOUR COMPANY BY 50%
Analogy between on-the-job autonomy and driving a vehicle

Documents can be seen as an automobile airbag: it is 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?

\[ \text{OTE}^{*} = \text{GOOD DRIVER} \]

\[ \text{ODE}^{**} = \text{GOOD AIRBAG} \]

\[ \text{OTE} = \text{CONFIDENCE RATE IN THE DRIVER} \]

*OTE: OVERALL TRAINING EFFICIENCY RATE
**ODE: OVERALL DOCUMENT EFFICIENCY RATE
ABOUT ALTRAN

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The Group has been providing its expertise for over thirty years to key players in the Aerospace, Automotive, Defence, Energy, Finance, Life Sciences, Railway, and Telecoms sectors, among others. In 2015, the Altran group generated revenues of €1.945bn.

With a headcount of nearly 26,000 employees, Altran is present in more than 20 countries.
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