



intégration triLogique

Business Process Management (BPM) Based
Pharmaceutical Quality Management
Systems:

A Win-Win Between Compliance and
Competitiveness

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This article shows how a BPM-based Quality Management System optimizes the way to comply with today's evolving regulations and standards, while being even more competitive in the marketplace.



Summary

1. **Why are Quality and 'Quality Management Systems' priorities in Healthcare ?**
2. **What is Quality in the Pharmaceutical Industry and Elsewhere?**
3. **What are the Quality Essentials ?**
4. **Who must be in charge ?**
5. **How BPM is a lever for Quality Management Systems**
6. **What's Next?**

ter a market, thus creates value, and is always profitable in the long run. In addition, an improvement in the manufacturing process, for example, often brings an improvement both in terms of profit and in product consistency and quality control.

- **Logic of Capitalization of Competencies, Knowledge Management, Business Process Modeling and Management:** a system is to be thought of as a systemic topic, built with a systematic approach, ensuring that what is done is solid and will be the basis for future steps, combining all of the company's dimensions.

People often oppose those dimensions, thinking that an effort in one of them will jeopardize the other. "I don't have the time to think about optimizing that domain, I am not concerned by these topics, which are not being inspected, I need to focus on the certification in XX months". "We should develop a workgroup to optimize that domain, and we'll pass the chosen solutions through the quality department and regulatory affairs in the end to ask them if what we set up is acceptable". "Let us begin with this first step, we'll think about the rest later, we have no time to document it all..." It is such a pity to function in compartmented departments, in compartmented objectives, whereas having everyone on board would result in better ideas for all departments and all objec-

tives. Maybe a workgroup for optimization will find a way to achieve conformity through a simple process; maybe the quality person, if participating in the group, will say that the operational people have an exaggerated idea of the constraints and that a win-win solution for both inspectability and operations is possible; maybe being courageous enough to build a structured documentation, will save a lot of time when preparing for inspections, and give opportunities to optimize. If we don't try, we will never know. Experiences in industries like the automotive sector or the food industry ... show how much it pays off to follow that road. Seneca (1) stated it : 'It is not because things are difficult that we do not dare; it is because we do not dare that they are difficult.' The key is in the synergy. We must stop thinking these are efforts in addition to what we already do. These are efforts that replace other efforts that we had planned, and that allow us to eliminate far bigger efforts that we would have had to do. Do we prefer simple projects that generate complicated processes or projects that deal with complexity in order to generate simple processes?"

Compliance, Competitiveness, Competencies... a Challenge and a Potentially Dramatic Winning or Losing Strategy

In Figure 1, you can see the application of several principles:

- The domains are classified under three categories: management, execution, and support. In order to clarify the representation and simplify the use of the modeling afterward, represented in the middle is the critical path and nothing else (for example: produce product), then we put at the bottom of the graph the 'support' (for example: maintenance), and on the top, the processes that pilot it all. An important point: some people may feel bad if their department is mentioned at the bottom of the map or not mentioned at all. This is an incorrect interpretation of the graph. The objective of the map is to describe the main flows so that it may very well not mention certain Departments that are still very important in many respects. Thus, an HR or Finance Director, for example, may not be mentioned, but still plays a very crucial role as both a member of the Executive Committee at the top, participating in transversal decisions, and as the one managing support processes that are essential to the company, and contributing to the execution processes.
- The logic for the "cut" between modeled domains has nothing to do with department silos, but

aims at an optimum connection of activities that produce the main products, documents and data and which may be achieved by the teamwork between many departments. For example, Design and Development doesn't mean R&D, but rather the process to transform an idea into a fully defined product, ready to be manufactured and commercialized. The process is the result of teamwork between Research, Development, Marketing, Regulatory Affairs, Quality, and some Industry and Logistics services that anticipate the downstream processes.

- The map is used like an intranet page with hyperlinks: each domain will then be described in a lower level map.

Each process is then described with a simple map which we will call an actigram, showing each element of inputs and outputs (product, document, information), constraints and objectives (requirements, goals, indicators) and resources and supports (roles, IT Applications, Material Resources). These are the objects that are the subject of the modeling, and at the very heart of any Process project. All areas in the company must agree on the inventory list of these objects (what are the master data, main shared documents, the requirements, etc.) then in the representations that show the flows and the interrelations between those

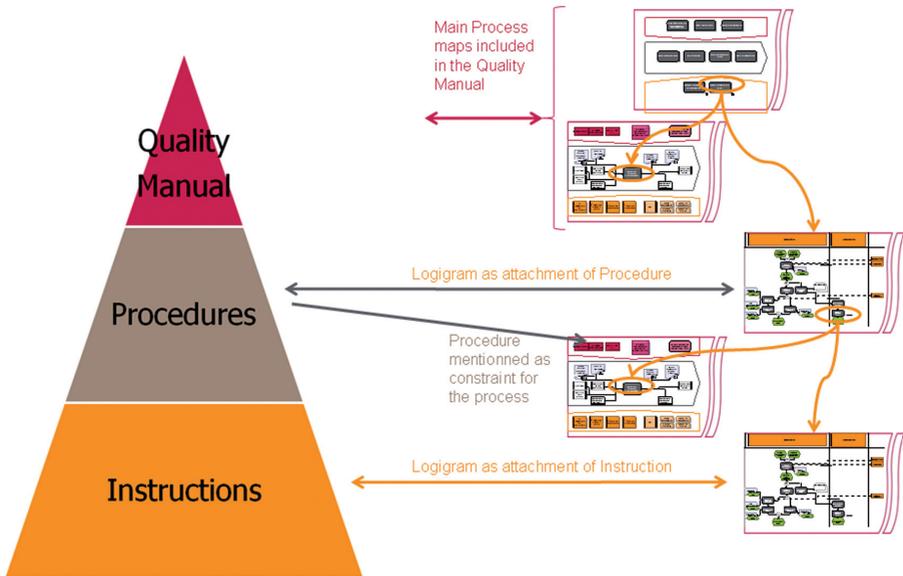


Figure 3 – ‘BPM’ and ‘QMS’ : Process maps show the ‘why’ and the ‘what’, and structure the documentation detailed logigrams describe the ‘who’, ‘when’, ‘how’

It creates very efficient documentation. The navigation in the Process representation serves as a GPS in the whole paperwork, allowing anyone - operator, manager, or auditor - to see the general picture then focus in on the appropriate area.

Therefore, a major benefit is that the quality documentation is very close to reality, built with the real players, and focused on the essentials; no long sentences that may be interpreted several ways, a focus on the main objects that are coherent throughout the whole company.

It is all the more powerful if the project adheres to the rule of modeling: first

describe a generic model and then create versions of it to accommodate differences between some of the cases. It requires a lot of effort, but this is the key. Even if it is difficult, we should prevent the technicians, who work with an HPLC, from creating their own instruction for their specific equipment; the different departments from describing how they manage their teams’ training; and each corridor of the building from documenting their own way of how to follow safety instructions. We must require as much as possible that similar activities be described by a unique model on which all involved people agree, and then