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## Pharma 4.0 – The New Frontier for the Pharma Industry

**By Teresa Minero, Alberto Augeri**

In pharma, as with the rest of the industries, the 4.0 concepts are not precisely new, yet the new scenario opens a brand-new perspective: everybody is involved, with new technologies, and new, pervasive information. This means increasing patient demand for information, identification between information and the product itself, and need for transparent and reliable knowledge of the process from operations to the Authorities. In this frame, the real focus is on the aptitude of the Pharma world to evolve and to continuously change.

Pharma has been working hard on the concept of change in the last two decades. At the dawn of the third millennium, the pharma industry realized that the zero-defects quality concept could not be pursued any longer with old logics of exhaustive control on “immutable” procedures, but rather through a continuous improvement process to detect, analyse, correct, and prevent the issues, through the development of knowledge.

From the very beginning, there was also the awareness that such a process could not even take place in a paper-based environment, but only with the systematic adoption of digitalization at its best potential.

As a matter of fact, regulations constructively pushed in this direction, a path that results now in the achievements of data integrity concepts. Owing to this, now electronic data is more reliable, secure, and usable than any paper-based method: now, electronic data can be valuable information.

A proper blessing to the full adoption of all the 4.0 criteria, also in [Pharma 4.0 technology](#), with its wider information at hand, is the enabler of change.

Seizing this opportunity at its best is mainly a matter of attitude, approach, and culture. This is operational excellence, the child of the lean revolution and widely recognized in all industry sectors. Pharma has approached operational excellence with close care and constructive humbleness, accepting the debate with the rest of the industrial world.

This has allowed pharma to pragmatically and eventually realize that operational excellence is the attitude and culture for constant change and the best environment to sustain continuous discontinuity, which is what it takes now to cope with the Pharma 4.0 changes, creating further value from them.

## VERTICAL INTEGRATION: FROM THE PROCESS SENSOR TO THE REGULATORY AUTHORITY

A culture for change, the [data integrity principles and techniques](#), a determined attitude, and a route supported by evolving regulations are the basis of building pragmatic principles for a to-be information process in pharma R&D and manufacturing.

In short, two main elements deserve a mention:

- Vertical integration of the information from the physical process up to the business management
- Increasingly leaner and integrated exchange of information with the Regulation Authorities

It is more than a trend, it is the practical experience made by many parts, and a precise perspective for the near future.

## HORIZONTAL INTEGRATION: THE NEW SUPPLY CHAIN

From this newly conceived vertical integration, in a frame of full control of our newly organized information, we can look with confidence to the challenges of the new pharma supply chain, which faces a complex reality where demand and relationships are changing.

Hence the role of Pharma 4.0 technology and attitude gets central to provide near-real-time data visibility, to support the end-to-end process collaboration, to enable new models, and a new potential, which has been inaccessible so far.

## WHAT'S NEXT: CHALLENGES AND DIRECTIONS

In a recent paper, by the Gartner Group, on the state of the art 4.0 transformation in the industry, they made a few recommendations including:

- Cultivate the culture of change and innovation
- Identify key metrics aimed at internal organization and processes
- Exchanging experience with peers

In our opinion, these are the most important points when beginning the path to Pharma 4.0.

From a pharma perspective, we explicitly share the quality-related metrics both internally to our Company and externally with the Regulatory Authorities, in view of the rapid process of rationalization of the information flow. This appears to be a good starting point for pharma, without forgetting that pharma has a consolidated tradition of networking to pool experiences and ideas.. Among them, ISPE, with initiatives like the Pharma 4.0 Special Interest Group.

Then let us get ready, and start acting 4.0.

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