Facing Cross-Industry Challenges in the Food and Pharma Industries

Both industries may benefit from adopting best practices

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Food companies are becoming pharma companies. Pharma-foods, the intersection between food and pharmaceuticals, represent an area of growing opportunities for the food sector. In a recent statement that Nestlé made when it set up a separate company, "We believe that the largest drug in your repertoire is the food that you eat three times a day, every day of your life," says Luis Cantarell, President and CEO of Nestlé Health Science.[1]

Driving the need for constant product innovations in a legislation-complex industry such as food and pharma is a challenge. Furthermore, as the consumer demand becomes more sophisticated, companies are under pressures to generate substantial margins and meet financial objectives. The increasing pressures have facilitated companies to examine the current technology environment and seek potential areas of improvements.

Thus, questions have emerged: Why is the adoption of new research and manufacturing processes not always deployed in other business areas? How can industries maximize utilization of the massive social media and virtual networks?

What are the roadblocks? Is it just about technology deficiency, or is it something else? Although both food and pharma industries have parallels between their overall business practices, they also have their own distinct challenges. For example, in the food industry, the same branded product in many different regions may have alternate formulations or labeling; while in the pharma industry, in most cases, one identical product is sold on a regional or global basis.

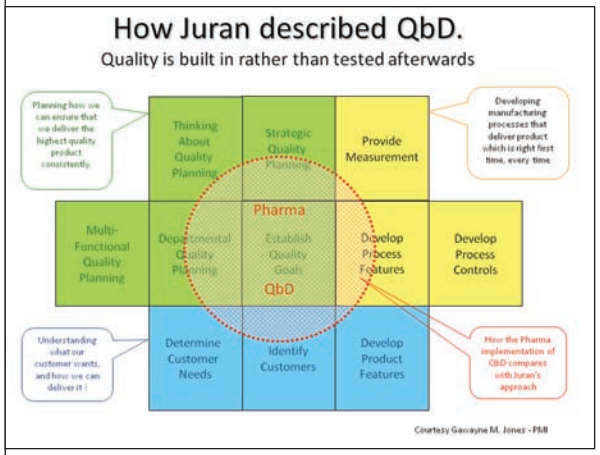
In this article, several overlaps and differences are discussed to spur a discussion on how both pharma and food industries may benefit from adopting best practices.

THE MINDSET AND HUMAN FACTOR

Research proved that adding more operational capabilities, such as new enterprise software, sophisticated hardware appliances and manufacturing equipment, is on many occasions not the answer to attain success. Also, streamlining cross-functional interfaces, processes and capabilities associated with product

development and manufacturing excellence is not enough to enable the operational and R&D functions to jointly outgrow the organization. The food industry, for instance, has proven that shifting from a passive to a proactive, quality-oriented mindset will increase overall success.

Also, it must be noted that both industries have strict compliance regulations. In many cases, they use similar manufacturing machineries, and both operate on a global basis. However, while the pharma industry is just exploring how this shift of mindset can be adopted to ensure their continued success in the future, the food industry has already adopted, very early on, a more holistic approach to improve their processes. Continuous quality improvement processes, such as Six Sigma and Juran's Quality by Design (QbD),[2] have been successfully adopted in almost all industries. In the pharma industry, the QbD practices are still nowhere near mainstream. Generics and biotech manufacturers, supported by the U.S. Food and Drug Administration (FDA) and its European counterpart, the European Medicines Agency (EMA), are adopting QbD in order to improve the quality of submissions. [3]



QbD refers to a set of principles that seek to remedy quality problems by addressing the approach to quality up front as a design issue, rather than after the fact as a control issue.

"If you can't describe what you're doing as a process, you don't know what you are doing"

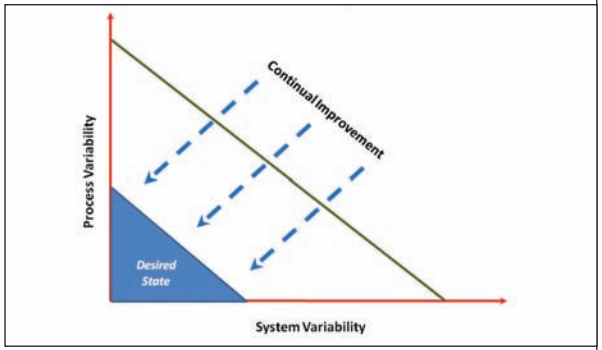
–W. Edward Deming

Many pharma organizations continue to focus mainly on the near-term regulatory inspections and have been spending an increased amount of money to fix problems. Here is what they can learn from industries such as food manufacturing: the traditional quality control method is redundant when the quality mindset is embedded in the business culture and overall processes. In other words, organizations should move away from issues management to predictive quality management.

Cross-functional collaborations among research, development, quality assurance and manufacturing will help corporations to focus on managing the shop floor. Through investigating quality events with science-based approaches, such as root-cause analysis, organizations can learn from every occurred event to drive continual improvement and eliminate non-quality-oriented behavior. Regular pre-planned systematic review of quality performance, including metrics with key quality indicators (KQI), is essential in order for companies to transform a reactive to a proactive, quality-oriented mindset.

CROSS-INDUSTRY LEARNINGS

Despite many operational and cost saving benefits provided by process analytical technology (PAT), the adoption of such technologies in the life sciences sector is significantly slower than the food industry. In 2003, Dr. McClellan, Commissioner for the FDA, lectured the pharma industry by stating that "The pharmaceutical industry has a little secret: even as it invests futuristic new drugs, its manufacturing techniques lag far behind those of potato-chip and laundry-soap makers."[4]



Avoiding surprises means understanding what the customer wants and how it can be delivered.

Now, almost 10 years later, what has really changed? In the food industry, almost all products are individually tested on their critical quality attributes (CQA), while in the pharma sector, on many occasions, a reduced sampling method of manufacturing

batch is still accepted. Some of the most common reasons for this are:

1. the natural resistance to change
2. what's-in-it-for-me syndrome
3. perceived costs
4. complexity
5. regulatory concerns
6. perceived risky deployment methodology

Pharma organizations need a wake-up call to move away from their outdated healthcare and regulatory systems. Instead of having the glass half empty and debating on new technologies and processes, taking a fresh look at the current barriers and investigating how they can be changed to produce benefits is a more effective approach.

Pharma companies are in a unique position to learn from their industry counterparts about how these new innovative technologies can be utilized in a complex health and hygiene governed environment. The implementation of PAT requires a fundamental change from the pharmaceutical manufacturing methodology to a more dynamic approach delivering a more predictable process.

Nothing comes for free, so that the challenges facing PAT implementations need to be investigated.

- Firstly, there are legacy practices to be replaced. Individuals generally do not like changes, especially those that may occur outside of their technical expertise comfort zone.
- Secondly, the human resources department also has concerns, because the perception that the implementation of PAT may adversely affect roles and responsibilities.
- Thirdly, the financial liability may cause internal interest conflicts. It is possible that a PAT investment initiated by the development group mainly benefits the manufacturing operation.
- Fourthly, regulatory requirements still have to be met at the time of a great change; but the FDA has created opportunities for streamlined registration of such changes.
- Finally, skilled resources are needed. PAT deployment calls for a wide range of multi-disciplinary skill sets.

Visualization technologies and analytics produce qualitative and quantitative summaries of scientific simulation data, providing critical insights to help organizations better understand the overall process. A survey conducted by the International Society for Pharmaceutical Engineering (ISPE) concluded that no significant overall increase in resources is expected, but a shift from resource upstream, requirement of additional skilled workers (e.g., statisticians, chemometricians) and multi-disciplinary work are predicted.[5]

There are two major areas where PAT can be utilized:

- **In development:** PAT will lead to more process knowledge. More knowledge results in better understanding, less product variations, higher quality prediction, more robust processes and, because

Acronyms

■ **AMC** American Motors Corporation ■ **CAPA** Corrective and Preventive Action ■ **CQA** Critical Quality Attributes ■ **ELN** Electronic Laboratory Notebook ■ **EMA** European Medicines Agency ■ **ERP** Enterprise Resource Planning ■ **FDA** U.S. Food and Drug Administration ■ **ISPE** International Society for Pharmaceutical Engineering ■ **KQI** Key Quality Indicators ■ **LES** Laboratory Execution Systems ■ **LIMS** Laboratory Information Management System ■ **MES** Manufacturing Execution Systems ■ **PAT** Process Analytical Technology ■ **PLM** Product Lifecycle Management ■ **QbD** Quality by Design ■ **SDMS** Scientific Data Management Systems

Process analytical technology (PAT) uses many tools.

Food and Pharma

Similarities	Differences
Manufacturing technologies	Product margins
Operating globally	Product development life cycle
MES, ERP, LIMS, ELN, CAPA, LES, PLM	Regional specifications
Compliance & labeling regulations	Mindset
Consumer/Patient safety	Agile
	Interaction with consumer of product

A basic comparison of the food and pharmaceutical industries

we have more knowledge, identification of products that will not make final investigation will be earlier in the life cycle, resulting in major savings.

- **In production:** PAT will lead to faster release of batches, because no off-line (laboratory) testing will be needed. QbD scientific risk-based approach will result in less testing, because we gain more knowledge in the different manufacturing stages. Batch release can change from days to hours.

THE CONSUMER BECOMES THE NETWORK

Internal cross-functional collaboration among research, development, quality assurance, marketing and manufacturing is not enough anymore. The use of social networking tools has illustrated how technology can enhance collaboration once some rudimentary data standards are in place. Research is undergoing a fundamental shift from the three traditional paradigms of theory, experiment and computation to incorporating a new fourth paradigm of data-driven discovery. Mass-market manufacturers, including makers of generics, might position themselves as high-volume, low-cost providers, taking lessons in areas of lean manufacturing, agile strategic pricing and inventory management from the consumer products industry. But, even more important, is the connection to their customers. It is time for the entire industry to reset its clock and start by looking beyond those walls. Let's take social media as one example — Pfizer has just over 50,000 Facebook fans, while Starbucks has 27 million! Consumers will play a significantly bigger role in determining how they are treated, as well as deciding how much money they want to spend on their consumables and drugs. The Internet gives them access to more insights and virtual communities. More importantly, consumers are willing to contribute to the industry! When played right, it is truly a win/win situation.

Originally invented by the American Motors Corporation (AMC), product lifecycle management (PLM) is the process of managing the entire lifecycle of a product. Many point software solutions have developed to organize and integrate the different phases of a product's lifecycle. PLM should not be seen as a single software product, but as a collection of software tools and working methods integrated together either to address each individual stage of the lifecycle, connect different tasks or manage the whole process. It integrates people, data, processes and business systems, providing a corporate product information backbone. Manufacturing execution systems (MES), enterprise resource planning systems (ERP), scientific data management systems (SDMS), laboratory information management systems (LIMS), electronic laboratory notebooks (ELN) and laboratory execution systems (LES) provide logical building blocks for assembling such a hub.

CONCLUSION

A stronger focus on consumers is becoming more important for both industries. Adopting a new mindset will be crucial for pharma organizations to stay competitive. Developing a pro-active approach, adapting QbD as a standard model and implementing new tools such as PAT, KQI and CQA, will leverage expertise from both industries. Agile processes integrating "intelligent equipment" will result in a new system landscape allowing a seamless dataflow from start to end. Big data, paperless processes, cloud strategies and secure deployments of mobile devices are just key enablers. Makers of generic drugs can play a crucial role, as they accelerate the adoption of change and deploy new strategies. Exciting years with less paper are ahead of us. SC

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