Globalization and Innovation Encompass with Regulations

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Abstract *— Our economy is outdoing a profound transformation within globalization, innovation and the regulations required for each market. Although the individual elements feel familiar, the combined contours are unprecedented- in scope, speed and scale. The globalization is a business model that describes the coherence in the strategic choices, cross-sector relations and strategic levels in the organization. The cost, time, and risk to develop and commercialize innovative technologies may prohibit market-driven development of new tools and technologies in areas of critical importance to business. For this reason, the embracing of global business model principled can robust the use of modern innovation tools for problem-solving and acquisition can result in better problems solution, more engagement, connection and outward-looking workforce, and economic benefits.*

Key Terms *— DMAIC, Lean Principles, Process Map, Regulation Classification, SIPOC, GAMP 5.*

PROBLEM STATEMENT

The industry challenges are not only driven for new brand products, attractive cost, impressive marketing campaign and top-qualified personnel. If the industry does not have the same capacity to improve it's regulatory or compliance profile at the pace of its innovation or globalization strategies the launch of new product, technologies or services could be unsustainable.

Research Description

This research will provide the necessary elements to evaluate how the industry must assurance the innovation carry-out through a globalization strategy reducing the cost, optimizing the capital and the manpower.

Research Objectives

This research pretends to deepen on the business model, the regulations required for computerized system and the innovation acquired under a globalized culture.

- Ones of the objective of this research is to clearly establish the sustainability of the process (e.g. innovation or globalization) within a regulated markup able to attractive for a business and for the investors.
- Other objective is the incorporation of the new tendencies or approach such as risk management elements to optimize the implementation window, reduce testing and improve resource management.
- Another objective is to maximize the use of new technologies and infrastructures providing an optimum global profile in terms of innovation.

Research Contributions

The main contribution of this study is to focus or lead the innovation and globalization efforts encompass with the regulations assuring to obtain equivalent benefits for investors, for manufacturer, for supplier and for clients. In addition, to highlight that proper sustainability process must be established when innovation and globalization is our business trademark or life philosophy.

LITERATURE REVIEW

The global business model [1] is the platform that connects resources, processes and the supply chain to obtain profitable in the short term. It represents the emphasis to focus and connect our business interrelations from a core model to global

model. This business model dramatically changes how we make things, what we make, and where we make them change the production, agriculture, politics, technology and the international security environment. This model promotes the following:

- Provide more comprehensive and adaptive perspectives based on shared trust.
- Enhance and unify existing, noncoherent knowledge development techniques in various organizational subunits, including the promotion of personalized learning
- Promote communities of interest that would encourage lifelong learning and knowledge generation.
- Systematically capture knowledge in ways that support leaders and organizations in working better together
- Make knowledge persistent in organizations so they can be less reliant on access to subject matter experts, who may not be available when needed.

The application of innovative mind [2] set together with technology tools ensures a robust business pipeline. The costs of technology development can be driven by applying modeling and simulation tools, leveraging existing commercial innovations and technologies, and using open system architectures, frameworks, and technologies.

The coordinated and effective use of prototyping [3] and the intelligent management of risk from basic research through acquisition can also reduce costs, increase capabilities, and maintain technical expertise and organizational agility in the workforce. Shortening the lifecycle of capability development can allow more effective response to emerging needs, provide additional technology-development experience for the workforce, enable a higher cadence of technology refreshment, and promote industrial innovation.

Embracing principled and robust use of modern innovation tools [4] for problem-solving and acquisition can result in better problems solution, more engagement, connection and outward-looking workforce, and economic benefits. Innovative approaches to acquisition and intellectual property create opportunities for companies. Non-traditional contracting mechanisms, incentive prizes, advance market commitments, challenge-based acquisition, and agile approaches to software development and information system procurement—increase the speed, quality, diversity, and number of performers contributing to company missions.

Achieving this vision will require targeted strategic coordination and investment in four key areas: (1) workforce, (2) facilities and infrastructure, (3) governance roles and responsibilities, and (4) innovative capacity to transform ideas into working technology [5].

METHODOLOGY

To achieve the objectives of this project, the DMAIC methodology will be executed since is a powerful five-phase approach to address a process that needs improvement. DMAIC is an acronym meaning Define, Measure, Analyze, Innovative Improvement, and Control. It is a structured, disciplined rigorous approach to process improvement consisting of the five phases mentioned, where each phase is linked logically to the previous phase as well as to the next phase.

- **Define** is the first phase of methodology. In this phase, the project purpose and scope are defined providing a background information of the process to be evaluated and collecting the customer information about this.
- **Measure** phase is to focus the improvement effort by gathering information on the current station.
- **Analyze** phase is to identify the root cause and confirm then with data. The output is a theory that has been tested and confirmed. The verified cause will form the basis for solutions in the next phases.
- **Innovate Improvement** phase is to try out and implement solutions that address root causes. The output is planned, tested actions that should eliminate or reduce the impact of the identified

root cause. Additionally, a plan is created for how results will be evaluated in the next phase.

- **Control phase** is to evaluate the solutions and the plan, maintain the gains by standardizing the process, and outline steps for on-going improvements including opportunities for replication.

RESULTS AND DISCUSSIONS

The Project Charter is the first step and one of the most important parts of any six-sigma project. The document provides an overview of the project and serves as an agreement between management and the team regarding the expected project outcome. Refer to Figure 1 for Project Charter visualization.

Project Title: Optimize Computerized System Validation (CSV) through Pharma and Bio sectors harmonization.	
Project Lead:	Carmen Marrero
Project Sponsor:	Department Manager
Objective:	To simplify and harmonize CSV practices between Pharma and Bio sectors at Manati Site.
Current State:	The CSV practices used in Pharma and Bio sectors are different carryon additional cost in projects, inconsistencies in validation requirements and largest projects window.
Future State:	• Standard process for whole site • Avoid inconsistences in CSV practices • Improve the personnel resource utilization • Improve the project window utilization • Improve the Site competitiveness
Milestone:	1. Collect 2016 Change Control Data 2. Perform a Voice of the Customer to evaluate current CSV process 3. Design the future state process 4. Develop a visual aid for new process 5. Establish a Change Management strategy 6. Roll out new CSV process 7. Train personnel 8. Identify a pilot project and acquire the data 9. Optimize the new process (if is needed)
Resource Requirements:	Execution System Quality Assurance Engineering and Maintenance Operations Information Technology
Project Risk and Mitigation:	Evaluate the impact to have on-going projects with the deployment of the strategy to avoid past due or additional cost.
Key Stakeholder:	Quality Assurance
Benefits Achievable:	The harmonization and simplification represents approximately a cost avoidance of 30% of the activities performed during project implementation in terms of documentation deliverables, resource allocation and project bouget.

Figure 1
Project Charter

Also, the Voice of the Customer (VOC) was used to capture the customer needs, wants, perceptions, and preferences gained through questionnaire.

A total of 30 questionnaires were completed including the departments directly affected by CSV process, Execution System, Information Technology, Quality Assurance and Engineering and Maintenance. Most of the user are worries for the process complexity, the time required for system implementation (project window) and the methodologies differences observed between Pharma and Bio sectors.

Based on the results obtained in the VOC, a SIPOC process map was used to identify the suppliers, inputs, output and customers of the process. Refer to Figure 2 for SIPOC Process Map. In addition, a process map was developed to identify the steps performed as part of system implementation and to be clear the impact of these steps in the current CSV flow.

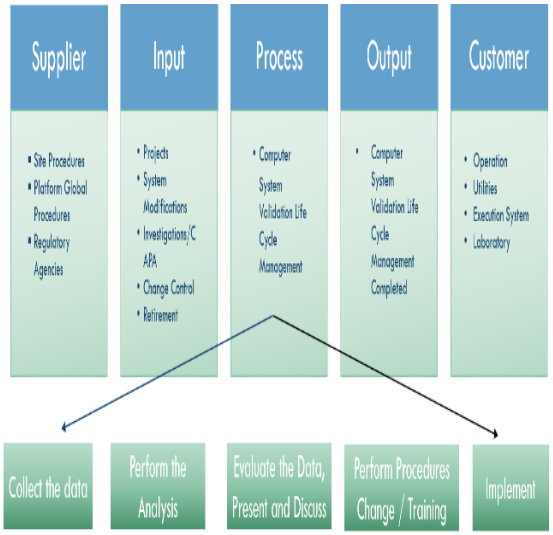

Figure 2
SIPOC Process Map

In addition, the process map was developed to identify the steps performed as part of system implementation to understand the impact of the current CSV project flow. The early steps of the project directly impact the CSV process representing a large part of project cost. Refer to figure 3 for System Implementation Project Map for more details.

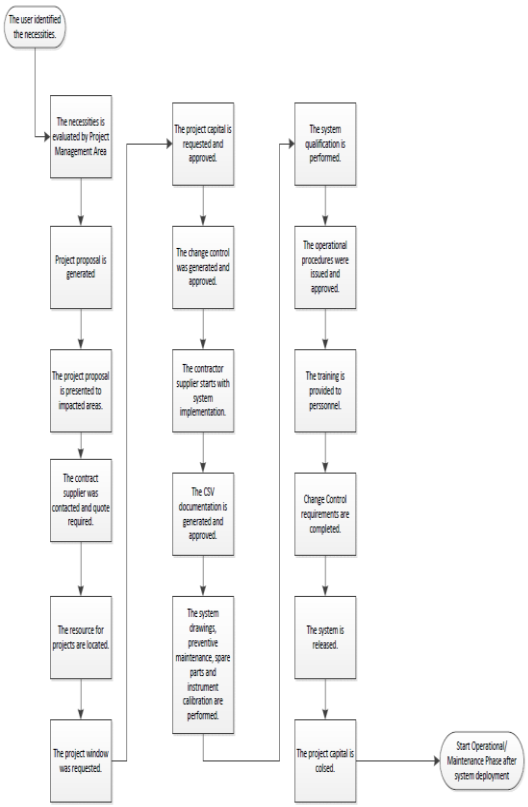

Figure 3
System Implementation Project Map

Data Analysis

The data collected was based on the change controls generated for Pharma and Bio sectors during the 2016 year. The cost associated with the validation activities performed during this year was $1,123,920.00.

The collaboration acquired as part global structure was used to analyze and leverage the innovation used in other sites.

A CSV Community of Practices (CoP) [6] was implemented during this year (2017). The ten (10) members are part of the team from Pharma, Bio and API sectors. All the members are from Europe located in Ireland, England, Switzerland, Holland and Italy.

A brainstorming tool was used to generate a lot of ideas quickly identifying the potential opportunities in the CSV process, encourage the creativity within team members, involving everyone in the discussion and generating the proper energy for ideas creation.

Most of the ideas are focused to implement a risk methodology in the CSV process and to leverage the best practices performing within the cross-sectors units. In terms of the analysis presented, several systems with different complexity required the same deliverables for its implementation. In addition, the documentation generated as part of the project required at least four (4) functional areas for the revision / approval of these. After evaluates the presented data using a global perspective, it can be concluded that a risk assessment elements need to be incorporated in CSV deliverables and required approval signature per document.

Based on that, the proposed solution was focused in these system in which the human intervention is required for intended use configuration. Meaning that a reduced deliverables strategy will be used to implement system categorized Software 1 (SW 1) / Software 2 (SW 3) and baseline deliverables for system categorized as Software 4 (SW 3) / Software 5 (SW 5).

In terms of hardware, the system infrastructure is the combination between software and hardware. Based on this, changes to Hardware 1 (HW 1) and Hardware 2 (HW 2) will be handled / implemented within the deliverables associated with its software classification.

Same approach will be used for required documentation approval to implement system categorized Software 1 (SW 1) / Software 2 (SW 3) and baseline deliverables for system categorized as Software 4 (SW 3) / Software 5 (SW 5).

Innovative Improvement

Change Management process was used to provide a systematic approach to dealing with change from the perspective of an organization and the individual. This process helps in the adaption of the change, to control the change, and make effective the change. To proceed with the process, individual meeting was performed with each functional manger. After that, each functional manager assigned a core member to help in the change management for each affected. Once the core team was aligned and the communication

occurred within areas, open training sections were performed to whole population to present the new CSV strategy. As a result, some additional recommendations were acquired and included in the model.

The new model falls in reduced deliverables strategy (e.g. SW 1 & SW 3), a traditional deliverables strategy (e.g. SW 4 & SW 5) and approval signature rationalization. Based on that, the CSV deliverables required for implementation decreased from nighty-eight (98) to forty-six (46). As a result, the approval signature was decreased also from six (6) to three (3). The estimated cost avoidance was $178, 894.

Once provided the business benefits, the new model was implemented in the CSV procedure, associated personnel were trained and one project was selected to go-live.

New Model Go-Live

The project selected for the go-live was an upgrade in system infrastructure (software and hardware) through the implementation of recipe management and review by exception. Refer to figure 4 for Batch Application Representation.

One master recipe was created under Batch application that will be used as a base to create the other product recipes. The batch application is a collection of documentation, equipment phases, support routines, and associated Human Machine Interface (HMI) components that can assist in the development of a batch Solution using Integrated architecture or distributed control system.

The Batch application was designed by using a three-unit process. These units illustrate the use of shared resources, coordinated transfers between units, and a wide selection of common equipment modules and phases found in most batch control applications. The application integrates batch process control with process objects (e.g. pump, valve, motor, tanks) providing a consistent look and feel at the phase and unit levels.

Once the master recipe is configured with process steps, required equipment, critical process parameters, critical process steps and alarms. A report was generated under another application to provide of the batch lot results. If the report does not present any abnormal condition or alarms related with critical steps and critical parameters, the batch report is released for next manufacturing step. Only batch lot presented abnormal condition will be reviewed and released for next by Quality Assurance.

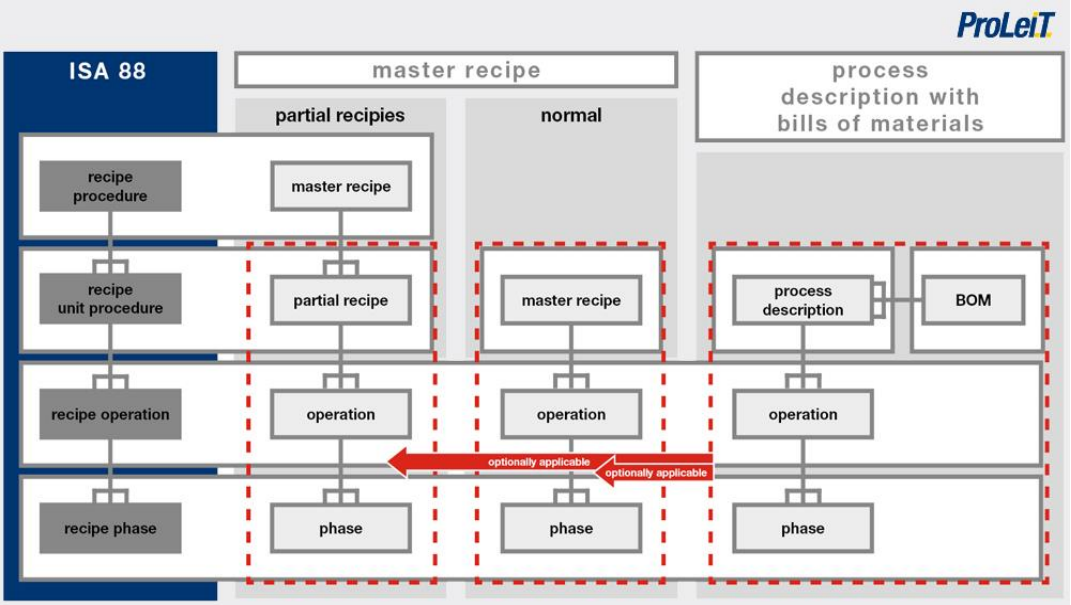

Figure 4
Batch Application Representation

CONCLUSIONS

During this design project, the current Computerized Validation System was evaluated to improve the project lifecycle and to meet with user and business need. Several six sigma tools were used to obtain the data, analyze and to develop a proper recommendation.

Most of critical items of this process were the integration of a global mindset to moving forward an innovate strategy aligned with risk strategy to align the deliverables required based on the computerized system classification. Also, the change management that was the must harder part to move from a traditional approach to reduce deliverables approach during the system implementation.

The cost avoidance projection estimated for 2018 taking in consideration the sixteen implementations performed in 2016 is $178,894. The cost avoidance obtained during Go-Live for the selected implementation was $ 43,200.

A cost reduction of 50% of the deliverables required as part of CSV implementation and 50% of the approval signature required for the documentation generated. The benefits were directed observed in project bouget, timeline, implementation window and in the resource allocation.

The new model represents the user and business needs under the new environment of globalization and innovation in a regulated industry.

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