

# ***Development of an Automated Program to Help Monitor, Document and Measure Regulatory Affairs and Registration Activities within a Consultation Company***

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**Abstract** — *Although necessary, documentation activities take away valuable time that can be spent in technical work so they don't add much value to processes. A single database was created to consolidate 2 databases in order to reduce the time spent by employees in documentation activities. The design for this data base was based specially on the need of this specific company dedicated to consultation in Regulatory Affairs. This database is able to track current, past and future projects on their different stages, generate a tracking form without the need of filling an additional document, and also produce metrics that will measure project performance and improve personnel productivity. The positive outcome is that the documentation time is significantly reduced and the metrics will be automatically produced in no time, saving time for the employees to focus on technical activities.*

**Key Terms** — *Database, DMADV, Metrics, Microsoft Access.*

## **PROBLEM STATEMENT**

The problem statement is discussed by explaining the Research Description, Objectives and Contributions.

### **Research Description**

Working in a consultation services Puerto Rican company that is growing internationally, there is an increase in the need to have a robust Quality System. This company is dedicated to professional services in Regulatory Affairs, to clients in the Veterinary, Pharmaceutical and Medical Devices fields. The clients are based all over the world, from South America to Europe. The company's day to day practices include presenting the clients' legal and technical

documents to government agencies for commercialization purposes.

Within this business, there is a special need of keeping track of a lot of information, including the availability of documents to submit to the competent authorities internationally; a wide variety of dates ranging from the date the project started to the date the project was approved; the licenses/certificates emitted by the authorities and all the products covered by that license. Every step of the process needs to be documented. Many documents and data bases have to be updated periodically, which takes a lot of time and is prone to data entry error.

Because of the company's line of work, it is essential to meet requirements, not only from the client, but also the regulations from national Ministries of Health. To help meet the requirements, a few years ago the company decided to build a quality system and began with the efforts to be certified by International Organization for Standardization 9001 (ISO9001). The company encountered a challenge when trying to meet with the 8th clause of the ISO9001 standard: Measurement, analysis and improvement. This is why having a database that can also produce metrics, will benefit the company in terms of quality and time saving.

Rody Ryan says in his article Managing Metric Management in ISO 9001 [1] that "This requirement poses a significant, and hopefully positive, challenge for many companies". This is because "In implementing ISO 9001, some companies need to introduce, for the first time, a formal system to measure and improve their own performance." This problem is consistent to the challenge that the company has encountered.

Because of the problems discussed above, came the decision of building a data base that groups the necessary information included in different data bases and is able to deliver metrics. A new data base that makes the documentation process leaner oriented, eliminating several steps that do not do not add any value to the process. It contains most of the information to be tracked and once implemented, the cycle time for the documentation activities will be reduced to half or even less. Also, there is the need to build a formal metric system to meet with the 8th clause of the ISO9001 standard. This program will measure, at least, the times involved in all the steps of the company's processes.

### **Research Objectives**

After the completion of this research project, the company should have a user-friendly program available to keep track of all the projects, while managing all the key performance indicators and obtaining the metrics required to meet quality requirements within the company and the clients. The main objective is to develop a program that will combine the company's current data bases in order to reduce the documentation tools that need to be updated periodically. As a plus feature, this database is able to deliver different types of metrics. Also, during the implementation of the program, it will be clearer as to which specific aspects could be measured, other than the times. The employees will be able to use the program to deliver their metrics and it is expected that the program will be implemented in different departments. Once the program is available and the metrics are obtained, the company might be able to reconsider the certification.

### **Research Contributions**

The major contributions expected from this project will be to increase quality, save time and also economic benefits. By reducing the documents to be updated at every step of the process, there is less room for human error, increasing quality. Also, instead of updating 3

documents or databases, only one will need to be updated. This will at least reduce the documenting time in half. By reducing cycle time, the personnel will have more time and will be able to focus more on registration projects instead of documentation tasks or producing metrics.

By having an automated database that can produce metrics, the quality system will be reinforced. The metrics will provide visibility of the processes performed within the employees of company, as well as the contractors working for the company in other countries, and the Ministries of Health. The metrics might eventually be shared with the clients to demonstrate that quality standards are being followed. The metric system can save the employees' time, when trying to measure the processes. Eventually, the program will be implemented in several areas saving time in different areas of the company. Finally, the economic contributions are closely related to the quality contributions. By meeting the customer's quality requirements, the company's work of quality will be acknowledged. This can have as consequence, clients' referrals and customers might be retained, thus maintaining and increasing business.

### **LITERATURE REVIEW**

Six main articles were reviewed in the research for this project. The Polytechnic University Library databases were used to find relevant information for the development of the metrics program. The principal areas of research were (1) Using Microsoft Access for developing metric programs, (2) ISO9001 and its clauses, (3) the development of a metrics program in general, and (4) using the DMADV methodology.

The objectives in the article "Development, implementation and benefits of a rheumatology-specific electronic medical record application with automated display of outcome measures" [2] by Anand N. Malaviya and Shashi B. Gogia resemble the objectives of this consultation company on the need of designing a software that will help focus

their time on the main procedures and responsibilities while saving time in conducting other practices that don't add value to the processes. Specialized software is very expensive and with specific disciplines it is hard to find software that will be useful to perform day-to-day tasks. Just like Malaviya and Gogia decided to design a software dedicated to the practice of their discipline, the consultation company had the initiative of building specialized software designed specifically for their needs. On their case, they needed more time to focus in practicing clinical rheumatology while in the case of this consultation company, they need to focus their time on registration projects, while reducing the possibility of human error.

For a better understanding of the purpose of this project, Rody Ryan's article "Managing Metric Management in ISO 9001" was very helpful and it provided great insight showing that the problem that triggered the need for the metrics program, is more common than it was known and expected. This article explains the major clauses to achieve the implementation of an effective metric management system. According to the article, these major clauses are Clauses 4-8. The most relevant for this study is Clause 8: Measurement, Analysis and Improvement. Rody mentions an interesting point in his article, in which he explains that many companies struggle in the creation of the metric system because generally *"they find themselves for the first time in the need to bring together a formal system to measure and improve their own performance"*. The companies that already have a metric system in place, might also face the challenge of making sure that their metrics are useful and measure continuously the key aspects of their businesses. In the case of this specific study, the problem is that a formal metric system does not exist.

On the introduction of the article, Rody explains that since the ISO 9001 revision in 2000, many companies have been implementing Quality Systems. The consultation firm has implemented and is looking for continuous improvement within

its Quality System. As previously mentioned, the challenge has been to develop a metric management system. After reading the article, it was easier to understand the reason why this has been the challenge. As the article says, *"the quality system was simply not designed to support an effective metric management system"*. Ryan Rody's article looks to serve as a framework for implementing an effective metric management system.

Since the problem was understood, the next step was to find the adequate platform for the development of the database. From the beginning the only thing that was clear about the program was that it should be user friendly. Then, the idea was to find a strategy for the design and development, in order to implement it in the future. For this purpose, the article "Creating user-friendly databases with Microsoft Access" [3] by Joanne Kraenzle Schneider, PhD was used. Since the initial stages of the research, it has been thought that the best tool to use for the creation of the metric program is Microsoft Access. This program is useful, easy to use, is not too expensive and it is accessible. Schneider describes in her article that Microsoft Access is a user-friendly database that minimizes entry errors.

This is exactly what this company was looking for. This type of business is maintained by sales. Consultants can't afford to spend time in data entry and producing metrics, they should mostly invest their times in registration projects. Also, by having to enter data manually, multiple times, and produce the metrics themselves, the opportunity of data entry or human error increases and this should be avoided.

The article "Development and implementation of a benchmarking and metrics program for construction performance and productivity improvement" [4] was very helpful in terms of finding the strategy for the development of the program. It has given a lot of vision on how to develop the methodology of the research. This article was written by Hassan Nasir and, as the title suggests, explains the process of the development of a benchmarking and metrics program in the Civil

Engineering/Construction field. This field is not related at all to what the consultation company does, but the article gave a lot of insight of what is needed for the development and future implementation of the program.

According to the article, the development of the program was divided into three phases. For that particular research, phase I was the establishment of the program. In the case of the consultation company, the project could also be divided into three phases. The difference is that Phase I should be to be familiarized with the platform to be used and establish which Key Performance Indicators (KPI) will be measured. After these aspects have been established, then comes the development of the program, which can be Phase II. Initially, it was thought that Phase III could be the deployment of the program, but as will be discussed further, Phase III was the improvement and verification of the program.

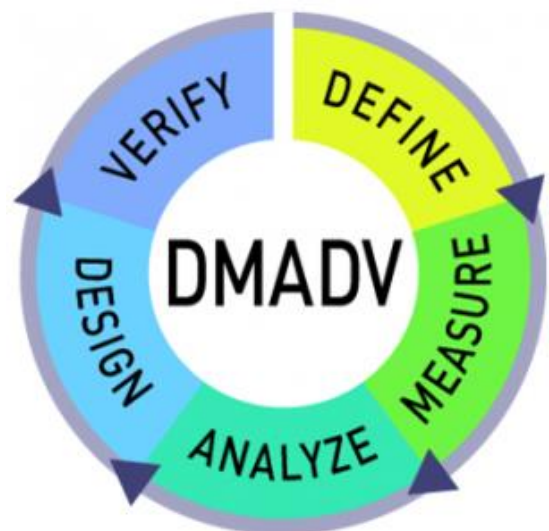
The last phase was subject to many variables such as time, success of the program and acceptance of the management to continue with the efforts. The article has a section called Challenges in implementing benchmarking and metrics programs. In the case documented by Nasir's article, challenges include time, developing the program, resources, etc. Their first phase took too long. After having the program, they didn't have enough data to measure and they needed many resources, such as industry champions. In the case for the consulting Regulatory Affairs Company, the development of the program took more time than expected, but the availability of the data was never issue because plenty of data is available from past and current projects. As it was anticipated, the biggest challenge was to build the program. Many research and self-training was needed in order to understand the use of the platform to build the program and find the best way to make it useful, user friendly and accurate.

The last topic used was the DMADV discipline to better define the methodology. The web was used and also a research articles to better understand the use of this methodology. DMADV

means Define-Measure-Analyze-Design-Verify. This is the methodology to use for the development of this project because it focuses on developing a new service, rather than improving an existing one. According to the article by Allen Graves "What is DMADV" [5], the methodology should be used in 2 occasions: "(1) when a non-existent product or process needs to be developed at a company, and (2) when an existing process or product already exists but still needs to meet a Six Sigma level or customer specification". Graves states that the goal is to "to address an identified issue and produce desired results in a way that can be maintained through normal operations". In this case, the identified issue is the plenty of time that is invested in non-value adding activities such as documentation, data entry and metrics development. These problems will be discussed further in the next chapter

## PROJECT METHODOLOGY

The methodology used was the DMADV Method. Please refer to figure 1.



<http://www.sixsigmadaily.com/what-is-dmadv/#>

**Figure 1**  
**DMADV**

- **Define:** In a consultation company dedicated to registration projects in Central and South America, there are many tasks that must be tracked and documented, these documentation

activities take too long and don't add value to their processes. Another problem is that to be able to comply with the 8th clause of the ISO9001 standard Measurement, analysis and improvement, the company needs to be able to produce metrics of the different parts of the process. Currently, the metrics aren't being produced because it takes too long.

- **Measure:** The new database designed combines 3 databases/documents currently used to track projects, so all the documentation can be done simultaneously. Thus, reducing the documenting time at least to half. For the metrics part, this database will be able to provide the information needed in form of queries. Also, queries will be run to determine the number of projects submitted and/or approved by country or total.
- **Analyze:** The CTQ (Critical to Quality) aspects are time and human error. Combining the documents and databases will decrease the most CTQ aspects.
- **Design:** The design of this database is based on the needs of the employees, according to their day-to-day work. Two databases were merged into one, containing all the information corresponding to the project aspects that are tracked from beginning to the end. Another important feature this program contains is the ability to work on a form simultaneously as the database is being fed. To solve the metrics problem, queries were designed to supply the information needed to measure every step of the process.
- **Verify:** For this step of the methodology several pilot runs were made. Due to the pilot runs, several corrections were made, as it was acknowledged that fields were missing.

## RESULTS AND DISCUSSION

For the development of an automated program, it was known that the limiting step would be the development of the program. A program was designed to reduce the time spent on documentation

activities to focus on technical work. This database contains the information currently documented in 3 documents/databases. It was designed based on the specific needs of the discipline and it is able to deliver metrics that measure time in the different steps of the process and give information of all the current and approved projects.

Of all the variables that can be measured, the most critical to quality is time. Time is the most important and valuable KPI for the company and, once implemented, it will allow the measurement of project performance and the productivity of the employees and the suppliers of services on the different countries. Current and past projects provided the data necessary for the verification of the process. After measuring the times, the company will be able to measure project performance and improve personnel productivity, thus increasing the quality of their services. This information will also give some insight on the times spent locally by the professionals on the different countries for their evaluation.

The methodology used for the development of the program was the DMADV and was divided as follows:

### Define

In a consultation company dedicated to registration projects in Central and South America, there are many tasks that must be tracked and documented. Currently, there are many forms that need to be filled and data bases to feed constantly. When there is a large workload and many approvals are received simultaneously, the time spent in documentation doesn't add much value to the process and is time that could be spent in value-adding activities.

The company attempted to be certified by ISO9001, but encountered a problem when trying to comply with the 8th clause of the ISO9001 standard Measurement, analysis and improvement, because they needed to produce metrics of the different parts of the process. Mostly, the employees don't have the time to calculate all the metrics. Also, the employees are asked to track

how many projects have been submitted and/or approved in a certain amount of time. Calculating this number is also a non-value adding activity.

Because of the problems mentioned above, arose the need of a simple database that contains the information contained in the different forms and databases to reduce the time spent in documentation. This new database will have the ability of producing metrics and reports. Also, it could send emails to the clients when approvals are received and send reminders for when the licenses are about to expire in order to submit the renewals.

### **Measure**

Once an approval is received, filling out the proper documentation could take from 15 to 30 minutes for each project. A project tracking form must be completed, the ongoing projects database and the registration database must be updated. The new database to be designed will combine these 3 documents/ databases, so all the documentation can be done simultaneously. Thus, reducing the documenting time at least to half. Once all the information is added to the database, the report can be sent as an email on a previously prepared template that contains the necessary information.

For the metrics part, this database will be able to provide the information needed in form of queries. There will be different queries to calculate all the times for every part of the process. Calculating the times for every step of the process will give insight of the project performance and where the most resources are spent. This will help improve personnel productivity, thus increasing the quality of their services.

Also, queries will be run to determine the number of projects submitted and/or approved by country or total. The number of projects is needed to focus on future plans and evaluate current resources. To calculate these numbers a query might take 1-10 seconds to run, while making it manually can take 30 minutes or more. This reduces the calculating time in almost 100%, giving extra time to focus on the value-adding activities.

### **Analyze**

As previously mentioned, the CTQs are time and human error. Combining the documents and databases will decrease the most CTQ aspects. Data entry will only be made once, decreasing the opportunities of entering erroneous data. Also, to maintain the quality work, the employees' time must be spent doing quality work, instead of calculating metrics or on documentation activities.

To eliminate the CTQ factors, the databases currently used were combined in only one database. The form used to report every step of the projects is automatically filled at the same time the information is being entered to the database, so there is no need to fill an additional document. The design of the database is a complete database that contains all the information required to track each project from the beginning to the end. The cells are restricted to only contain the possible values including specific countries, type of project, dates and hyperlinks to easily find documents within the server.

### **Design**

The design of this database is based on the needs of the employees, according to their day-to-day work. Two databases were merged into one, containing all the information corresponding to the project aspects that are tracked from beginning to the end. Also, these projects keep running after they are finished. This database makes it possible to track approved projects to work on their renewals when they are soon to be expired.

The most important fields contained in the database are related to three major things. First, the information of the project, refer to Figure 2. These fields are basically the Project ID, information of the type of project, country to be registered and manufacturing site. These fields are also required on the Project tracking form. Another important feature this program contains is the ability to work on the form simultaneously as the database is being fed.

Project ID	Project Type	Country	Product Name	Franchise	Manufacture	Origin
	Extension New Registratic Other Re-Registration Variation	El Salvador				

**Figure 2**  
**Project Information View**

Engagement Date	Materials Requested	Materials Received	Begin File Assembly	Complete File Assembly	File Forwarded to Country	File Received	Filing Date

**Figure 3**  
**Dates View**

Actual Appr	Expiration Date	Target Filing Date	Request Materials By
*			

**Figure 4**  
**Registration Information View**

For tracking each project, the employees fill an additional form including all the information. This is another step that will be eliminated. This form is sometimes used as a report and the database is able to generate the form automatically, so the report is still generated. The form also contains the documents required for each country of registration with a checklist to mark those documents required.

Next, there are the fields to track the dates of the steps of the projects, refer to Figure 3. When the project engagement is received, followed by when the materials were requested and received are all dates tracked on the database. Other dates include when the files are sent to the country, received, and filed to the Ministry of Health, if observations are received and managed, approval notification received and client notification.

For the last part, the information is related to the registration certificate, refer to Figure 4. The registration number is documented and contains a

field that includes a hyperlink to easily access the certificate. The date the certificate was emitted and its expiry date are included. Finally, the dates to request the clients the materials for the renewal and the date to submit the renewal serve as internal queues for the registration renewals.

To solve the metrics problem, queries were designed to supply the information needed to measure every step of the process. These queries are designed to measure the times of each step. This is information that wasn't calculated previously due to lack of time. With this database, the times will be measured automatically, without the need of spending time on the manual calculations. Queries were also designed to quickly calculate the amount of projects managed on different periods of time. Calculating these numbers could take up to 30 minutes, while with the queries these numbers are available in less than 10 seconds.

## Verify

For this step of the methodology several pilot runs were made. A sample of several projects were entered into the database to make sure all the fields are contained on the database. Also, the queries had to be run with several projects to make sure that the correct metrics are being delivered. Due to the pilot runs, several corrections were made, as it was acknowledged that fields were missing. Queries also had to be corrected as some of the dates were used incorrectly.

The outcomes of this project will be constantly verified. Upon implementation of the database for daily use in the company, every client and technical area within the company will have a similar database. The areas and clients are all different, this means the needs are variable. The main purpose for this project is to simplify the documentation process in which too many time is spent in activities that don't add much value to the processes.

## CONCLUSIONS

The creation of this program/data base was made considering the specific needs of a company that provides consultation services on Regulatory Affairs. It was designed to contain the specific fields to be able to document and track present, past and future projects. This database is basically 3-in-1, because it has merged 2 databases and 1 form that need to be constantly updated, and is proven that it reduces the documentation time as it removes steps to the documentation process.

The design of the program resulted in a data base capable of reducing the time spent in documentation activities and capable of delivering metrics on the Regulatory Affairs processes by measuring the processes' KPI (time). The metric calculation time was reduced in 100%. This program produces the required metrics automatically by running queries. The times for each step of the process for every project are measured in less than 10 seconds.

The database solves two main problems that the company currently faces, and the outcome is that it saves the employees' time so that they can dedicate their time to technical duties. As previously mentioned, it saves time on the documentation process and it will make possible the automatic generation of metrics to measure their own processes. These metrics aren't being generated as they take too long to calculate. Eventually, after the company is able to measure their processes, they can re-consider being certified by ISO9001 as they will be able to meet with the 8th clause that is related to metrics.

## REFERENCES

- [1] R. Rody, *Managing Metric Management in ISO 9001*, NSAI Newsletter, 2011.
- [2] A. N. Malaviya and S. B. Gogia, "Development, implementation and benefits of a rheumatology-specific electronic medical record application with automated display of outcome measures," *International Journal of Rheumatic Diseases*, vol. 13, no. 4, July 2010, pp. 347-360.
- [3] J. Schneider, J. Schneider and R. Lorenz, "Creating user-friendly databases with Microsoft Access," *Nurse Researcher*, vol. 13, no. 1, 2005, pp. 57-75.
- [4] H. Nasir, C. Haas, J. Rankin, A. Fayek, D. Forgues and J. Ruwanpura, "Development and implementation of a benchmarking and metrics program for construction performance and productivity improvement," *Canadian Journal of Civil Engineering*, vol. 39, no. 9, 2012, pp. 957-967.
- [5] A. Graves. (2012, December 10). *What is DMADV?* [Online]. Available: <http://www.sixsigmadaily.com/what-is-dmadv/#>. [Accessed: Sep. 29, 2016].