Database of the SBELLA system based on the SCRUM framework for decision-making of the Functional Unit of Health Products in the Local Government

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Summary- Within this context, the Functional Unit of Sanitary Products (UFPS) is responsible for the granting of rights under the denomination of Obligatory Sanitary Notifications (NSO) of the sanitary products, whose normative framework is composed by the supranational norm of the Andean Community of Nations (CAN), Decision 516 and the corresponding national normativity.

The General Directorate of Medicines, Inputs and Drugs (DIGEMID),National Regulatory Authority (ANR), a line organ of the Ministry ofHealth, has the mission of guaranteeing the efficacy, safety and qualityof pharmaceutical products, medical devices and health products, contributing to their access and rational use for the benefit of the population's health.

Currently the Functional Unit of Sanitary Products (UFPS) does not have an updated database of Sanitary Notifications both issued, notified, canceled from 2017 to the present, also on the part of the data,they are not reliable or consistent source for a subject of consultationsfor the executive directors for the respective decision making.

Keywords: Queries, database, decision making.

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INTRODUCTION

The team of the functional unit has as a goal, based on all the information collected from 2013 to the present, to have updated information regarding cosmetic products that are being authorized in the Functional Unit of Medical Devices, which over time havea change in the name of the product, a transfer of products to otherholders, change of brand, change of manufacturers, and the last to reflect the cancelled products that are referred that can no longerbe marketed in our country Peru, everything mentioned will be reflected in the system "Sbella" which is internal to the area.

Manage of our project is based in the books of PMBOK 6th Edition, Sommerville, Ian (20211). Business Process Management, Schenone (2011). A Practical Approach. (7th Edition) for streamlining the product delivery process in both the updated database, the use of Agile Scrum methodology.

This structure consists of acquisition, analysis and design, development and implementation. In Scrum, according to the requirements at the level of analysis in certain tasks in the depreciation of the product, because then prioritized according tothe degree of difficulty and importance that the development team has been taken into account, and this procedure will set the Sprints (4 in total) and each final product at the end of each of these.

The main objective of this research is to meet the theoretical bases, methodology and tools that will help the health sector in the development of the database update and improvement of the Sbella system. In addition, previouspurchases must be present that show evolution and benefits caused by the continuous use of the system.

I. CONCEPTUAL FRAMEWORK

A. BPM

It is a methodology to improve the processes of a tool or technological system, it makes that it points everything to aspecific goal, the advantages of using it is that it can improve the agility in the process, to have more effectiveness and above all to improve the levels efficiency,which, with aids of some steps to be able to arrive at the required goal, using diagrams, flows. [1].

Figure 1. Parts of the BPM

B. Visual Fox Pro

Visual Fox Pro is a Microsoft language, with development of object-oriented desktop applications, has been on the market for a long time, has its own integrated database, consisting of tables, currently the entire architecture of the company's systems is based on Visual Fox Pro and its database in dbf. [2]

C. UML

They are the best practices to reflect a database, the business process, core business, is defined as an iterative process, and it isa standard model for any type of development for both web and desktop, used by various developers around the world. [3]

II. METHODOLOGY

A. Type of research

This pre-professional internship research project has used Applied Research, in such a way that a project can be carried out over time.

This applied research is understood as empirical or practicalresearch. We as students have obtained previously acquired knowledge to then be able to implement or systematize the practice. This case is a research project within the public labor market, and belong to the Ministry of Health. Our knowledge that we have adopted throughout our professional career will serve us to be able to provide solutions to the problems that exist in this part of the healthsector of our country.

B.   SCRUM Methodology

Scrum is an iterative and incremental framework for projectdevelopment and is structured in job cycles called sprints. These are iterations of 1 to 4 weeks, and you take one afteranother. At the beginning of each Sprint the cross- functional team selects items (customer requirements) froma prioritized list. They commit to completing the items by the end of the Sprint. During the Sprint, the team cannot change the selected items. At the end of the Sprint, the teamdebriefs with those who are interested in the project and shows them what they have built. [4]
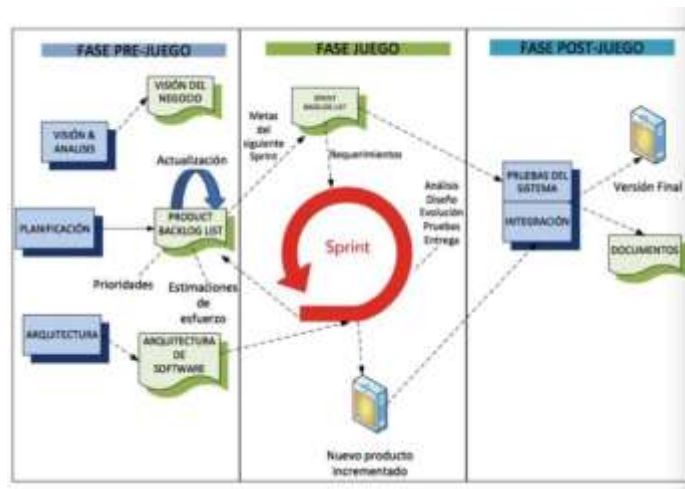

Figure 1Scrum Lifecycle

C.   Methodological proposal

In this first part, a sensitization work has been done with management and evaluation staff; so that they can commit to the need for a comprehensive solution. Not only includes an updated data record, but the implementation of work standards. Contributes to achieving the goal, which presents some problems that are attached in the respective table, many factors are involved, and one of them the most important is that the user is resistant to change, but despite everything we will achieve the goal set.

Optimización Procesos mediante las Tecnologías de la Información

	Objetivo	PESO	%	≤ Acumulado
001	Multiples aplicaciones de registro de datos por parte del evaluador	40	23.12%	23%
002	Impacto del % de Expedientes atendidos fuera de plazo	35	20.23%	43%
003	Procesos engorosos	30	17.34%	61%
004	Infraestructura tecnologica - hardware obsoleta	25	14.45%	75%
005	Falta de personal de TI para atender el requerimiento	18	10.40%	86%
006	Usuarios con resistencia al cambio	10	5.78%	91%
007	Dependencia de OGTI para implementacion de nueva solución	10	5.78%	97%
008	Normativa que estable el marco legal para la evaluacion no actualizada	5	2.89%	100%

Figure 2. Problem Table

For this project we have traced 4 sprints for the realizationof this project which are detailed as follows:

1.   Collection of requirements
2.   Requirements refinement
3.   Recording of data not reflected in the Sbellasystem
4.   Validation of the files of all the procedures.
5.   Development of registration forms forcancellations, renewals.
6.   Displaying Cancelled NSOs
1.   Collection of requirements:

First of all, the problem of outdated data was detected in aninstant where some data of a current procedure was required, which the data of that file was not updated as forexample a product had made a name change over time andthat caused that the report extracted was not completely truthful and which is a problem for the entire functional unit, and with the help of the evaluator and administrative staff was able to rescue all the necessary requirements for the information to be updated, both in the process and the data.

From the requirements rescued totally to carry out the project from the beginning of how they wanted the interface, what alerts, what additional features could have the system and detect from a starting point the problem which causes the data to be totally outdated which helps usa lot to be able to reduce the time and design of the entire system for implementation.

These collections are taken through the resources established by the data collection techniques:

•   Interview with the area manager.
•   Brainstorming.
•   Zoom Meeting (Video Call).
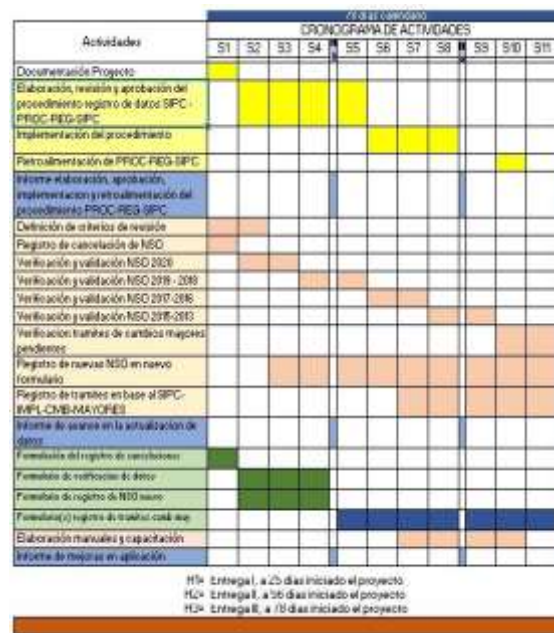•   Focus Group.

Figure 4. Work plan

2.   Requirements refinement

In this part through all the data collection techniques, we make decisions to carry out the project such as the standard structure in Excel to develop the Sprint templates. The part where it is detailed:

ACT-PASIPC	Nro.	Procedure
II	1	**Mapeo de procedimiento de transferencia** de NSO
		Revisión de procedimiento de transferencia
	2	**Revisión criterios de revisión de datos**
	3	**Actualización NSO transferidas**
		a) NSO con transferencia a solicitud del titular
		i. Registro de transferencias
	4	**Actualización NSO emitidas 2020**
		a) NSO con datos incompletos en SBELLA
		b) Validación y registro de datos de relación de NSO con datos incompletos en SBELLA
IV	5	**Aplicación: Transferencia NSO a solicitud del titular**
		a) Desarrollo del formulario transferencia a solicitud del titular
		b) Validación del formulario transferencia a solicitud del titular
	6	**Aplicación: Criterios de selección de datos a consisten ciar**
		a) Modelamiento de la base de datos
		b) Programación de formulario
		c) Validación de formulario

Figure 5. Sprint Template

3.   Recording of data not reflected in the Sbellasystem

Next, it is detailed how the process of registering thedata that were not registered in the Sbella system willbe done, taking sources of information such as:
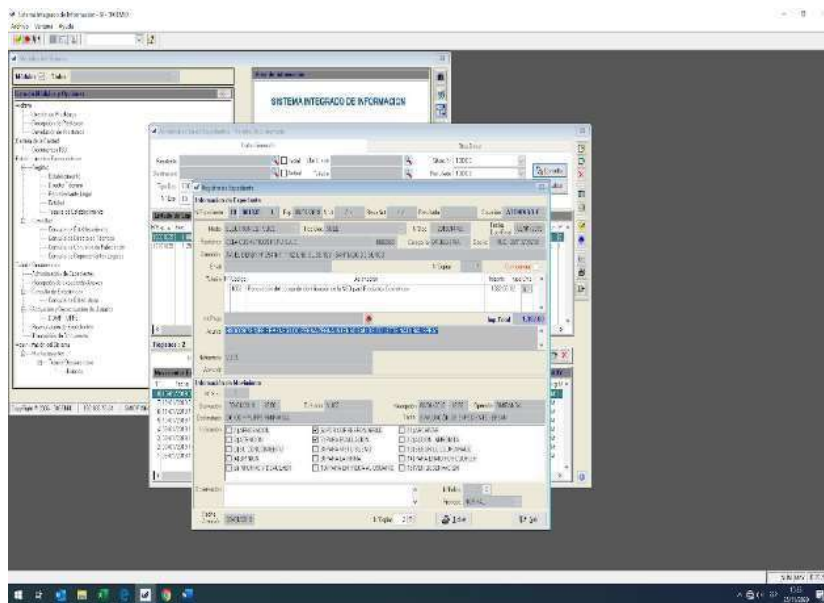
• SIDIGEMID

• EUV

• Prior Review

Figure 6. Digemid System.

4.   Validation of data recorded in the Sbella System

To corroborate that the data to be entered in the Sbellasystem such as product name, holder or applicant for authorization, product manufacturer, brand, cosmetic group, classification, cosmetic form and most importantly that it is correlated with the file number.
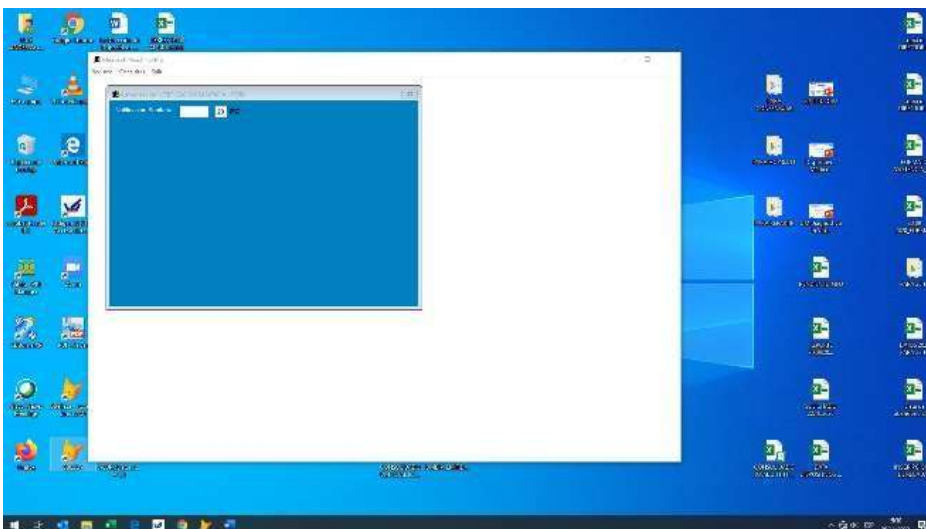

Figure 7. Sbella System

Figure 8. SW System.

5.   Development of registration forms for cancellations, renewal

At this stage, the required forms were developed to have the mostupdated data corresponding to the renewals and holder transfer. The process of granting the rights is detailed in a flow chart below.

Figure 9. *Granting process*

Figure 10. *Registration form*

6.   Display of canceled NSOs.

Once the information has been updated in the Sbella system and the Previous Review, the form with which the NSO will be cancelled is filled out, both individually at the request of the Holder, and the other is for the definitive closing of the pharmaceutical establishment, which is as many drugstores as there are laboratories.
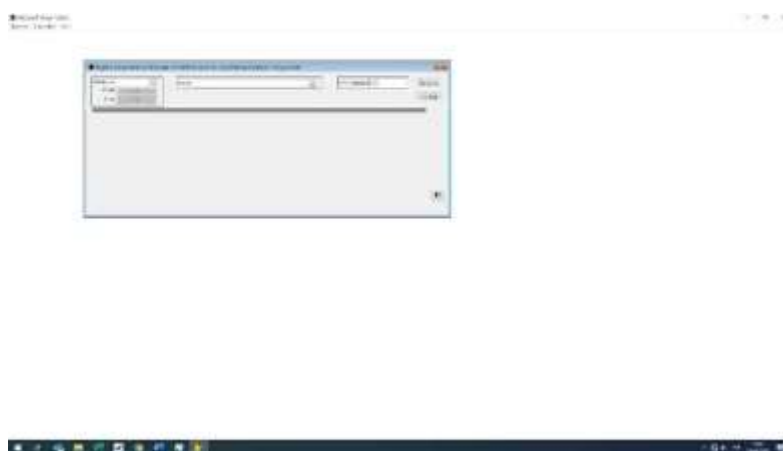

Figure 10. *Cancellation Form*

III.   RESULTS

The application of all the passes mentioned above has led us to good results for future decision making, having all the updated data with final product is that it can be viewed through queries that at the same time was implemented in order to make reports in Excel with updated data, then, the updated form will be shown
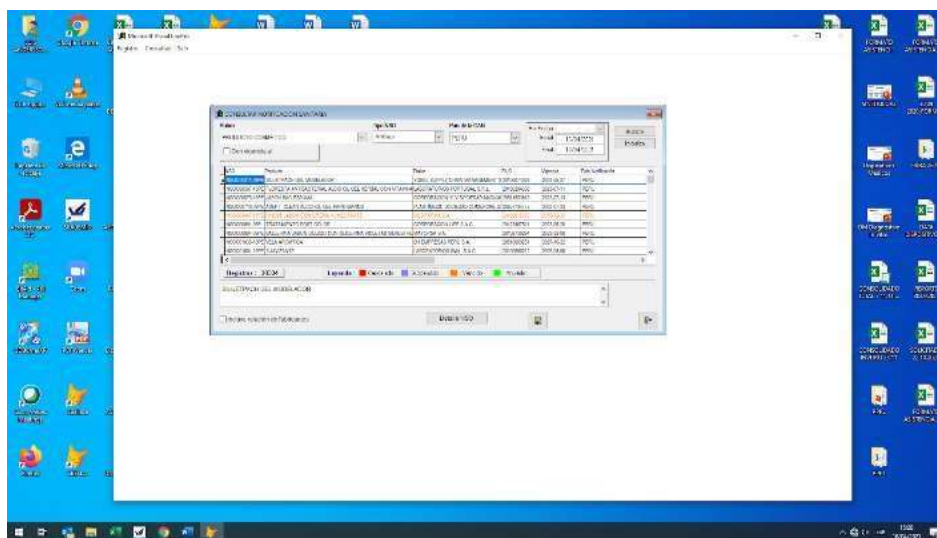

Figure 11. Query window with their respective legends

Which you can see every detail of each record with their corresponding data, in addition to viewing the traceability or timeline which may undergo a Mandatory Health Notification, such as notification process, process of change of owner, process of a renewal due to expiration of the authorized date.
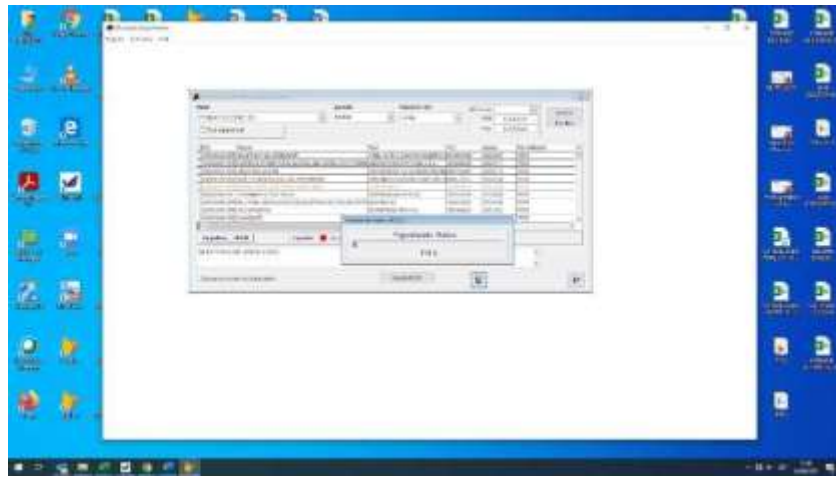
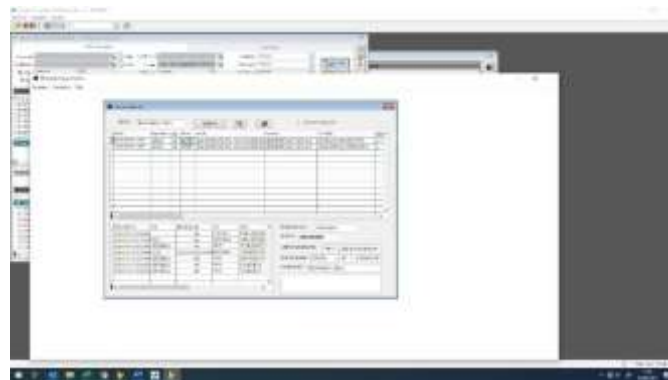Figure 12. *Exporting records to Excel*

Figure 13. *History of an NSO*

IV. CONCLUSIONS

The update and improvement of the system Sbella in the functional unit of Sanitary Products that was carried out was of agile way applying the methodology Scrum, since it guided us efficiently during all the process to arrive at the last end to have everything updated.

In conclusion, the update in a company of the state more still corresponding to the health sector, in this time in which we live of the pandemic of Covid 19, we need to have an updated and truthful information, for decision making corresponding to the mentioned area.

EVALUATION

The experience of having worked with the team of the Functional Unit of Medical Devices and also with the support of AIC (information technology) has been very satisfactory and I am proud to have had the expected results and to have taken advantage of the time and also to have acquired knowledge in this health sector and its requirements.

There were mistakes, but they could be corrected in time, giving that meticulous space to review each one of the file, the best thing was that everything was a team effort where everyone did their part to reach this goal.

REFERENCES

[1]   Bernhard Hitpass, Business Process Management Fundamentals and Implementation Concepts. P. 4.

[2]   L. D. Vásquez Fuentes, Manual de Introducción a Visual FoxPro. P. 2.

[3]   M. Fowler, K. Scott, UML drop by drop from Pearson Education. P. 37