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RESEARCH ARTICLE

Cost-Benefit Analysis of the Implementation of an Integrated Production Software in the Raw Materials Sector of A Pharmaceutical Industry

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ABSTRACT:

The pharmaceutical industry currently has computer systems that seek to optimize processes and allow the maximum performance of its resources through the use of computer tools. The objective of the work was to determine the costs and benefits of two different software in management of raw materials for the pharmaceutical industry.

Methods: observational, descriptive, cross-sectional, study that compared ONDANET and SAP software in positive and negative costs inferred in the implementation of the tools and the benefits in terms of the profitability of the management of raw materials for the elaboration of pharmaceutical products.

Results: it has been observed by using direct costs and benefits that the benefit-cost ratio of the SAP software implementation yielded a result of 15.37, whereas the ONDANET software presented a cost-benefit ratio of 0.05, which could have been demonstrated

Conclusion: A widely favorable cost-benefit ratio was found for SAP Software compared to the previously used ONDANET Software, indicating that the new software used is profitable. It is desirable to periodically carry out this type of analysis to guarantee not only that the Pharmaceutical Industry has a greater profitability, without also being able to provide its products with continuity and at affordable prices for the population.

KEYWORDS: Cost benefit, pharmaceutical industry, integrated production software.

INTRODUCTION:

The pharmaceutical industry needs to increase the speed of innovation in order to beat competitive pressures and rapidly launch new products with low prices for the community. At the same time, responses to requirements must be accelerated, rapidly updating formulations, specifications and labels to be able to meet national agencies regulations[1-3]. That means pharmaceutical industry (PI) need to accelerate the supply chain to develop agility to deal with fluctuations in raw materials, production and shipping[4,7].

Mastering these challenges means making improvements in production and productivity. To do this, it is need a resource planning system specifically designed to manage and streamline the critical processes required in the industry's manufacturing. In other words, IP need a solution that allows it to do more with less expenses, in order to be able to sell the medicines to the population, at a lower cost[8,9].

Certain deficiencies seen in the production process are caused by excessive document reviews and approvals, duplicate roles and responsibilities, or inconsistent practices. These have a negative impact on project timelines, increase costs, and cause non-value-added work. Possible approaches to address these problems are proposed in order to reduce costs and increase efficiency[10-15].

Innovations in Pharmaceutical procedures had certainly increased the number of united produced, its quality, and its effectiveness[16-19].

The implication of a computer software in these situations allows a vision of improvement, facilitating data management of all the company's resources, reducing costs and optimizing processes[20]. The aim of the present study was to provide a pharmacoeconomic analysis estimating the advantages/disadvantages of the implementation of two different software ONDANET and Enterprise Resource Planning System Software type SAP R/3 in the management processes of pharmaceutical processes.

SUBJECTS AND METHODS:

Type of Study:

cost-benefit study comparing two management software.

Study Objects:

two types of management tools in the pharmaceutical industry, an integrated SAP R / 3 software and a Classic ONDANET software.

Analysis Unit:

The analysis focused on the management of raw material to produce 3 pharmaceutical products: Valsartan, Menthol Cristal and Ginkgo Biloba

Methods:

an exhaustive bibliographic search was carried out on the operation and implementation of integrated production software in a pharmaceutical industry based on Relational Database Management Systems in order to identify an alternative software to the already available ONDANET program in local pharmaceutical industry. The SAP R/3 Integrated Software User Manual was revised and selected to perform the comparative analysis. Subsequently, the direct positive and negative costs inferred in the implementation of both programs were identified and quantified in monetary terms inferring positive and negative costs in the implementation of each software.

Variables:

Positive and negative costs associated to SAP or ONDANET system implementation. Benefit/cost ratio of both software

Statistical Analysis:

Once the data was collected, they were digitized and processed in a Microsoft office Excel 2013 spreadsheet. An exploratory analysis was carried out, identifying their distribution and atypical values, performing a bivariate statistical analysis.

RESULTS:

In order to determine the cost-benefit ratio, between the Software previously (ONDANET) currently used in the Local Pharmaceutical Industry, and the innovative SAP System; historical data of the shortages of medicines and costs originated by the lack of necessary “Raw Material” and thefinished products of each drug were analyzed. (table 1).

The public price per unit was calculated taking the values from February to November 2018 from the information of the Chamber of Pharmacies of Paraguay collected through the Fox Paraguay system. Dividing the quantity contained in each presentation gave as a result the unit price of each unit or gram.

The sale price to Pharmacies was calculated with a 30% discount from the public price, according to the current regulations for National Industry drugs.

With this processing of historical data, it was possible to calculate the monetary value of the loss in income from sales of medicines that could not be manufactured due to the lack of necessary raw materials (table 1).

In relation to the cost of usage of each software, it could be said that since the classic ONDANET software was developed module by module by the company's IP department, its modular cost was 15,000 USD. The cost in dollars transformed into Paraguay’s local currency (guaraníes Gs), considering the exchange as Gs. 6,200 for every dollar, means a cost of 93,000,000 Gs for the ONDANET system.

On the other hand, the innovative alternative SAP R/3 system is a globally used pharmaceutical management system. The company that wants to adopt must pay for a User License that has a cost of 1,500 USD each module. Taking into account that the raw materials requires 13 areas of the company, it demands 13 active licenses, which is equivalent to a total cost of 19,500 USD or Gs. 120,900,000 (table 2).

Table 1. Product management data with the “Classic” Computer System

Comercial designation	Missing Raw Material	Units Manufactured per day	Missing Time (days)	Missing quantity (units x days)	Price to the Public per Unit	Total amount of the missing
Tensional 160 coated tablets	Valsartan	1667	150	250050	4373	1093468650
Tensional 80 coated tablets	Valsartan	833	150	124950	3803	475184850
Dolo Reuma cream 20 g	Mentol cristal	23333	48	1119984	733	820948272
Memorial capsules	Ginkgo Biloba	2000	68	136000	1950	265200000
Total to the Public						2654801772
Total to Pharmacies						1858361240

*Prices are expressed in local currency (guaranies) **It should be noted that with the innovative SAP R / 3 System there were no shortages of raw material, or missing time.

Table 2. Cost-benefit ratio of the previous classical software ONDANET vs. the vs. the innovative SAP / R3 software

Type of Software studied	Profits	Costs	Benefit / Risk Ratio
ONDASET Classic Computer System	93000000	1858361240	0,05
Computer System SAP R / 3	1858361240	120900000	15,37

*Prices are expressed in local currency (guaranies)

The monetary value of the missing products constituted a negative cost (expense) caused by the non-complete integration of data for the classic ONDANET Software; and at the same time it turned out to be a positive cost (benefit) for the innovative SAP Software, because with this fully integrated system, there were no shortages of raw materials detected during the period of the study.

We also observe that the monetary value of the classic ONDANET system for the use of the software constituted a positive cost, due to its lower value; while the monetary value for the access to SAP Software was constituted in a negative cost, due to its higher value. In other words, more money was invested in the innovative system in order to solve the problems of shortages of raw materials. Hence, the costs of acquiring the license to use the new software, although more expensive, were ultimately amortized by the reduction in losses in raw materials.

DISCUSSION:

The results of the present study show a clear advantage in favor of the implementation of innovative tools such as an integrated SAP pharmaceutical production software, in terms of cost reduction and direct benefits[21].

The benefit-cost ratio of the innovative SAP software was 15.37, which indicates that this alternative tool is profitable, since the benefits obtained with its implementation justify its cost. On the other hand, the alternative of the previous classic software ONDANET showed a benefit-cost ratio of 0.05, which indicates that this alternative is currently unviable, since its costs exceed the benefits obtained with it, which implies a loss in term of profitability for the company at the long run period.

The advantages of the new systems like SAP is that its use is worldwide diffused, and its option of providing more functionalities and interconnecting modules is possible. Another advantage is that it allow to avoid shortages. The disadvantages of these new systems are related to the permanent need to pay for licenses, even if the costs may increase excessively. Likewise, it should be considered that the classic system (ONDANET) was developed tailored to the needs of the company, while the new SAP system falls into the category of "canned package", so if it is need to be modified, the job must be requested always to the supplier.

The results obtained in this study could have been more exact if the data of the real monetary value of the loss or its equivalent in the lack of income of the Pharmaceutical Industry caused by the lack of the products studied had been available. However, as this data is confidential, an approximation was made taking these two parameters: a- The value of sale to Pharmacies, which is not the net income value for the Pharmaceutical Industry, since it makes discounts and offers according to the quantities sold or other criteria, which depend on the marketing policy of each Industry[20]. b- The missing quantities were calculated based on the production data and they do not have a directly proportional relationship with the quantities that stopped being sold, since there could be products stored either in the Industry, or in distributors, at the time of production the lack of raw material[7]. The statistics or average of sales of each product is also a confidential data of the Industry.

It is worth mentioning that this study did not take into account indirect and intangible costs. Regarding to this point it could be mentioned the lack of drugs that forces patients to spend time and money in search of other drugs that can replace them (indirect cost) and their anguish and stress when faced with the uncertainly of whether the substituted drug will be as adequate as the one already being administered (intangible cost). These points should also be taken into account when making decisions between one or other alternatives.

CONCLUSION:

The present study allowed to quantify the costs of two alternatives software for pharmaceutical management: ONDANET and SAP, as well as the costs of missing raw materials, the period of time in which these supplies were missing, the missing of finished products and the sales revenue that the Pharmaceutical Industry stopped receiving for the missing referrals. The data expressed in monetary values showed that the benefit–cost ratiowas broadly favorable to the SAP software (index B / C 15.37), compared to the ONDANET software (index B / C 0.05).

The results of the study demonstrated the importance of conducting economic evaluations to strengthen the most accurate decision-making when implementing new technologies in the Pharmaceutical Industry; which would allow to maintain or even increase their profit margin, and at the same time, offer their products at a fair price for the community that needs them.

CONFLICT OF INTERESTS:

All the researchers belong to the National Public Universities of Paraguay and Argentina, and they do not have any type of conflict of interest with the management systems analyzed in this study.

REFERENCES:

1. Kumar JS, Kumar JR. Review of FDA Warning Letters to Pharmaceuticals: Cause and Effect Analysis. Research J. Pharm. and Tech. 2018; 11(7): 3219-3226
2. Kumar JS, Kumar JR. Evolution of GMP in pharmaceutical Industry. Research J. Pharm. and Tech. 2017;10 (2), 501-506.
3. Kumar JS, Kumar JR. A Study of Regulatory Agencies Inspected Global Drug Manufacturers. Research J. Pharm. and Tech. 2021; 14(2):1008-1016. doi: 10.5958/0974-360X.2021.00180.3
4. Meza DE. Study and analysis of the benefits of Sap Business One Software Implementation in various economic segments. 10Th Ed. 2020, Paris. Available on: http://biblioteca.usac.edu.gt/tesis/08/08_0317_CS.pdf.
5. Visual K. Manufacturing Software. Infor ERP. New York, 2021. Available on: https://www.visualk.com/software/software-erp-manufactura.html.
6. Kumar P, Kalaiselvan V, Kaur I, Thota P, Singh NG. Materiovigilance programme of India (MVPI): A Step Towards Patient Safety For Medical Devices; European Journal of Biomedical and Pharmaceutical sciences. 2016; 3, 12, 497-501
7. Dhamini M., Jawahar N., Vignesh M. Materiovigilance Programme of India – An Overview. Research J. Pharm. and Tech. 2021; 14(2):1137-1141. doi: 10.5958/0974-360X.2021.00204.3
8. Kovalyov V, Chetvernia S, Krechun A, Mykhailenko O. Establishment of the Main Technological Parameters of Iris raw material. Research J. Pharm. and Tech. 2019; 12(7): 3359-3364
9. Devasena L., Jegadeesan N, Alamelu R, Amudha R. Medical Instrumentation Industry- Indian Scenario. Research J. Pharm. and Tech 2018; 11(6): 2618-2620.
10. Fatima N. Understanding Data Mapping and Data Modeling Techniques. Westlake Village, CA. 2021. Available on : https://www.astera.com/type/blog/understanding-data-mapping-and-its-techniques/.
11. Blain J. Manual SAP R/3 Special Edition. World Consultancy, ASAP. Ed. Prentice, Madrid, Spain 2000.
12. Rascati KL. Measuring and estimating costs. In: Essentials of pharmacoeconomics. Lippincott Williams and Wikins. Baltimore, USA. 2009
13. Merethid, J.R; Shafer SM., Mantel, S. J. Project Management a managerial Approach (10th Ed) Editorial Wiley, Danver, MA, USA 2010.
14. Baca G. Project Evaluation. Mc Graw Hill. 7rd Ed. Buenos Aires. 2014
15. Deveswaran R, Bharath S, Basavaraj BV, Abraham S, Furtado S, Madhavan V. Concepts and Techniques of Pharmaceutical Powder Mixing Process: A Current Update. Research J. Pharm. and Tech. 2009; 2 (2): 245-249.
16. Amar S, Balamuralidhara V, T M Pramod Kumar. Manufacturing and Designing of Implantable 3D-Printed Medical Devices - An Overview of Regulatory Challenges. Research J. Pharm. and Tech. 2021; 14(3):1785-1790. doi: 10.5958/0974-360X.2021.00317.6
17. Eppler M.J. Making knowledge visible through intranet knowledge maps: concepts, elements, cases, *Proceedings of the 34th Annual Hawaii International Conference on System Sciences,* Maui, HI, USA, 2001; 4, 9. doi: 10.1109/HICSS.2001.926495.
18. Mankar S. D., Kale C, Kanchan J. 3D Printing Technology- A Computer Aided Design- A Review. Research J. Science and Tech. 2019; 11(3): 217-224.
19. Dubey R.D., Chandraker G., Sahu P.K., Paroha S., Sahu D.K., Verma S., Daharwal S.J., Prasad Reddy S.L.N. (2011). Computer Aided Drug Design: A Review. Research J. Engineering and Tech. 2(3): 104-108.
20. Majeed SM., Al-Shaheen MK., Al-Zidan RN. Quality control study on Conventional Metronidazole tablets available in the Iraqi market. Research J. Pharm. and Tech. 2021; 14(2):803-808. doi: 10.5958/0974-360X.2021.00141.4
21. Soto I. Validation Cost Reduction. J Valid Technol 2014; 20(3):32–4.