VIEW POINTS

Actions to Solve Failures in Critical Technological Equipment's on Cuban Enterprise

Acciones para la solución de fallas en equipos tecnológicos críticos de una empresa cubana

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ABSTRACT: The objective of this research was to propose actions for the solution of failures in critical equipment of the Unit of Capsules and Suspensions of the Pharmaceutical Laboratory "8 de Marzo". Initially, the most critical assets were identified from the application of a technology for the hierarchy of systems and technological assets for biopharmaceutical companies. For this, techniques from the field of research were used such as bibliographic search, document review, technology for the priority order of systems and technological assets in biopharmaceutical companies; in addition to Pareto analysis and Cause-Effect Diagram; applying the latter to equipment failures. Brainstorming work sessions were organized with the workers of the laboratories, maintenance department and the group of experts, yielding as the main conclusion of 8 actions to solve the problems of failure of the most critical assets and consequently the reduction of stops for this concept and its corresponding improvement in the general availability of the plant.

Keywords: Maintenance, Asset, System, Availability, Technique.

RESUMEN: La presente investigación tuvo como objetivo proponer acciones para la solución de fallas en equipos críticos de la UEB de Cápsulas y Suspensiones del Laboratorio Farmacéutico "8 de marzo". Inicialmente fueron identificados los activos más críticos a partir de la aplicación de una tecnología para jerarquizar los sistemas y activos tecnológicos para empresas biofarmacéuticas. Para ello se emplearon técnicas propias del campo de la investigación como son: la búsqueda bibliográfica, revisión de documentos, como principal hallazgo la tecnología para el orden de importancia de los sistemas y activos tecnológicos en empresas biofarmacéuticas; además de análisis de Pareto y Diagrama Causa-Efecto, aplicándose estos últimos a las fallas del equipamiento. Se organizaron sesiones de trabajo tipo tormenta de ideas con los trabajadores del departamento de mantenimiento del laboratorio y el grupo de expertos; arrojando como conclusión 8 acciones para lograr dar solución a los problemas de fallas de los activos más críticos de la UEB de Cápsulas y Suspensiones y por consiguiente la disminución de las paradas por este concepto y su correspondiente mejora en la disponibilidad general de la planta.

Palabras clave: mantenimiento, activo, sistema, disponibilidad, técnica.

INTRODUCTION

Good management of the maintenance process ensures compliance with the corporate purpose of the companies, which is why it constitutes one of the fundamental factors to guarantee that the costs of repairs are gradually reduced; without affecting their quality or the reliability of the equipment (Martínez, 2017).

The role of science, technology and innovation is placed in the foreground in all instances, with a vision that ensures achieving in the short and medium term the objectives of the Socially Economic Development Plan defined in the guidelines of the VII Congress of the PCC: 98, 100, 102, 104 and 185 PCC-Cuba (2016) and implemented with the help of resolution RS 116/2017 'Methodological indications that contain the minimum technical-economic requirements of the

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industrial maintenance system' (GOC- 116-- 2017, 2017).

Maintenance is an important activity to increase productivity and is a key element to face the growing competitiveness of the market. This has resulted in organizations belonging to the drug production group becoming interested in adopting more convenient strategies to stay at the forefront of global development trends, guaranteeing their organizational success. The maintenance activity needs to stop being barely effective to become effective. That is, it is not enough to repair the equipment or installation as quickly as possible but, mainly, it is necessary to avoid equipment failure and reduce the risks of an unplanned production stoppage (Kardec and Nascif, 2002).

This process has powerful tools and maintenance indicators that help us decide what action to take in a given situation since they help the decision-making of maintenance personnel and if they are met within the established indices, it can be almost categorically stated that the activity has all the possibilities of having the desired success within the comprehensive management system of an industry. These tools are: Reliability, Availability and Maintainability (Kardec and Nascif, 2002; Grajales et al., 2006).

The business complexity that the biopharmaceutical industry presents today, the technological development involved in production equipment and in buildings and service provision facilities, mean that maintenance must be studied and applied with greater scientific content if it is to reach its potential. main objective under the current and future conditions of its clients.

In the pharmaceutical industry, a failure implies the loss of a product, because the recovery of raw materials and packaging material becomes impossible due to the quality requirements that they have to meet, in addition to the supervision to which they are subject by regulatory bodies. of a national and international nature.

In the company that is the source of this research, up to now, an in-depth analysis of the equipment that has the most impact within the production process (critical) has not been carried out. The methodology used for the methodological treatment of the research was that referenced in the bibliography (Hernandez-Sampiere and Baptista-Lucio, 2006; Acuña and Miriam, 2006).

The classification of equipment as “critical” is that which presents failure modes that may give rise to unacceptable consequences, that is, assets with vital functions and failure modes with significant consequences for safety, the environment, operation and own maintenance, so this will imply the requirement of establishing some efficient maintenance task that allows reducing its possible causes of failure, therefore a proactive approach is what must prevail in the attention to these assets (Díaz and Benítez, 2012; Diaz -Concepcion, 2019).

A basic criticality analysis model is the equivalent of the one shown in Figure 1 (Díaz and Benítez, 2012) and is applied to any set of processes, plants, systems, equipment and/or components that require being ranked based on their impact. in the process or business where they are part.

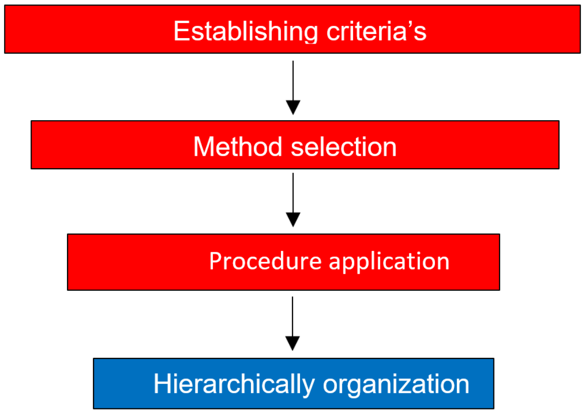


FIGURE 1. Basic Criticalitymodel. (Díaz & Benítez, 2012) [8].

METHODS AND MATERIALS

Applied methodology

In the investigation, all the documentation about the equipment that makes up the two production lines of the company was analyzed, a preventive diagnostic study of the availability and the service factor of the production process, through the history analysis of failures and repairs.

To do this, the importance of the equipment is first established through criticality analysis according to the role they play in the production process.

The criticality model used is that of weighted factors based on the concept of risk (del Castillo-Serpa et al., 2009)[10], this is a semi-quantitative method supported by the concept of risk: frequency of failures x consequences. The criticality analysis used in the research was the technology proposed and validated by Antonio Enriques Gaspar (Enriques-Gaspar, 2019; Enriques-Gaspar et al., 2020), a methodology that allows establishing priorities of processes, systems and equipment, with the objective to facilitate the making of correct and effective decisions, directing resources and efforts on those of greatest importance.

The criticality equation seen from a mathematical point of view developed as a result of this study is, equation 1

$$I.C(Criticity) = Severity * Failure\ frecuency * Detectability \quad (1)$$

Where:

Severity: Failures importance.

Failure frequency: Failure frequency in any system component that cause a product loss or an extension in product production time. Represent the number of times that failure represent the function loss of any system component or production loss in a year.

Detectability: Category that take into account the instrumentation level; facility to detect functional failures and allows operators to detect production operation, to take decisions and bring information about the failure model.

$$Severity = TPPR + NVA + CR + IO + ISSP + IA + CPF + AT \quad (2)$$

Where:

TPPR- Mean time to repair or time the equipment is out of service.

NVA- Automatization level. Limit the operator action and its influence on its decision error.

CR- Repair cost. Mean cost of failure repair. Includes all repair cost (material, transport, energy, ..).

IO- Operation impact. Production loss when failures occur.

ISSP- Failure impact on health and personal security.

IA- Background impact. Category that consider the background impact and cause of damages on installation.

CPF- Final product quality. Take into account the final obtain production.

AT- Technological actualization. Measure the technological state comparing it with Word level and obsolescence technology.

To validate each parameter of the equation was considered the general assent of an expert group. Considering the obtained validated parameters was calculated the criticity index. After that was applied Pareto diagram to obtain the more important equipment's and applied use on them a criticity analysis, using 5 variables: human consequences, background consequence's, cost consequence's total consequences.

Using obtain pondering parameters for each variable of mathematical model was calculated critical indexes values. Was taken historic information of failures on selected equipment's and was applied weapons of Pareto diagram to determine the most important and critical equipment's on production process.

To increase results was used a root cause analysis using adequate weapons. After that was realized critical analysis of equipment's to classify those that for its operational function represent risk for the human and economic point of view for the enterprise. Were taken 5 variables: human, background, public health, cost and imagines consequences. Not were consider detectability and complexity.

On research was applied a method and solution analysis developed at Macroeconomic Study Center of Argentine (UCEMA) on pharmaceutical laboratory in Buenos Aires.

To obtain the objective was used steps method to continue increase of improvement that are shown.

1. Problem selection.
2. Elements search.
3. Cause search.
4. Planification and implementation of solution.
5. Reflexing about process and selection of new problems.

Finally, were identified problems and obtain criterion to select the most priorities, introducing management weapons.

The used technology has scientific and engineer methods that conduce to how to do it and to propose proceedings for its application and to know how to do it. On Fig. 2 is exposed a map of the proposed technology with all the elements.

Mathematical model to calculate complexity index

The used complexity equation was, equation 3

$$I.C.(complexity) = CP + CT + CU. \quad (3)$$

Where:

C.P.- Production complexity: How much complex is active on its manipulation and the operator attention

C.T.- Technology complexity: Evaluate knowledge level that needs the maintenance personal to solve actions.

C.U.- Situation complexity: Consider certificated areas with difficult access that complicate the active attention.

Criticity vs Complexity matrix

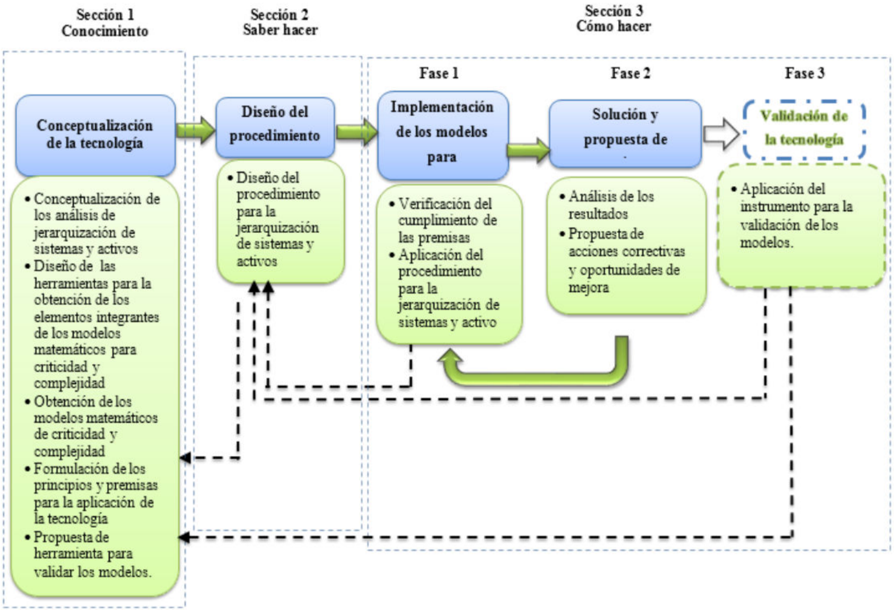
With obtain results with both mathematical models was obtained a matrix to organize hierarchically actives with criticity and complexity. On X axis were situated criticity values and its mean value and on Y axis were situated complexity values and its mean value. Obtain results were organized on a matrix Fig. 3.

First quadrant shows active of more complex and criticity; second quadrant shows active of high complexity and less criticity and so on. This allows to define an organizative form to define maintenance politic.This method contribute to consult experts, supported by their knowledges, expertise and research (Astigarraga, 2003; Hurtado de Mendoza-Fernández, 2012). After those results is developed a Pareto annalisys and a cause effect diagram (Ishikawa diagram) (Aguilar-Otero *et al.*, 2010; Paredes-Galindo, 2015).

OBTAIN RESULTS

Availability and failures number

Was analyzed production levels between 2015 - 2019. Results are shown in Table 1.



Enriques Gaspar, Antonio (Enriques-Gaspar, 2019; Enriques-Gaspar *et al.*, 2020)

FIGURE 2. Map to organize hierarchically systems and technologic actives on biopharmaceutical enterprises.

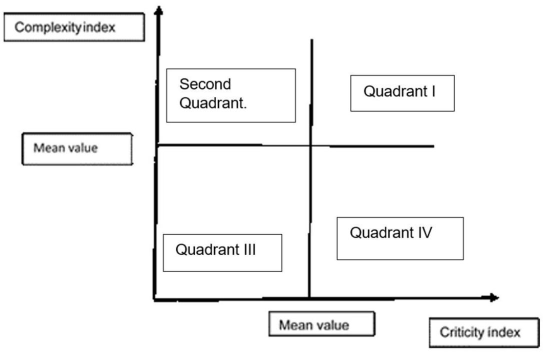


FIGURE 3. Complexity vs criticity matrix.

TABLE 1. Production level, availability and number of failures.

Year	Production (MU)	Availability (%)	Failures number
2015	156 470,90	91,3	522
2016	158 472,40	89,9	540
2017	140 904,30	87,2	688
2018	140 561,60	85,9	900
2019	132 980,70	81,7	723

Analyzing results was appreciated values variability, nevertheless was observed gradual correspondence between availability and number of failures as is appreciated in Fig.4. Parameters were extracted of work orders.

Is evident that availability and failures number are proportional inversed, considering that tendency in availability tends to diminish and failures number tends to increase; what showed inefficiency in maintenance management.

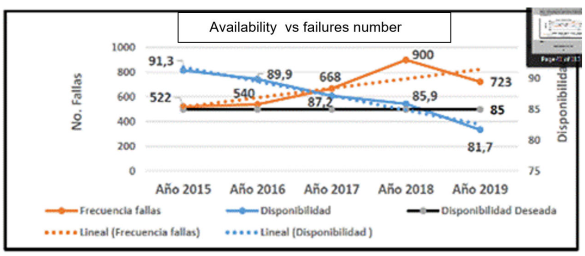


FIGURE 4. Availability vs. failures number.

Implementation of criticity model on equipment's

As result of the analysis of all the work orders were obtained result pondering of parameters used for criticity values calculus and the complexity of all actives (Diaz-Concepcion, 2019); all values more than mean value, which was 182. All is shown in Table 2.

TABLE 2. Criticity index of equipment's

No	Active denomination.	Criticity index.
5	Capsular Bosch	**810**
9	Blister 1	**456**
10	Blíster PMM	**435**
12	Satiating MAR	**222**
15	Prim ETIPACK	**324**
16	Case maker AV	**279**
20	Dobler	**225**
Mean value		182

Where also analyzed complexity index of actives; the most complex are shown on Table 3.

With obtain criticity and complexity values were developed criticity vs. complexity matrix shown in

TABLE 3. More complexity active index

Active number	Active denomination	Complexity index
5	Capsular Bosch	13
9	Blister 1	13
10	Blíster PMM	11
12	Satiating MAR	13
12	Blowing MAR	9
15	Prim ETIPACK	9
16	Case maker AV	11
17	Cluster AV	9
20	Prospect turner	11

TABLE 4. Actives shown in the first quadrant

FIRST QUADRANT			
Active number	Active denomination	Criticity index	Complexity index
5	Capsular Bosch	810	13
10	Blíster PMM	456	13
10	Blíster PMM	435	11
12	Satiating MAR	222	13
15	Prim ETIPACK	324	9
16	Case maker AV	279	11
20	Prospect turner	225	11

Fig. 4 (Gómez-Pérez *et al.*, 2016; Diaz-Concepcion, 2019).

In Table 4 are shown the more critical and complex actives. To them were put the biggest efforts and attention.

Considering that the number of equipment's on this first quadrant is high (7), and to establish an order for its attention was used the technology procedure of hierarchical organization. Results are shown on Table 5.

Taken in account the obtained results of the employed procedure was decided to priories research on Capsular Bosch and Blister 1, which are the first on the Table 5 and need great efforts to increase operational availability and to prevent failures and increase maintenance management.

Pareto analysis to locate the most recurrent failure in the selected critical equipment

Pareto analysis was realized to obtain the most recurrent failures on Capsular Bosch and Blister 1 equipment's which were selected as the most critics. For that purpose, was obtained information from work orders from 2017 and 2018. Were considered type of failure, its frequency, need time for its solution and its impact on production

Capsular Bosch'

Obtained information is shown on Table 6. Type of failures, failures frequency (FF) and mean type for failures recovery (TPPR).

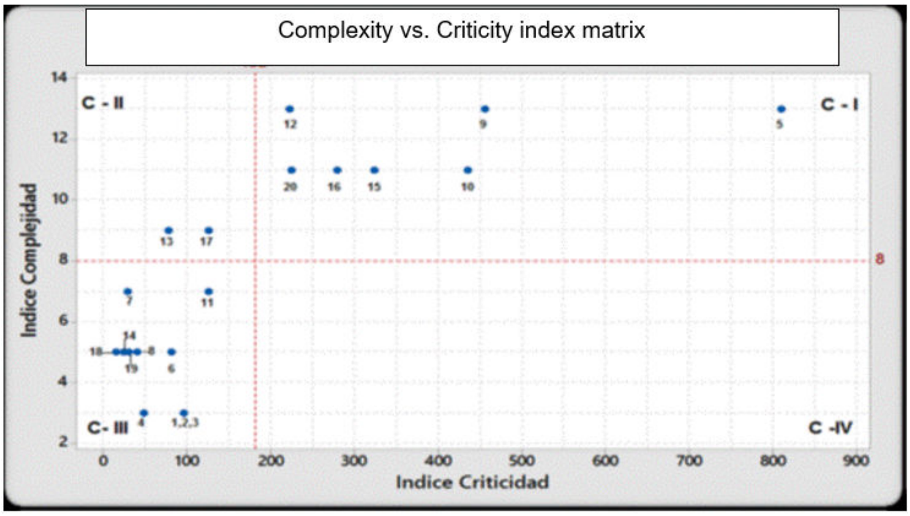


FIGURE 4. Complexity vs. criticity index matrix.

TABLE 5. Order of importance of actives on the first quadrant

Order	Equipment denomination	Equipment number	Complexity index	Ubication complexity	Technological complexity	Production complexity
1	Capsular Bosch	5	810	3	5	5
2	Blister 1	9	456	3	5	5
3	Blíster PMM	10	435	3	5	3
4	Prim ETIPACK	15	324	3	5	3
5	Case maker AV	16	279	3	5	3
6	Prospect turner	20	225	3	3	5
7	Satiating MAR	12	222	3	5	5

TABLE 6. Type of failures, failures frequency (FF) and mean type for failures recovery (TPPR) on Capsular Bosch

Failure number	Failure denomination	TPPR (h)	FF
1	Failures on dust aspiration system	20	49
2	Failures on capsule expulsion system	82	130
3	Failures on capsules orientation system	60	80
4	Failures on segments and segments holder system	228	420
5	Failures on motor system	16	39

Blister

In Table 7 are shown the failures frequency (FF) and man time to repair failures (TPPR) on Blister.

TABLE 7. Failures on Blister

Failure number	Failures denomination	TPPR (h)	FF
	Failures on motor system	121	186
	Failures on allotment system	46	70
	Failures on control system	21	32
	Failures on cooling system	14	21
	Failures on sealing system	27	42

Considering obtained results on Tables 6 and 7 was conclude that continued research will be on failures 2 and 4 on Capsular Bosch and failures 1 and 2 on Blister as they represent 72 % of all failures. Descend or elimination of those failures share to diminish production stop

Cause and effect diagram

Cause - effect diagram was done with a brain storming realized by experts that increase to conclude on causes that provoke selected failures.

Cause and effect diagram of selected failures.

Cause and effect diagram of failure number 2 (capsules expulsion system) on Capsular Bosch. Fig. 5.

Propose of actions to be done for diminish and elimination of detected failures

Were considered actions that will permit to diminish and eradicate equipment's failures. The equipment's failures were common in most cases, that's why are shown actions that ungloved all possible solution for eradicate failures.

1. Consider by maintenance and trade section to buy instruments for calibration for segments alignment, dynamometric weapons to guarantee exact adjust of segments for Capsular Bosch and others for Blister synchronization and mount punch on sealing.
2. Consider by maintenance to give to third specialist's production of pushers and pushing shafts and the heat treatment of Blister and Capsular Bosch elements.
3. Work with engineer's enterprise group maintenance active systems, such as change and calibration on Capsular Bosch, mounting and dismounting of punch in Blister sealing.

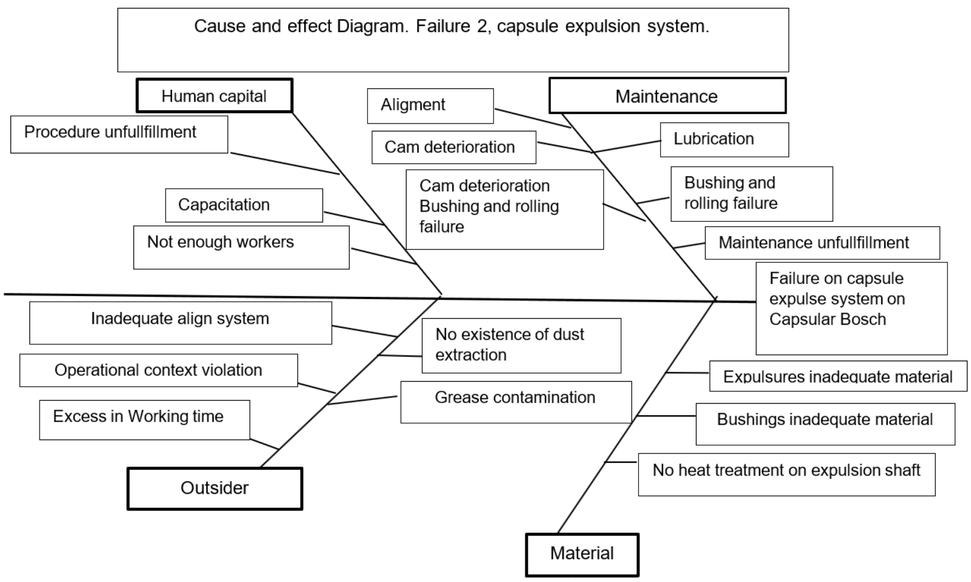


FIGURE 5. Cause and effect Diagram. Failure 2, capsule expulsion system.

4. Elaboration by adequate personal groups of different proceedings, such as change and calibration in Capsular Bosch, mounting and dismounting of punch in Blister sealing.
5. Consider by Capital human resources: to complete operational personal in capsular and suspensors operation, increase capacitation of maintenance personal on Blister sealing and cleaning to increase allotment system.
6. Increase by quality controllers and technical department supervision on maintenance operation.
7. Evaluate by Productive technical department compliment of work cycles considering actual capacity of equipment's.
8. Evaluate by inversion department the acquisition of a centralized climatic system and a dust extract system.

Economic valuation. Impact of analyzed failures on production

The impact of failures on production considered non produce physical units on considerate period on both considered actives, taking on account the real capacity of actives and the price of non-produced elements (0,05119 MT) where MT implies total money (national and foreign).

Obtained values are shown on Table 8.

TABLE 8. Failures impact on production

Equipment	Failures loose time (h)_	Real capacity (h)	Total not produced capsules	Total not income money (MT)
Capsular Bosch	310	88 400	26 784 000	1 371 072,96
Blister	167	72 000	12 024 000	615 508,56
		TOTAL	38 808 000	1 986 581,52

In Table 8 is observed that during 2017 - 2018 years loosed to enter 1 986 581,52 MT. Considering that medical treatment needs, at least, 1 tablet each 8 h by 7 days are required 21 capsules, were not offered, 970 000 treatments to population.

CONCLUSIONS

- Were given 15 actions for the solution of failures problems in the more active equipment's of the enterprise; that will increase production a diminish economical loses.
- Was obtained a hierarchized list of the enterprise actives that will permit to establish to govern financials, human and technical resources.
- Economic analysis shows that can be increased money income by more production and to reduced incineration and engraves of residues.

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