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Use of quality tools to resolve the problem of pot closing system

Summary

The focus on process management has become increasingly evident in organizations. Based on the need to solve a packaging leak problem in a company producing biological cardiovascular valves, a data survey can be carried out using the Quality Tools Check Sheet, Cause and Effect Diagram, 5W2H, Flowchart and GUT Matrix for identifying causes and failures in processes. Tests were carried out on a set of 93 packaging samples with 3 different moulds, evaluating the manual closure of the lids, based on the pot closure system, as well as analyzes with 2 torquemeters to compare results. The samples were submitted to a vacuum sealing system for visual analysis of the leak. *Power BI and Excel* software were used to record the data. Regarding the results, an approval rate of 96.73% was observed using the "torquimeter 1" for the three packaging models and for the "torquimeter 2", an approval of 71% of the packages and in comparison to the nonconformities, the "torquimeter 1" presented 4.3% of disapprovals and as for the 2, a value corresponding to 29% of the total of the executed tests.

Keywords: packaging, closure of pots, quality tools, cardiovascular valves, Power BI

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de Paula L Reis E, de Oliveira GF, de Oliveira GH, da Cruz KR, de Oliveira LH, Parreiras Gallegos RA, Dias Cangusus RL

Department of Engineering, University center – UNA, Brazil

Correspondence: Raphael Augusto Parreiras Gallegos, Department of Engineering, University center – UNA, Brazil, Tel +5531984024410, Email raphael.parreiras.gallegos@gmail.com

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Introduction

According to the Pan-American Health Organization (PAHO), the deaths registered due to cardiovascular diseases are expressive, on average 2 million per year and this is still the main cause of death in the Americas. It can be said that this result is mainly due to unhealthy practices maintained in the population's routines, such as consumption of processed and artificial products, with high levels of salt, fat, sugars, in addition to smoking and not performing physical activities.

Knowing the existence of this problem and with the technological advances in medicine, regarding the performance of cardiovascular procedures for replacing aortic valves, it is often necessary to have effective alternatives that can meet the needs of patients in an agile way, and, therefore, the use of these artificial aortic valves.

When developing valves, the internal environment, as well as all applicable steps and procedures, must be precisely controlled, following current and applicable legislation, so that there is a guarantee of compliance and the traceability of failures in the process and likewise, their storage must be carried out so that they are transported and still preserved, guaranteeing their sterility and their use in perfect conditions.

Today, adequate packaging must be part of the life cycle of the product they are storing, meeting technical, socioeconomic, aesthetic and even commercial criteria, becoming an essential part of every logistical operation to which it will be submitted.

This article shows the relationship between the manual practices of closing packages that contain cardiovascular valves and the leakage presented by them, during the execution of quality control in a company in the metropolitan region of Belo Horizonte - MG.

Knowing the existence of a problem, carefully evaluating the stages of production and storage in the packaging, what could be done to improve and control the process? Quality tools such as verification sheet, cause and effect diagram, 5W2H, flowchart and GUT matrix will be used for the primary identification of the causes of the leak and to ensure that improvements can be applied and the existing problem is remedied, meeting the needs and the objectives of the organization.

General objective: To analyze the closing system of cardiovascular valve pots, in order to guarantee the effectiveness of the packages that pass through the process, using quality tools

Specific objectives:

- Identify possible causes that impact and compromise the integrity of packaging for biological cardiovascular valves
- Propose solutions for the identified causes

Benchmark

Low pressure test system

To ensure complete customer satisfaction and product assurance, quality is objectively understood. Normative techniques are used to carry out tests applied to product packaging. For this certainty, the realization is carried out in accordance with the instructions regulated by ISO 2873:2000.[1]

According to regulations, the packaging of the product to be tested must be placed in a pressure chamber. During the test the pressure must be reduced so that the simulation represents the pressure of a pressurized aircraft flying at any altitude, thus the pressure is maintained for a predetermined period and then returning to ambient pressure upon completion of the test.[2]

Packaging

The packaging process of pharmaceutical products must follow the specifications of the National Health Surveillance Agency (ANVISA). In order to comply with the packaging process for pharmaceutical products, the Brazilian pharmacopoeia allows a wide range of closing torque values, varying according to the diameter, types of screw caps used in the pharmaceutical segment, are produced in polypropylene (PP) and can be used for glass or plastic packaging, intended for the packaging of liquid or solid products.

Polypropylene torque system

This test method involves applying a specified torque to a screw cap to a container and measuring the torque required to unscrew the

cap from a container. The values stated in units in the International System (SI) should be considered as standard. It is also up to the operator to define and evaluate the necessary conditions for carrying out the tests, following the pre-established parameters in regulations and internal operating procedures.[2]

Measurement, analysis and improvement

Measuring the activities to be developed begins with demands presented by certain areas; however, it is of fundamental importance to work proactively, identifying needs for improvement through data analysis or seeking solutions for critical processes, which are linked to the strategic objectives of the company.

The important thing is to look for indicators that can demonstrate how much the processes meet what they provide (effectiveness) and how much resources they consume (efficiency). This measurement will enable, at the end of the work, new measurements to be carried out in order to demonstrate how improvements in organizational processes can positively influence the results of the area.[3]

Some common failures in this phase should be avoided: creating an excessive number of indicators, demonstrating lack of care in data collection, presenting indicators that are not aligned with the strategic objectives, collecting data without analyzing them, presenting indicators of low relevance, measuring only for control of goals without a focus on improvement, measuring to cut costs instead of improving the management and quality of processes.[4]

It is not always possible to accurately and immediately identify all the causes of problems that affect the performance of indicators/processes. In this context, we can use some tools that will help identify and prioritize problems, analyze their causes and, finally, plan proposed solutions.[5]

Check sheet

To collect and organize data in real time, companies use the verification sheet, the quality tool, considered the simplest and easiest to demonstrate the variations of a process in a simplified way.

The verification sheet is based on organizing, simplifying and optimizing this data collection, according to the need and purpose for which it is intended. It can be used to verify the process and to control it.[3]

Cause-effect diagram (Ishikawa)

The Cause-Effect Diagram or Ishikawa Diagram is a quality tool used to analyze the various causes for an effect, that is, to identify reasons or characteristics that resulted in a given problem.

This diagram is also known as "Fishbone Diagram", since its graphic representation is similar to the skeleton of a fish and from this still, a dynamic visualization of a process is achieved, analyzing aspects that refer to the hand of work or people, materials, machines, methodologies, measures and environment.[6]

GUT matrix

The Gravity, Urgency and Trend Matrix - GUT, are a problem and cause tool that aims to facilitate the decision-making process and are analyzed by Severity, Urgency and Trend:

- Severity (G): impact and consequence if the problem occurs;
- Urgency (U): need to solve the problem, the bigger the faster it must be solved;
- Trend (T): is the chance of growth of the problem, reduction or extinction of the problem over time, basically represents its development.

The factors are scored from 1 to 5, in ascending order, from lowest to highest weight, and should classify the problem. Once the problems are classified, the product of the factors (G x U x T) should be calculated and those with the highest scores should be prioritized, which should be treated as more serious problems.[7]

5W2H

5W2H is a management tool that allows the identification of problems and the root causes that justify them. This tool can be presented with different names, but its application principle is the same. It is based on the elaboration of questions about a problem, as follows: 5W: *What* (What), *When* (When), *Why* (How), *Where* (Where) and *Who* (Who) and 2H: *How* (How) and *How Much*, that is, it is carrying out a complete checklist, for each non-compliance detected in a production system.[2]

Flowchart

Elaborated with the objective of representing the flow of a process, people, actions among others, the tool aims to use graphic representations to illustrate a certain flow to be followed, presenting alternatives when the correct flow cannot be executed. The symbology used for its elaboration is: Rectangles, rhombus, circle among other elements, with each one representing a stage of the flow such as: alternatives, descriptions to be followed, beginning or end, which may contain other stages. The flowchart also aims to facilitate the interpretation of measures that will be taken in certain processes.[8]

Maintenance management

Even with the advancement and new technologies regarding equipment and industrial facilities, maintenance is always necessary, in order to ensure greater reliability and safety against failures in a process.[9]

The Brazilian Association of Technical Standards (ABNT), defines in the Brazilian Standard (NBR) 5462/1994 maintenance as a combination of all technical and administrative actions, intended to keep an item performing in accordance with its required function, (BRAZILIAN ASSOCIATION OF TECHNICAL NORMS, 1994).

Knowing that the technical actions provide the use of the equipment so that it is in complete normality with its operation, one of the three types of maintenance is necessary: Corrective Maintenance, Preventive Maintenance, and Predictive maintenance.[9]

Corrective maintenance

Unlike preventive maintenance, corrective maintenance is given by an unexpected occurrence, in most cases completely unwanted, as they usually involve higher expenses in replacing parts, longer periods of downtime in the factory and also compromising the useful life of the equipment. Maintenance can also happen on a scheduled basis, since there is a prediction of the occurrence of the failure.

Preventive maintenance

Normally, preventive maintenance is characterized when maintenance is carried out without failures and without urgency, since there is a periodic planning of what must be done in the equipment in order to avoid possible stops during the process and operation of the equipment, however this classification of maintenance tends to be characterized as cheap maintenance as it prevents plant shutdowns among other events such as replacement of parts without having time for budgets and quality analysis.[9]

Maintenance predictive

It is the most efficient maintenance of maintenance, because in this one, the conditions of equipment are evaluated through the collection of data and history of previous occurrences, so that the estimated time until the failure of the equipment can be predicted, allowing strategic planning and anticipation; maintenance, avoiding breakdowns and stoppages of the production line, thus reducing operating costs.[10]

Calibration

For the certification of the results obtained by a process, the methodology that such service is being performed must be certified, for this, the conditions of the instrument must be verified through calibration, since the value of the measurements of the instrument used is compared to a standard to record how close the measurement is to the actual value. The periodicity of calibration can be defined according to the criticality of the process and the frequency of its use, certain that using it too frequently can promote wear and tear and compromise the useful life of the instrument.[5]

Methodology

Introduction

The elaboration of the project on the closure system in pots was based on sampling for data analysis of the failures of this process.

In a company in the health area, the closing system in pots is used for control and accuracy of the packaging of its products, after closing the system is subjected to a vacuum chamber to verify the efficiency of closing the product packaging, to carrying out the test, the "Product packaging" sector has three employees to carry out the packaging and tests

The analysis consists of carrying out closure tests on products packaged in pots made of polypropylene material, and analyzing the entire process to verify the root cause of the leaks that the product has presented. The actions were taken based on the results obtained through the samples using quality tools, analyzes of indicators and statistics.

Variables

For the analysis of the variables, 3 tests were separated, because during the process that the lid of the pot is closed in the pot closing system, there are 3 molds with similar dimensions , however, the extracted data are intended to classify which mold has greater number of disapprovals can be "1", "2" or "3". The second data analysis is given by the torquemeter variables, since, to carry out the process, two units are available to perform the closing.

Sample

The data were extracted from the qualification table, the process carried out by the company's Quality Engineering department, the data comprise the period of the first 3 months of the year. For data collection, tests were carried out in empty pots and recorded in spreadsheets with the help of Excel, and thus the results obtained were separated individually by operators, molds and tachymeter, the results obtained are in reports for the conclusion of the qualification of the process.

Measuring instruments and techniques

All data were collected through tables, available at the Quality Engineering Department. The period from January to March 2023 was used for data collection, where data on process failures was obtained in this period.

Excel was used for data recording and better visualization and Power BI for plotting graphs based on data collected from Excel. Finally, after validating the data, generating results and graphs, Word was used to build a model of the new process flow, based on the scenario obtained and the respective actions taken to improve the process.

Procedures

He was appointed to collect and analyze the data, as well as monitor the process in real time to understand the operation and workflow of the jar closing stage. To perform the service, 3 employees responsible for closing the pots and the leak test were selected, 93 samples of 3 different types of pots were selected to submit them to the test, in addition, they have 2 different types of torquemeter, therefore, the study evaluating torquemeter 1 and torquemeter 2 and consequently obtained the number of disapprovals of each pot, containing variations linked to the labor of the operators of the sector and of the torquemeter.

Working hypothesis

Through the data collected, it is possible to raise important points for carrying out the work.

- Samples from jar 2 have 15% more leaks than the others during the leak test
- Number of times the operator makes the move to close the pot can compromise the final quality
- The manometer installed can compromise the reading because it does not allow a very accurate reading and the amount of vacuum applied can be greater than the established one, causing the lids of the pots to close.

Results

Obtaining the result of the work was divided into stages of data collection, analysis, meetings, action plan, elaboration of justifications and implementation of a flowchart, for this, samples were used for the case study.

Step I was designated as the starting point for data collection with the test samples. Some variables were defined at this stage, namely: the three batches of existing pots for closure, two torquemeters, the number of 93 samples in addition to the visual inspection method, as per Table I attached.

Through the information collected from the approvals and disapprovals on the tests performed on the samples, a a percentage comparison for the first critical analysis of the situation and better visualization of the possible sources of the problem presented by the pots leaking after closing.

Figures 1 and 2 show the number of samples that were approved and disapproved using two different types of torquemeters for the execution of the closing process of batches 1, 2 and 3.

In this test, there are a high number of approved packages, with the use of "torquimeter 1". Of the total of 93 samples, 96.73% correspond to the compliant ones, that is, they did not show leakage, being 33.3% for package 1, 33.3% for package 2 and 29.03% for package 3, respectively. During the test, only 4 packages of lot 3 leaked, corresponding to 4.30%.

In Figure 2, the data refer to the closing of the jars using "torquimeter 2".

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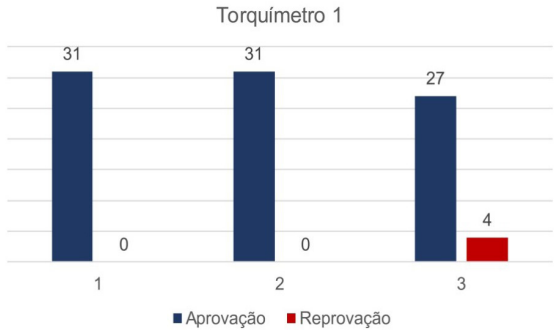

Figure 1 Torquemeter 1.

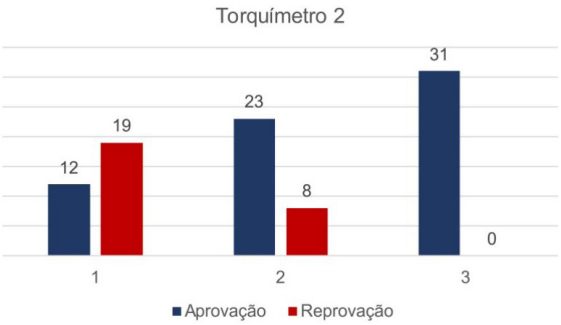

Figure 2 Torque wrench 2.

For batch 1, the non-conformities were accentuated, with 12 packages passing the test and 19 packages not approved, equivalent to 12.9% and 20.43% respectively. For lot 2, there are 23 packages approved, that is, they did not show leakage and 8 packages were disapproved, being 24.73% and 8.60%, in that order, for lot 3, the 31 packages are in agreement and, therefore corresponding to 33.33% of the total analyzed

Through the graphic demonstrations, a problem was found in torquemeter 2 with closing the pots of batch 1 and batch 2, with a higher number of failures. After identifying the problem, a brainstorming session was carried out with the sector's employees so that new information about leaks in closed pots could be collected and, therefore, enabling the elaboration of the Cause and Effect Diagram, as shown in Figure 3.

With the development of the diagram, the possible causes that cause failure in the pot closing system were identified. The prevalence of causes was observed in the work method, highlighting as points the lack of preventive maintenance, the uncontrolled use of temperature in the sealing process and the use of molds without appropriate measures for the storage of the valves. As for the raw material, the possible fragility of the pot's composition stands out, being inappropriate for the pot closing system. From this, one can assess the inefficiency of the methodology applied and the procedures performed, since deviations from good results are strictly linked to this step.

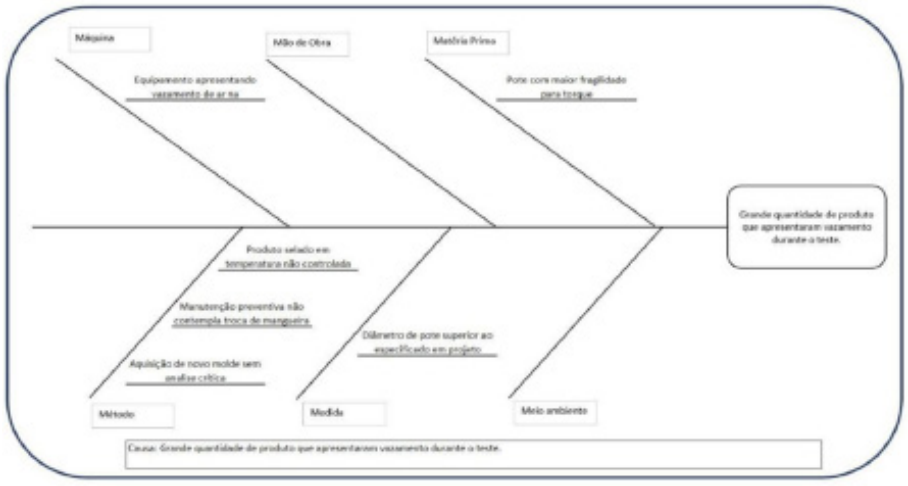

Figure 3 Ishikawa diagram.

Changing the new molds for making the pots was not a point of analysis by the engineering team, since it is not an emergency. However, it is worth considering that packaging with diameters outside the previously recommended specifications may cause difficulties in closing and thus result in their leakage.

Still in the methodology, the company's preventive maintenance does not include changing the hose, which is directly related to leaks in them and which was observed during the sampling process of the study. The step of sealing the products at an uncontrolled temperature can also be pointed out as a possible cause of deformation of the pots and thus, causing the product to leak.

Faced with the problems postulated in the diagram, a matrix was developed to analyze Severity, Urgency and Tendency for taking immediate measures or not on each one, as shown in Table 1.

Table 1 GUT matrix

Problem	Gravity	Urgency	Trend	GxUxT
Air leak in hose	3	4	1	12
Pot with greater fragility for torque	5	4	1	20
Uncontrolled temperature sealing	4	5	1	20
New molds without critical analysis	5	5	3	75
Pot with a diameter greater than the design specification	4	5	3	60

The acquisition of a new mold without critical analysis by the company's engineering sector was the most urgent degree to be dealt with. Correlated with this problem and also of high urgency, there is

the problem of pots with a diameter greater than that specified in the project. Both were rated and sent as priorities to be resolved by the responsible Engineer. The other problems will be resolved with less urgency and through the elaboration of plans, such as the elaboration of a preventive maintenance flowchart and the action plan.

Conclusion

Due to the large number of failures in the process of closing pots of biological cardiovascular valves, there was a need to mitigate the possible causes of problems for decision making. For this, conducted a survey and applied techniques to solve the problems found. The proposed specific objectives of identifying possible causes that impact and compromise the integrity of the packaging of biological cardiovascular valves and Propose solutions for the identified causes were accomplished and brought new perspectives for the elucidation of the causes of leaks from the packaging used in the company's routine and for the improvement in all internal operating procedures of the company.

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Conflicts of interest

The authors declare that they have no competing interests.

Annexes

Table 1 Leakage test carried out in a Polypropylene pot - Visual inspection test

Sample	Batches of test samples	Torquemeter result 1	Result torquemeter 2
AM 1	1	Approved	failed
AM 2	1	Approved	failed
AM 3	1	Approved	Approved
AM 4	1	Approved	Approved
AM 5	1	Approved	failed
AM 6	1	Approved	failed
am 7	1	Approved	failed
am 8	1	Approved	failed
AM 9	1	Approved	Approved
am 10	1	Approved	failed
AM 11	1	Approved	failed
AM 12	1	Approved	failed
AM 13	1	Approved	failed
AM 14	1	Approved	failed
am 15	1	Approved	Approved
AM 16	1	Approved	Approved
AM 17	1	Approved	failed
AM 18	1	Approved	Approved
AM 19	1	Approved	Approved
am 20	1	Approved	failed
AM 21	1	Approved	failed
AM 22	1	Approved	Approved
AM 23	1	Approved	Approved
AM 24	1	Approved	failed
am 25	1	Approved	failed
am 26	1	Approved	failed
AM 27	1	Approved	failed
AM 28	1	Approved	failed
AM 29	1	Approved	Approved
am 30	1	Approved	Approved
AM 31	1	Approved	Approved
AM 32	two	Approved	Approved
AM 33	two	Approved	Approved
AM 34	two	Approved	failed
am 35	two	Approved	Approved
AM 36	two	Approved	Approved
AM 37	two	Approved	Approved
AM 38	two	Approved	failed
AM 39	two	Approved	Approved

Table I Continued...

Sample	Batches of test samples	Torquemeter result 1	Result torquemeter 2
AM 40	two	Approved	Approved
AM 41	two	Approved	Approved
AM 42	two	Approved	Approved
AM 43	two	Approved	failed
AM 44	two	Approved	Approved
AM 45	two	Approved	Approved
AM 46	two	Approved	Approved
AM 47	two	Approved	failed
AM 48	two	Approved	failed
AM 49	two	Approved	Approved
am 50	two	Approved	Approved
AM 51	two	Approved	Approved
AM 52	two	Approved	failed
AM 53	two	Approved	Approved
AM 54	two	Approved	failed
AM 55	two	Approved	failed
AM 56	two	Approved	Approved
AM 57	two	Approved	Approved
AM 58	two	Approved	Approved
AM 59	two	Approved	Approved
AM 60	two	Approved	Approved
AM 61	two	Approved	Approved
AM 62	two	Approved	Approved
AM 63	3	Approved	Approved
AM 64	3	Approved	Approved
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AM 86	3	Approved	Approved
AM 87	3	failed	Approved
AM 88	3	Approved	Approved
AM 89	3	Approved	Approved
AM 90	3	failed	Approved
AM 91	3	failed	Approved
AM 92	3	Approved	Approved
AM 93	3	failed	Approved

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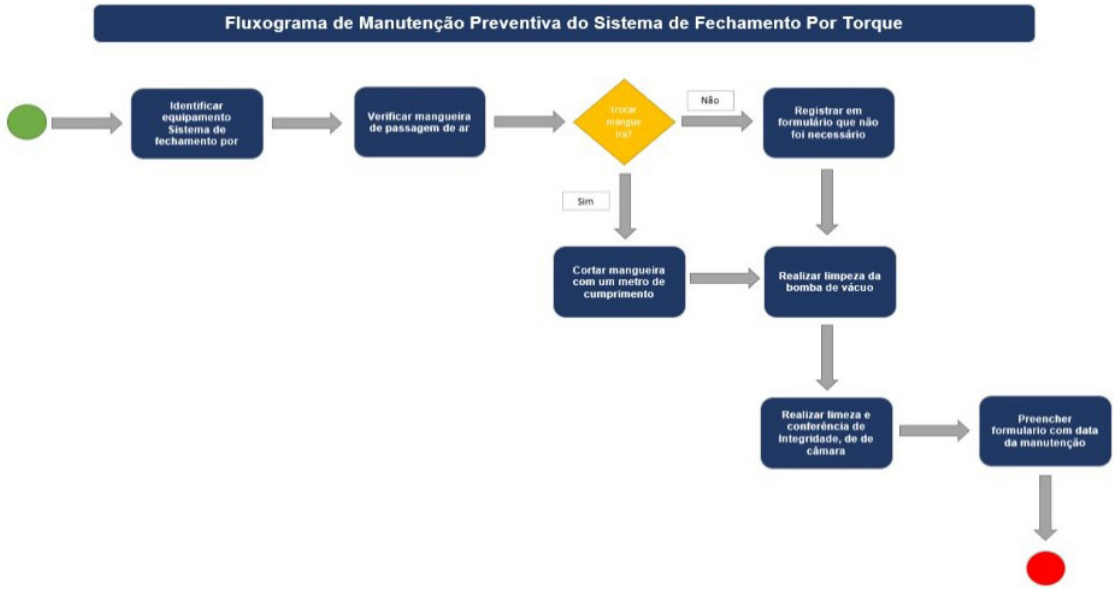

Attachment II Preventive maintenance flowchart of the pot closing system

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