Using the attribute control chart to monitor a chemical manufacturing process

Usando o gráfico de controle de atributos para monitorar um processo de fabricação de produtos químicos

Bruno Mendes de Jesus¹
Isabela Salete Mesquita dos Santos²
João Vitor Marinho de Albernaz³
Ronald Palandi Cardoso⁴
Nilo Antonio de Souza Sampaio⁵

Abstract

The chemical and pharmaceutical industries have quality as a prerequisite for the smooth running of their processes. Quality monitoring in this type of industrial activity is carried out using attribute control charts, among others. The aim of this article is to show a case study carried out in a company in the south of the state of Rio de Janeiro which used this type of control chart, more specifically the NP control chart, to monitor an antibiotic manufacturing process. The results showed the need for some adjustments and management actions will be

¹ Graduado em Engenharia de Produção, Universidade do Estado do Rio de Janeiro, Rod. Pres. Dutra, km 298, Polo Industrial, Resende - RJ, CEP: 27537-000. E-mail: brunomendesdejesus@outlook.com
Orcid: https://orcid.org/0000-0003-2277-7243

² Graduanda em Engenharia de Produção, Universidade do Estado do Rio de Janeiro, Rod. Pres. Dutra, km 298, Polo Industrial, Resende - RJ, CEP: 27537-000. E-mail: isabela.santos@discentes.fat.uerj.br
Orcid: https://orcid.org/0009-0008-3779-7179

³ Graduando em Engenharia de Produção, Universidade do Estado do Rio de Janeiro, Rod. Pres. Dutra, km 298, Polo Industrial, Resende - RJ, CEP: 27537-000. E-mail: jvmalbernaz@gmail.com
Orcid: https://orcid.org/0009-0000-4747-5757

⁴ Graduando em Engenharia Mecânica, Universidade do Estado do Rio de Janeiro, Rod. Pres. Dutra, km 298, Polo Industrial, Resende - RJ, CEP: 27537-000. E-mail: ronaldpalandi0805@gmail.com
Orcid: https://orcid.org/0000-0002-7335-2280

⁵ Doutor em Engenharia Mecânica, Universidade do Estado do Rio de Janeiro, Rod. Pres. Dutra, km 298, Polo Industrial, Resende - RJ, CEP: 27537-000. E-mail: nilo.samp@terra.com.br
Orcid: https://orcid.org/0000-0002-6168-785X
taken to improve the process.

**Keywords:** Statistical Software. Control Charts by Attributes. NP Chart. Drug Manufacturing Process.

**Resumo**
As indústrias química e farmacêutica têm a qualidade como pré-requisito para o bom funcionamento de seus processos. O monitoramento de qualidade nesse tipo de atividade industrial é feito por meio de tabelas de controle de atributos, entre outras. O objetivo deste artigo é mostrar um estudo de caso realizado em uma empresa do sul do Rio de Janeiro que utilizou esse tipo de gráfico de controle, mais especificamente o gráfico de controle NP, para monitorar um processo de fabricação de antibióticos. Os resultados mostraram a necessidade de alguns ajustes e ações de gerenciamento serão tomadas para melhorar o processo.

**Keywords:** Software Estatístico. Gráficos de Controle por Atributos. Gráfico NP. Processo de Fabricação de Medicamentos.

**Introduction**

The launch of a new product and/or process usually involves working with a large number of variables. Conscientious planning of the experiments that must be used to manipulate these variables and arrive at the desired answers is indispensable if reliable results are to be obtained and if consistent statistical analyses are to be carried out. In this context, it is no longer possible to develop products and processes through trial and error procedures, as was done at the beginning of the last century. The strong competition, the diffusion of technological processes as well as the responsibility of the scientific community now make such procedures unfeasible. The optimization of processes and products requires more than ever a robust statistical study. Control charts are used for the purpose of detecting assignable causes that affect process stability (A. F. B. Costa & Rahim, 2004; M. C. B. Costa, 2011; Sales et al., 2021).

The main objectives of using SPC (Statistical Process Control) are to get to know the production process in order to assess quality, prevent defects, avoid waste, eliminate anything that compromises efficiency and reduce costs. The characteristics of using SPC within a company's production processes are: rapid reporting of defects and immediate corrective action; any information is relevant (working with sample results); defect prevention and the
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Quality is a challenge and needs to be implemented for industrial processes to occur with sustainability to have a real impact on reducing and consequently eliminating environmental damage. Statistics is an essential tool and has been used in several applications and in all areas of human knowledge to improve processes, as decision making and to ensure that the environment is preserved (Cardoso, R.P; Sampaio, N.A.S; Reis, J.S.M; Silva, D.E.W; Barros, 2023; Cardoso et al., 2023a, 2023b; H. D. O. G. da Silva et al., 2021; Fonseca, D; Correa, M.P.O; Santos, R.R; Cardoso, R.P; Reis, J.S.M; Sampaio, 2023; Gomes et al., 2022; Felipe C. Mazza et al., 2023; Reis, Espuny, Cardoso, Sampaio, de Barros, et al., 2022; Reis, Cardoso, et al., 2023; Rezende et al., 2023; Rubert et al., 2023; A. C. P. da Silva et al., 2023; Yamada et al., 2023).

The control chart by attributes is simpler, as it only consists of visually identifying whether the process is satisfactory or not. Therefore, in order to use the control chart by attributes, we must separate the data that will be analyzed into data referring to defects or defective. The product may have defects, but it is only considered defective if the customer does not tolerate such defects. In this way, control charts by attributes are recommended for use when you want to control the number or percentage of defective items in a given total of items. The control chart by attribute np has the characteristic of a binominal distribution and its approach is to identify the number of items with defects. Although Attribute Control Charts were created to monitor processes, today their application is much broader, also covering the service area. Once the special causes have been diagnosed and eliminated, an np chart can be drawn up for each aspect of a process or service (Antonio Fernando Branco Costa et al., 2016).

In view of the above, the research question that guided this work is: to visualize a practical application of Attribute Control Charts. The aim of this work is to show this application, but specifically to show the application of the NP Chart, which has great power to carry out statistical process control. Initially, the article will cover the concepts of Attribute Control Charts, more specifically NP Charts and the case study in question. Next, the results and discussions of the proposed objective will be presented. Finally, the conclusion will be
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Theoretical Referential

Today, statistics has made a significant contribution to the decision-making process because much of what is produced is based on quantitative methods, and statistics is one such area. In the information and knowledge age, statistics uses mathematics to support business professionals, government and researchers (Cardoso et al., 2023b; Fonseca, D;Correa, M.P.O;Santos, R.R;Cardoso, R.P;Reis, J.S.M;Sampaio, 2023; Junior et al., 2023; Leiroz et al., 2023; Felipe Cury Mazza et al., 2022; Moura et al., 2023; Oliveira et al., 2023; Reis, Espuny, Cardoso, Sampaio, Barros, et al., 2022; Reis, Neto, et al., 2023).

To analyze the results of the control chart, we need to review the definitions of common causes and special causes. Thus, all variations that occur between the SCL and the SCL are considered common cause variations, as long as they are random. Therefore, all variations that occur above the LSC or below the LIC are considered special cause variations and must be resolved. However, if there is any pattern between the variations (even if they are within the limits of the SCL and SIL), it means that the process is not compliant and that there are special causes. (Montgomery, 2009).

Common causes are those that are commonplace and inherent to the process, which are relatively predictable and expected. Special causes are those that are unknown and can cause major changes in the process. There are several ways of detecting special causes:

- **Points outside the control limit:**
  Points within the upper and lower control limits show that the process has suffered variations from common causes. In this sense, if one or more points cross these lines, the variations have occurred due to special causes. In this case, the manager should pay attention to this factor.

- **Periodicity:**
  If the graph shows a variation of values up and down, with a frequency in similar intervals, it means that some point in the process needs to be adjusted.

- **Sequence:**
  When seven or more points appear on one side of the average line (above or below), it is an alert to observe that point and then look for some potential improvement.

- **Trend:**

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Occurs when seven or more points appear continuously, up or down, like a trend line. It is therefore possible that a particular cause is at work at this stage of the process and needs to be assessed.

- **Approaching the control limits:**

  If two or more lines are very close to the upper or lower control lines, this is a sign of instability. Thus, the closer the points are to the average line, the more stable the process will be (Chen et al., 2014).

  The NP chart (Number of Non-Conforming Units) requires the sample sizes to be equal and to remain constant. It is based on the number of non-conforming items and is used when the actual number is more expressive and easier to record. The parameters for calculating the control limits for the defective proportion chart are: individual points, Center Line (average defective proportion - average of proportions), Upper Control Limit and Lower Control Limit. If the lower control limit is less than zero, then it should be $= 0$. If the upper control limit is greater than 1, it must be equal to 1. This is because there is no way that the number of defective parts can be less than zero, or greater than the sample size (Gadre & Rattihalli, 2005; Khoo, 2004; Leiva et al., 2015).

**Research Method**

This paper can be classified as an applied research, as it aims to provide improvements in the current literature, with normative empirical objectives, aiming to develop policies and strategies that will improve the current condition (Stüpp et al., 2015). The approach of the problem is quantitative, as the research method of modeling and simulation. The research steps were carried out following the sequence shown in Figure.1.

- **Step 1:** The experimental data was selected from a chemical company in the south of the state of Rio de Janeiro. This choice was based on the fact that the company had a process that could be monitored using a control chart by attributes.
- **Step 2:** Making a control chart by attributes (Np chart) for the manufacture of a certain type of antibiotic using Minitab 19 software.
- **Step 3:** The interpretation of the results was carried out.
- **Step 4:** The situation of the problem was analyzed and possible decision making based on the results obtained.
- **Step 5:** The conclusions presented at the end of this article are drawn from the results obtained in the previous steps.
3.1 Case Study

A quality engineer assesses whether the process used to manufacture a certain type of antibiotic is under control. The engineer tests 500 products per hour in three 8-hour shifts and records the number of products that fail the company's quality test.

<table>
<thead>
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<th>ID</th>
<th>Defects</th>
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<tr>
<td>101</td>
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<tr>
<td>102</td>
<td>8</td>
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<tr>
<td>103</td>
<td>13</td>
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<td>104</td>
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<td>114</td>
<td>8</td>
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<td>115</td>
<td>13</td>
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Table 1. Number of defects in the 24 hours monitored

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<td>123</td>
<td>3</td>
</tr>
<tr>
<td>124</td>
<td>6</td>
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Source: Authors (2023).

Results And Discussions

4.1 Case Study

Figure 2 shows that one point is out of control on the NP chart (the test failed at point 16). There is probably an attributable variation, because when there are only random causes the process is under Statistical Control. One of the reasons for considering the process out of control is a point above the Upper Control Limit or below the Lower Control Limit. The engineer concludes that the process is not stable and must be improved.

Figure 2. Control chart for Attributes (NP) for the Chemical Process using Minitab 19 software
Source: Authors (2023).
Conclusion

The aim of this study was to show the importance of using Attribute Control Charts for quality control in industrial processes. Processes with points outside the control limits need to be studied and analyzed to find the special causes. A suggestion for future work would be to use other types of control charts in chemical companies to improve the production process.

References


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