VAC_19 - Continued Process Verification for COVID-19 Vaccine Formulation and Packaging (recombinant)

Paulo Vitor Carvalho da Silva[1]; Pedro Guilherme Muniz Correia[1]; Daiane Martins Grugel[1]; Victor de Oliveira Silva Ferreira[1]; Rayane Natashe Gonçalves[1].
[1]Fiocruz/Bio-Manguinhos.

Introduction: According to IN 47 (2019), process validation is a documented evidence that a process, operated within pre-established parameters, can perform its functions effectively and reproducibly to produce a drug within its pre-established specifications and quality attributes. In addition, ongoing process verification is documentary evidence that the process is kept in control during commercial production.

Objective: The objective of this project is to provide evidence that the manufacturing process of the COVID-19 (recombinant) vaccine is under a state of control during the first year of commercial production – 3a phase of the product lifecycle.

Methodology: Critical and key parameters and attributes are selected to be monitored and evaluated in a specific time interval for decision making. Descriptive statistics, capacity index, normality tests and preparation of control charts are performed. Three criteria were considered to analyze whether the process is under control, on alert or out of control: analysis of the index of process performance (Ppk), presence/absence of excursions (results outside 3-sigma limits) and presence/absence of displacements/ trends that are not part of the normal variability of the process. If the process is in control, the parameter/attribute is removed from the next stage or monitoring period of the CPV; if the process is on alert, the parameter/attribute is kept in the next stage or monitoring period; if the process is out of control, a deviation is opened to assess possible causes and risks to the process.

Results: Considering the established criteria, from the statistical evaluation, it is possible to identify and evaluate the status of the parameters. All variables will remain under quarterly monitoring for another year as part of 3b phase of this CPV.

Conclusion: The data collected for the year 2021 of production of the covid-19 vaccine (recombinant) were evaluated and considered in sufficient quantity for the evaluation of 3a phase of the CPV even in a period of less than 1 year of production, as 391 batches were produced. All variables evaluated are under control or on alert. As this is a new product, it is understood that some variations may be inherent to the process and therefore, all will continue to be evaluated on a quarterly basis until completing the period of one more year for the evaluation of phase 3b of the CPV.

Keywords: CPV; Control charts; Covid-19