September, 2021

APPROVAL OF THE GUIDE FOR TECHNOLOGY TRANSFER OF PHARMACEUTICAL PRODUCTION PROCESSES

The National Drug Agency Department of the Institute of Public Health, through exempt resolution No. 01746 of September 6, 2021, approved a guide to provide guidelines regarding the technological transfer of pharmaceutical production processes, necessary to obtain the authorization of a new manufacturer of a medicament, maintaining the previously authorized one.

The guide contains mainly the following:

I. *Definition of transfer of the manufacturing process of a pharmaceutical product*

According to the World Health Organization, being understood as "a logical procedure that controls the transfer of any process together with its documentation and professional experience between development and manufacturing or between manufacturing sites", and indicating that the process ends with the execution of the validation of the same, having to comply with certain technical levels:

1. Validation of critical support systems.
2. Validation of analytical methodologies.
3. Validation of cleaning.
4. Consistency with documentation.
5. Risk analysis and sampling plan.
6. Compliance with acceptance criteria.
7. Intra lot statistics; and
8. Inter lot statistics.

In addition, it refers to the identification and control of risks within the transfer process, noting that the ICH Q9 "Quality Risk Management" and/or the WHO annex "Annex 2 WHO Guidelines on Quality Risk Management, WHO Technical Report series, No. 981, 2013" should be used as references and attaches a diagram that shows a quality risk management process.

II. *Requirements and background information*

Required to carry out an adequate technology transfer of a pharmaceutical production process.

III. *The scope of the guide*

Extending to pharmaceutical products that require accrediting the transfer from a pilot plant to an industrial scale manufacturing plant and products for which it is required to accredit the transfer of the production process to a new plant, either by a change or inclusion of a new manufacturing site; and having as legal framework the Supreme Decree No. 54 of 2019, which modified the Supreme Decree No. 3 of 2010.

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IV. *The technology transfer process*

Counting with sequential stages that include:

1. Preliminary evaluation and preparation of the pharmaceutical laboratory of origin to transfer a productive process.
2. Development and approval of the technology transfer protocol that establishes the technical aspects, tests, analysis methods, acceptance criteria and considers statistical tools to analyze the results.
3. Validation of the process in the receiving unit.
4. Technology transfer report.

It further indicates the **elements and requirements to be considered to develop a plan** to support the transfer, being these:

1. CCharacteristics of the origin unit (OU) and the receiving unit (RU), and the information of the OU must be compared in order to be reproduced routinely in the same way in the RU. In addition, both units should cover the following aspects of the transfer: organization and management of the facility/process; product development and production information; evaluation of facilities and equipment; transfer of the analytical methods involved; and records of personnel training and skills evaluation.
2. Documentation with scope of transfer, process development, production records, and quality system characteristics.
3. Personnel records.
4. Description of the analytical methods for the control of excipients, characterization of the active ingredients (API), methodologies for in-process controls and for the control of the finished product.
5. Information on the manufacturers of APs.

V. *Background information to successfully accredit the transfer*

Which must be formalized through a protocol and a report, which must have the following elements:

1. Scope of the transfer.
2. Certificate of compliance with the Good Manufacturing Practices (GMP) of the RU, issued by the competent authority.
3. Comparison between the OU and the RU including comparisons of flow chart, equipment, equipment qualification status, among others.
4. Validation of the process in the RU.
5. Risk analysis.
6. Results and Conclusions.

The complete document is available in the following link.