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Short communication

Batch certification document Certificate of Analysis / Certificate of Compliance

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Introduction

Batches of medicinal products should only be released for sale or supply to the market after certification by a Qualified Person (QP). Until a batch is certified, it should remain at the site of manufacture or be shipped under quarantine to another site approved by the relevant Competent Authority.

According to Annex 16, Appendix 1 and Appendix 2, different certificates are initiated to comply with the batch's EU certification.

The ultimate responsibility for the performance of a medicinal product over its lifetime, safety, quality and efficacy lies with the marketing authorization holder (MAH).

However, the QP is responsible for ensuring that each batch has been manufactured and checked in compliance with laws in force in the Member State where certification takes place, in accordance with the marketing authorization (MA) requirements and with Good Manufacturing Practice (GMP).

The process of batch release comprises:

1. Chek of the manufacture and testing of the batch in accordance with defined release procedures.

2. The certification of the finished product batch performed by a QP signifying that the batch complies with GMP and its MA's requirements. This represents the quality release of the batch.

3. The transfer to retail stock and export of the finished batch of products should consider the QP's certification.

If this transfer is performed at a site other than that where certification takes place, then the arrangement should be documented in a written agreement between the site in accordance with Good Manufacturing Practice (GMP) and marketing authorization.

This is to certify that all the manufacturing and packaging processes of this Batch of Products have been carried out in full compliance with the cGMP requirements and with the requirements of the Marketing Authorisation and the relevant SOPs.

Materials

Every batch produced according to the GMP should issue some form of certification of analysis done as required.

Batch certification can have qualitative and quantitative research on one/ two, or more active parts only to prove that the product produced complies with the release specification and has been manufactured as established by the Marketing authorization in that country.

Certificate of Analysis (CoA) should detail the specification of the product and all analytical methods used to reference the result obtained with analysis and a final statement that says that manufacturing, packaging and transport are done according to GMP and Good distribution practice (GDP).

Batches of medicinal products intended for the EU after release by a QP from a Non-Eu country must also be certified by a QP from EU territory. For these cases, it is issued only a Certificate of Compliance (CoC).

Certificates also are issued for the drugs from contract production, i.e., for those produced by a partner company. Still, they are released, and the QP listed in the marketing authorization is responsible for their quality.

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Discussion

The certificate provides information on the parameters that are produced, the results obtained and finally contains the final statement from the qualified person confirming that the production, packaging and transport of the batch of medicine are in accordance with the GMP and GDP.

According to Appendix II, an essential part of the certificate is the name of the drug, the strength, the pharmaceutical dosage form and the size of the package, which should be identical to those of the drug packaging, drug series, country/countries for which the drug series is intended, name and the signature of the qualified person as well as the date of signing. All records should be complete and noted.

All in-process and quality control results are checked and within specification limit, which are pointed out in the validated computer program over software SAP.

Results are notated in matrix characteristics created and can be changed only by the control laboratory. Notification should be punctual and followed by guidelines and Standard Operational Procedure (the policy for decimal numbers and units of measure).

Every matrix characteristic is carefully selected and introduced in matrix instruction for that specific product. After all, the data are completed, we have an electronic generation of the results, which is the most accurate, punctual method of doing CoA or CoC.

Every CoA is viewed by a qualified person and signed with electronic signature. Results from electronic generation of the CoA / CoC were especially beneficial after COVID -19 and realizing the simplicity.

Conclusion

The introduction of electronic generation of CoC / CoA shortens the time of preparation of certificates, which can pay more attention to quality assurance of the drug product, in addition to obtaining more reliable certificates, as it reduces the possibility of a technical error in the preparation of the same.

The accuracy of the data is higher because it works with validated computer software SAP. Certificates are attached in the SAP system, available to both sites.

Further, electronically signed certificates are obtained, facilitating work, especially during pandemics.

As an example of the time saved with the introduction of this improvement, before the opening of electronic certificates on an annual basis, the production of certificates was spent seven months, i.e., 134 working days, while generating electronic certificates is spent one month in their preparation or 18 working days.

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