

# **EU Annex 11 Guide To Computer Validation Compliance For The Worldwide Health Agency GMP By Orlando Lopez**

**By Orlando Lopez**

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<http://www.learnaboutgmp.com/book/an-easy-to-understand-guide-to-annex-11-17>

By Sion Wyn, ISPE Technical Consultant. January 2011. The EC has announced a new revision of EU GMP Annex 11 Computerised Systems, and consequential amendment of EU

<http://www.ispe.org/news/2011/revision-of-eu-annex-11-chapter-4>

Revised EU Annex 11 Computerized Systems, Applying the GAMP Good Practice Guide Electronic Records and Signatures Principles (T08) - Also Available Online;

<http://www.ispe.org/training/gamp5-revisedannex11>

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<http://www.spectroscopyonline.com/computer-validation-do-all-roads-lead-annex-11?rel=canonical>

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Orlando Lopez is the author of Qualification of SCADA Systems (4.00 avg rating, 2 ratings, 0 reviews, published 2002), An Easy to Understand Guide to 21

[http://www.goodreads.com/author/show/3123472.Orlando\\_Lopez](http://www.goodreads.com/author/show/3123472.Orlando_Lopez)

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the responsibility and accountability for GMP compliance remains EU Annex 11 guide to Computer Validation Compliance for the Worldwide Health Agency GMP,

<http://www.scientificcomputing.com/printpdf/articles/2014/10/cloud-meets-gmp-regulations-%E2%80%93-part-1-applicable-regulations>

The Rules Governing Medicinal Products in the European Union amendments are also proposed for Chapter 4 of the GMP Guide. Annex 11 Final 0910

[http://ec.europa.eu/health/files/eudralex/vol-4/annex11\\_01-2011\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-4/annex11_01-2011_en.pdf)

In the following piece, we attempt to give you an overview of some of the key points that you need to understand when complying Eudralex Annex 11.

<http://blog.montrium.com/blog/the-beginners-guide-to-eudralex-vol-4-annex-11>

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