



EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP

By Orlando Lopez, Markus Roemer

Download now

Read Online ➔

EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer

Good Manufacturing Practice (GMP) ensures medicinal products are produced consistently and controlled to the quality standards appropriate for their intended use and as required by product specifications or marketing authorization. Annex 11 details the European Medicines Agency (EMA) GMP requirements for computer systems.

The purpose of Annex 11 is to provide the EMA healthcare industry with consistent criteria for effective implementation, control, and use of computer systems. **EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP** supplies practical information to facilitate compliance with computer system GMP requirements, while highlighting and integrating the Annex 11 guidelines into the computer compliance program.

The ideas presented in this book are based on the author's 25 years of experience with computer validation in the healthcare industry with various computer systems development, maintenance, and quality functions. The book details a practical approach to increase efficiency and to ensure that software development and maintenance are achieved correctly.

Examining the implementation of the computer systems validation entirely based on EU Annex 11, the book includes examples from laboratory, clinical, and manufacturing computer systems. It also discusses electronic record integrity associated with stored information.

 [Download EU Annex 11 Guide to Computer Validation Compliance...pdf](#)

 [Read Online EU Annex 11 Guide to Computer Validation Compliance](#)

[...pdf](#)

EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP

By Orlando Lopez, Markus Roemer

EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer

Good Manufacturing Practice (GMP) ensures medicinal products are produced consistently and controlled to the quality standards appropriate for their intended use and as required by product specifications or marketing authorization. Annex 11 details the European Medicines Agency (EMA) GMP requirements for computer systems.

The purpose of Annex 11 is to provide the EMA healthcare industry with consistent criteria for effective implementation, control, and use of computer systems. **EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP** supplies practical information to facilitate compliance with computer system GMP requirements, while highlighting and integrating the Annex 11 guidelines into the computer compliance program.

The ideas presented in this book are based on the author's 25 years of experience with computer validation in the healthcare industry with various computer systems development, maintenance, and quality functions. The book details a practical approach to increase efficiency and to ensure that software development and maintenance are achieved correctly.

Examining the implementation of the computer systems validation entirely based on EU Annex 11, the book includes examples from laboratory, clinical, and manufacturing computer systems. It also discusses electronic record integrity associated with stored information.

EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer **Bibliography**

- Sales Rank: #2348493 in Books
- Published on: 2015-04-06
- Original language: English
- Number of items: 1
- Dimensions: 1.00" h x 7.10" w x 10.10" l, .0 pounds
- Binding: Hardcover
- 379 pages

 [Download EU Annex 11 Guide to Computer Validation Complianc ...pdf](#)

 [Read Online EU Annex 11 Guide to Computer Validation Complia ...pdf](#)

Download and Read Free Online EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer

Editorial Review

About the Author

Orlando López is the SME for the GAMP Data Integrity SIG. He has 25 years of experience in worldwide pharmaceutical experience with relevant work in computer systems regulatory requirements including US, EU, Australian, Japanese, WHO, PIC/S, and ICH regulations and guidance. His special interest is the GMP compliance issues applicable to computer systems.

He has experience with direct participation in FDA agency remedial action plans, regulatory inspections, response activities, and consent decree remediation-related verifications. He is the author of two other books: *21 CFR Part 11?A Complete Guide to International Compliance*, Taylor & Francis/CRC Press, 2004, and *Computer Infrastructure Qualification for FDA Regulated Industries*, Davis Healthcare International Publishing, 2006.

Users Review

From reader reviews:

Lucille Chenier:

The book EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP gives you the sense of being enjoy for your spare time. You can use to make your capable much more increase. Book can being your best friend when you getting stress or having big problem along with your subject. If you can make examining a book EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP to become your habit, you can get a lot more advantages, like add your personal capable, increase your knowledge about some or all subjects. You could know everything if you like open and read a publication EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP. Kinds of book are several. It means that, science publication or encyclopedia or other people. So , how do you think about this guide?

Michelle Oquinn:

Information is provisions for those to get better life, information nowadays can get by anyone on everywhere. The information can be a knowledge or any news even a huge concern. What people must be consider if those information which is inside former life are hard to be find than now is taking seriously which one works to believe or which one the resource are convinced. If you get the unstable resource then you obtain it as your main information it will have huge disadvantage for you. All of those possibilities will not happen with you if you take EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP as your daily resource information.

Nathaniel Mitchell:

Is it a person who having spare time after that spend it whole day by simply watching television programs or just telling lies on the bed? Do you need something new? This EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP can be the reply, oh how comes? A fresh book you know. You are so out of date, spending your time by reading in this new era is common not a geek activity. So what these textbooks have than the others?

Maria Peterson:

What is your hobby? Have you heard that question when you got learners? We believe that that problem was given by teacher with their students. Many kinds of hobby, Every person has different hobby. And you also know that little person like reading or as examining become their hobby. You should know that reading is very important and also book as to be the factor. Book is important thing to incorporate you knowledge, except your current teacher or lecturer. You get good news or update in relation to something by book. Amount types of books that can you decide to try be your object. One of them are these claims EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP.

Download and Read Online EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer #4TKUIZCG58D

Read EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer for online ebook

EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer Free PDF d0wnl0ad, audio books, books to read, good books to read, cheap books, good books, online books, books online, book reviews epub, read books online, books to read online, online library, greatbooks to read, PDF best books to read, top books to read EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer books to read online.

Online EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer ebook PDF download

EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer Doc

EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer Mobipocket

EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer EPub

4TKUIZCG58D: EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP By Orlando Lopez, Markus Roemer