

## Presentation "Risk-based Approach" - Applied to Automation Systems

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### Listado Portales en Internet con Datos de Referencia

Dirección del Portal	Descripción
<a href="http://www.fda.gov/ora/Inspect_ref/igs/csd.html">http://www.fda.gov/ora/Inspect_ref/igs/csd.html</a>	Guide to Inspection of Computerized Systems in Drug Processing, Reference Material and Training Aids for Investigators, February 1983
<a href="http://www.fda.gov/ora/compliance_ref/cpg/cp_gdrg/cpg425-100.htm">http://www.fda.gov/ora/compliance_ref/cpg/cp_gdrg/cpg425-100.htm</a>	CPG 7132a.11: Computer Drug Processing; cGMP Applicability to Hardware and Software, 1987
<a href="http://www.fda.gov/cdrh/comp/guidance/938.html">http://www.fda.gov/cdrh/comp/guidance/938.html</a>	General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002
<a href="http://www.fda.gov/oc/guidance/gmp.html">http://www.fda.gov/oc/guidance/gmp.html</a>	Pharmaceutical CGMP's for the 21 <sup>st</sup> Century: A Risk Based Approach, August 2002
<a href="http://www.fda.gov/Cder/guidance/5667fnl.htm">http://www.fda.gov/Cder/guidance/5667fnl.htm</a>	Final Guidance for Industry: Part 11, Electronic Records; Electronic Signatures — Scope and Application, August 2003
<a href="http://www.fda.gov/Cder/gmp/gmp2004/GMP_finalreport2004.htm">http://www.fda.gov/Cder/gmp/gmp2004/GMP_finalreport2004.htm</a>	Pharmaceutical CGMPs For the 21 <sup>st</sup> Century - Risk Based Approach – Final Report, September 2004
<a href="http://www.fda.gov/CDER/guidance/7153fnl.htm">http://www.fda.gov/CDER/guidance/7153fnl.htm</a>	ICH - Guidance For Industry – Q9 Quality Risk Management, June 2006
<a href="http://www.ispe.org/galleries/reg-new-gallery/Risk-Based_Approach_to_21_CFR_Part_11.pdf#search=%22ISPE%20Risk%20Based%20Approach%22">http://www.ispe.org/galleries/reg-new-gallery/Risk-Based_Approach_to_21_CFR_Part_11.pdf#search=%22ISPE%20Risk%20Based%20Approach%22</a>	ISPE FDA Risk Based Approach to 21 CFR Part 11 (2002)
<a href="http://www.ispe.org/Template.cfm?Section=Regulations&amp;Template=/TaggedPage/TaggedPageDisplay.cfm&amp;TPLID=12&amp;ContentID=5236">http://www.ispe.org/Template.cfm?Section=Regulations&amp;Template=/TaggedPage/TaggedPageDisplay.cfm&amp;TPLID=12&amp;ContentID=5236</a>	ISPE Part 11 White Paper "Risk-Based Approach to 21 CFR Part 11" (January 2003)
<a href="http://www.ispe.org/cs/baseline_guides">http://www.ispe.org/cs/baseline_guides</a>	Baseline® Pharmaceutical Engineering Guides for New and Renovated Facilities, Volume 5: Commissioning and Qualification (March 2001)
<a href="http://webstore.ansi.org/RecordDetail.aspx?sku=ASTM+E2500-07">http://webstore.ansi.org/RecordDetail.aspx?sku=ASTM+E2500-07</a>	ASTM E2500 – "A Standard Guide for Specification, Design and Verification for Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment" (May 2007)