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GAMP RECORDS DATA INTEGRITY ISPE
PDF - Search results, GAMP® Good
Practice Guide GxP Compliant Laboratory
Computerized Systems (2nd edition) Tom
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Benelux 19 November 2013, Legacy
Systems ©Copyright ISPE 2003
NOVEMBER/DECEMBER 2003
PHARMACEUTICAL ENGINEERING 1
GAMP Good Practice Guide: The Validation
of Legacy Systems This Guide ...,
CLASS-Agent offers total data management
of all laboratory instruments from
chromatographs to balances. CLASS-Agent
complies requirements of the FDA 21 CFR
Part 11 (Electronic Records, Electronic
Signatures)., Objectives. This is why you
should attend this course: You will
systematically be introduced to the principles
and methods of the validation of
computerised systems (according to
GAMP®), Guidance for Industry 1 Part 11,
Electronic Records; Electronic Signatures -
Scope and Application. Contains Nonbinding
Recommendations. This guidance

represents the Food and Drug
Administration's (FDA's) current thinking on
this topic., PharmOut white paper: Computer
System Validation PharmOut Pty Ltd, ABN:
85 117 673 766, Unit 10, 24 Lakeside Drive,
Burwood East, Victoria 3151., 21 CFR Part
11 Compliance Package. Comply with FDA's
Ongoing Part 11 Inspection Practices - With
two audio seminars and free on-line updates
- July 2016, A focus on patient safety,
product quality and data integrity; A
science-based quality risk management
system as part of the quality lifecycle;
Reportable item and process-based
traceability throughout the lifecycle, EU
Annex11 US FDA " 211, 820, 11; other
guidelines Orlando López " 11-MAY-2011
www.computer-systems-validation.com 2
References Concept Old Annex 11,
Background. A major consequence of the
Barr Ruling in 1993 was the significantly
greater emphasis FDA inspections placed on
the management and performance of quality
control laboratories particularly the handling
of Out of Specification results., Board of
Supervisors. The Milwaukee County Board of
Supervisors is a body of 18 legislative

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