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~~Key Principles of GAMP®5 for
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Basic Principles of Computerized
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Training Course Demo **Brief on**

Computerized System Validation

~~KEY COMPLIANCE DRIVER GAMP5~~

~~Making the Risk Based Approach work~~

~~for CSV~~ **Experts Talk: Using**

Pharmaceutical ALM for GAMP 5

Compliance FDA CFR Part 11, ICH

GCP, GMP, (CSV)- What's the hype

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all about? *How to Validate*

Computerized GxP Systems in the Life Sciences 11 08 16 The Importance of Computer System Validation for Regulated Systems “Computer Software Assurance for Manufacturing, Operations, and Quality System Software Validating

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~~Hardware Software~~ SharePoint 2013 for 21 CFR Part 11
Environments Webinar **Agile**

**Validation in GxP Projects Good
Automated Manufacturing Practice**

What is PROCESS VALIDATION?

**What does PROCESS VALIDATION
mean? PROCESS VALIDATION**

meaning ~~Computer System Validation~~

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IQ OQ PQ | Process Validation |
Equipment Validation | Equipment
Qualification | Medical Devices **What**

**is GOOD MANUFACTURING
PRACTICE? What does GOOD
MANUFACTURING PRACTICE
mean? Process Validation in
Pharmaceutical Manufacturing** *What*

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Manufacturing Execution System (MES)? ~~Computer system validation~~

~~by Nirali Shah~~ **PQ, OQ, IQ - ISPE**

**Baseline Guide 5 - What are the
Required Documents? What is**

COMPUTERIZED SYSTEM

VALIDATION? What does

COMPUTERIZED SYSTEM

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VALIDATION mean? GAMP® RDI
Good Practice Guide: Data Integrity –
Key Concepts Explore GAMP® Hot
Topics in 3 Questions **PHARMAELITE**
- Computer System Validation
\u0026 its applications in
PHARMACEUTICAL INDUSTRY
Introduction to Good Automated

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Manufacturing Practices

CSV(Computer System Validation) as
a service

COMPUTER SYSTEM/ PLC

VALIDATION #V-model: The
validation concept in #pharmaceuticals

~~FDA Computer System Validation~~

~~Steps Ispe Gamp 5 Software~~

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Categories Hardware Software

ISPE GAMP 5 Software Categories:
Hardware & Software. As discussed in
ISPE GAMP 5 the GAMP Categories
for hardware and software have been
retained in GAMP 5, all be it in a
modified format from GAMP4.

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*ISPE GAMP 5 Software Categories:
Hardware & Software ...*

Achieving & Maintaining GAMP 5
Compliance: Risk-Based Approach to
Software Development & Verification 1
March 2017 Given the growing level of
automation, validation of computerized
systems must be an integral part of

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Hardware Software
projects to guarantee the quality of
products and process controls.

*GAMP® 5 | ISPE | International
Society for Pharmaceutical ...*

GAMP ® 5 provides pragmatic and
practical industry guidance to achieve
compliant computerized systems fit for

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intended use in an efficient and effective manner. This technical document describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification.

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*GAMP 5 Guide: Compliant GxP
Computerized Systems - ISPE*

International Society for
Pharmaceutical Engineering (ISPE)
sets the guidelines for manufacturers
and the current Version is GAMP 5.
GAMP describes a set of principles
and procedures that help ensure that

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pharmaceutical Software (Like QMS software, LMS software, DMS software etc.) has required quality.

GAMP 5 Categories, V Model, 21 CFR Part 11, EU Annex 11 ...

GAMP® 5 defines Software Categories that may be used along

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with risk assessments and supplier assessments to develop a suitable and streamlined validation strategy for your software application. So how do you go about selecting the right GAMP® 5 Software Category for your SharePoint application? Here are some guidelines to help you decide.

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*How to Select the Right GAMP® 5
Software Category for your ...*

GAMP 5 Page 7 A Risk-Based
Approach to Compliant GxP
Computerized Systems Table of
Contents 1 Introduction11

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Table of Contents - ISPE

The GAMP 5 software categories represent a broad indicator of likelihood of software failure. They can be a factor in planning test rigor – but not the only one. Large systems often comprise components of several categories; therefore, each category

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can help assess overall risk/impact of
the compo- nents.

GAMP 5 Quality Risk Management Approach

Page 4 of 10. 4 GAMP 5 Appendices.
Practical guidance on a wide range of
specific topics is provided in the

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Following appendices, which are grouped as management, development, operational, special interest, and general appendices. Management Appendices.

*GAMP 4 to GAMP 5 Summary -
Techstreet*

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*Ispe Gamp 5 Software Categories
Hardware Software*

Category 5 software is “custom software” in GAMP 4 and “custom products” under GAMP 5. This type of

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Hardware Software
system generally refers to directly programmed systems that require coding. However, it also includes any systems that require any new code, even if that code was created using non-custom functions within the application.

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*Using the ISPE's GAMP Methodology
to Validate ...*

Difference between Category 4 and
Category 5 in GAMP 5. Configuration
and customisation of software are
terms that are poorly defined in the
validation world and frequently used
interchangeably ...

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*A brief on GAMP 5 Categories, V
Model and 21 CFR Part 11 ...*

GAMP5 Software Categories As
discussed in ISPE GAMP 5 the GAMP
Categories for hardware and software
have been retained in GAMP 5, all be
it in a modified format from GAMP4.

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*GAMP5 Software Categories ~
Computer Systems Validation*

Yves is strongly engaged within ISPE; he edited the French version of GAMP® 4 and GAMP® 5. He is also member of the French affiliate board. Yves is co-founder and chair of the

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French Speaking GAMP® Community
of Practice "GAMP® Francophone"
and member of the GAMP Europe
Steering Committee.

*Item Detail - GAMP® 5 Series: IT
Infrastructure Compliance ...*

Basic Principles of Computerized

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Systems Compliance Using GAMP®
5, Including Revised Annex 11 and
Part 11 Update (T45) - Updated!
Overview. This online training course
includes the new revised EU GMP
Annex 11, and an update on 21 CFR
Part 11.. This two-day fundamental
course* introduces participants to

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regulatory requirements for
computerized systems in the
pharmaceutical industry and ...

*GAMP® 5, Annex 11/Part 11 Basic
Principles ... - ISPE*

Good Automated Manufacturing
Practice (GAMP®), is a technical sub-

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Hardware Software
committee of the International Society
for Pharmaceutical Engineering
(ISPE). The goal of this committee is
to promote the understanding of the
regulation and use of automated
systems within the pharmaceutical
industry.

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*What is GAMP®? | ISPE |
International Society for ...*

GAMP Software Category 5 –
Bespoke software is software that is
generally written from scratch to fulfil
the business need. This software
could be written in-house and is
possibly the highest risk of the

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Hardware Software as it is customised and there is a higher level risk of errors within the application code.

*GAMP 5: ARE YOU UP TO DATE
WITH THE LATEST VALIDATION
BEST ...*

ISPE GAMP®5: A Risk-Based

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Approach to Compliant GxP

Computerized Systems⁶ presents four software categories in Appendix M4 to help focus effort where risk is greatest and to help select the appropriate system life cycle activities and deliverables.

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*Harmonizing USP <1058> and GAMP
for Analytical Instrument ...*

GAMP 5 – Good Automated
Manufacturing Practice. Although
GAMP has more benefits than
challenges the system still suffers
some setbacks. Guidelines is a major
commodity used by the

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pharmaceutical industry. Kovacs;
Gerhard Werling 11 March A Quality
Management Software system is the
crux of any quality and compliance
process.

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