GAMP® 5, wat is er nieuw?

COP’s, regelgeving en GAMP®

René van Opstal
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Inhoud

- ISPE Community of Practice
  - GAMP
  - PAT
- Nieuwe regelgeving
- GAMP® 5
- Overige ISPE Guidelines
What is a “Community of Practice”

“Group of people who share a concern, a set of problems, or a passion about a topic, and who deepen their knowledge and expertise by interacting on an ongoing basis.”
GAMP Forum

GAMP Family

GAMP Americas
GAMP Europe

JETT
GAMP Brazil & GAMP Puerto Rico are part of GAMP Americas

APV
Namur

Supplier Forum
GAMP Nordic, GAMP DACH, GAMP Francophone, & GAMP Italia are part of GAMP Europe

GAMP Japan

February 27-28
Tampa ISPE Conference
GAMP COP Benelux

Steering Committee
- Tim Goossens – TyGox (co-Chair)
- René van Opstal - Koning & Hartman (co-Chair)
- Frans Leijse – ITCVC (Secretary)
- Paul Dols – Atos Origin
- Frans Boeijen – iValidate IT
- Tom De Rudder – Alcon
- Danny Van Hemelen - GSK Biologicals
- Nico Groot – DSM
- Betty Jansen - Blom – Solvay Pharmaceuticals

Sponsors
- Joop Hoving – DSM (ISPE Dutch affiliate)
- Yves Buelens – NextPharma (ISPE Belgium affiliate)
Web site www.GAMP-Benelux.eu
Risk Assessment expert workshop

- 17 November 2009
- Presentaties + workshop (expert niveau)
- Locatie: Solvay Pharmaceuticals – Weesp
- Tijd: 14.00 – 20.00 uur
- Registratie verplicht (gratis) via de website
PAT COP Benelux

- Process Analytical Technology
  - neemt wereldwijd een enorme vlucht
- Ondersteunt bij onderzoek naar, voorbereiding voor en implementatie van PAT-technologie door verschaffen van kennisinformatie
- Sponsors
  - ISPE Nederlandse en Belgische secties
- Deelname
  - Janssen Pharmaceutica, Xendo, Schering-Plough, Pharma Insight en Koning & Hartman
- www.pat-forum.eu
- Volgend event
  - Quality by Design, medio november, zie website
Nieuwe regelgeving en richtlijnen

- ICH
  - Q8(R1) - Pharmaceutical Development
  - Q10 - Pharmaceutical Quality System
- FDA
  - 21 CFR part 11 – Electronic records & signatures
- EMEA
  - Volume 4 EU Guidelines to Good Manufacturing Practice
    - Chapter 4 - Medicinal Products / GMP
    - Annex 11
- PIC/S
  - Inspectors
Guidance for Industry

- ICH – International Conference on Harmonisation
  - Harmonizing registration requirements between Europe (EMEA), Japan (MHLW) and USA (FDA)
  - Joint regulatory / industry project

- Harmonised Tripartite Guideline
  - Safety
  - Quality
  - Efficacy
  - + Multifunctional
Quality Guidelines Update

- Q8(R1) Pharmaceutical Development
  - Revision 1, June 2009

- Q10 Pharmaceutical Quality System
  - April 2009

- Enhanced, Quality by Design Approaches
  - Improved Product and Process Understanding
  - Continuous Improvement
  - Implementation of Process Analytical Technologies (PAT)
  - Establishment of Design Space
  - Focus on Control Strategy and Robustness
GAMP®4 naar GAMP®5

- A science and risk-based approach to computer validation
- Update naar concepten en terminologie van recente ontwikkelingen in industrie en regelgeving
- Focus op:
  - Product Kwaliteit
  - Patiënt Veiligheid
  - Data Integriteit
Standaarden en regelgeving

- ICH Q8, Q9 en Q10
- PQLI (Product Quality Lifecycle Implementation)
- ITIL (IT Infrastructure Library)
- Industrie standaard ASTM E2500
- SOX
- PIC/S
- cGMP for the 21st century
- ISO 9000
Concepten GAMP®5

- Life cycle benadering
- Product en Proces kennis
  - fitness for intended use
- Voorkomen van dubbel werk
  - Gebruik maken van leverancier documenten
- Science Based Risk Management
- Stimuleren Continue verbetering
- Schaalbare benadering afhankelijk van
  - Noviteit
  - Complexiteit
  - Risico voor patiënt veiligheid, product kwaliteit en data integriteit
Project life cycle

- Plan
- Specify
- Configure & Code
- Verify
- Report
Life Cycle benadering

Potential Retention, Migration, Destruction

Retirement

Changes

Risk Management, Design Review, Change and Configuration Management, Traceability, Document Management

Supporting Processes

Concept

Project

Operation

Retirement

Supplier Involvement

Planning

Specifiication

Configuration and/or Coding

Reporting

Verification

Source: Figure 4.1, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.
Maintain Control in Operation

System Operation

Operational life of system begins

Service or support required

System security issues and administration requests received

Security and System Administration

A system change is required

Change Management Process

An incident occurs

Incident Management and CAPA Process

Incident escalated

Business Continuity Management Process

Corrective actions identified

Audit and Review Process

Operational records generated

System superseded or ready to be replaced

Scheduled record management activity/task becoming due

Records Management Process

Records available for audit and review

Service records and performance information generated

Other supporting processes: Document Management, Calibration, Training, Maintaining End User Procedures

Source: Figure 4.5, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org
Schaalbaarheid

- What are the overall risks to the business?
- System GxP Determination
- What is the overall impact of the system?
- Are more detailed risk assessments required?

Consider

Initial Risk Assessment

User Requirements Specification

Functional Specification

Design Specification

Module (Unit) Specification

Code Modules

Requirements Testing

Functional Testing

Integration Testing

Module (Unit) Testing

Testing of Functional Controls

Testing of Design Controls

User Testing of Controls and Procedures

Iteration as required

Identify and Define

- Identify risks to specific processes
- Identify risks to specific functions
- Define controls to reduce risks

Source: Figure M3.8, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.
Schaalbaarheid

- What are the overall risks to the business?
- System GxP Determination
- What is the overall impact of the system?
- Identify risks to specific requirements
- Define controls to reduce risks

Source: Figure M3.6, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.
Voordelen

- Reductie van tijd en kosten
  - Om te voldoen aan regelgeving
  - Om ‘fitness for intended use’ te bewijzen
  - Pragmatische benadering, Risk based
- Kwaliteit gedurende gehele life cycle
- Stimulans van proces- en systeemverbeteringen
- Sneller doorvoeren van wijzigingen (kwalificaties)
ISPE Guidelines

GAMP 5 Guide Principles and Framework

Appendices
management  development  operation
special interest  general

Good Practice Guides
laboratory  global information systems  process controls
infrastructure  calibration management  testing
electronic data archiving  electronic records and signatures

Other Information
papers and articles  templates and examples  training materials

Source: Figure 1.2, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.
Verwacht

- MCO
  - Maintain Control in Operations
  - Strasbourg 29 september – 1 oktober 2009

- VPCS
  - Validation of Process Control Systems
  - Milaan maart 2010

- Calibration Management
  - Begin 2010
ISPE GAMP COP Benelux

Thank you
& we hope to welcome you as a COP member!

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