

ENGINEERING PHARMACEUTICAL INNOVATION



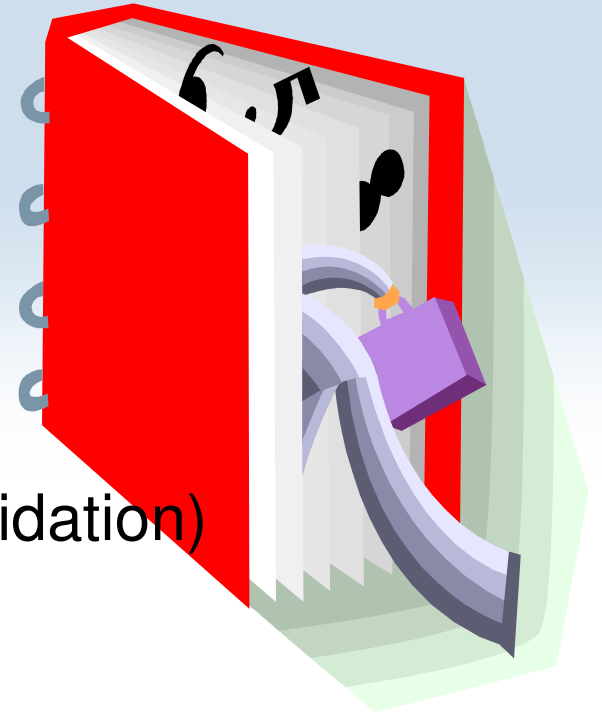
GAMP Italia Update



Carlo Bestetti – www.convalida.net

abstract

- Hits of ... Italian team (s)
- membership
- working groups
- activities of GcM (Equipment Validation)
 - Workshop/Seminar
 - articles
- other activities of GAMP Italia
 - Comments to GAMP5
 - cooperation
- events



- Italian Affiliate
- GAMP Italia

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Hits of the Italian team

(tbc)

(please refer to previous presentations for details)



Italy Affiliate

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PHARMACEUTICAL
INNOVATION



Gamp
Community of Practice
Italia

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Membership

- Membership steady (> 50)
Suppliers, Consultants, Manufacturers, Academia, Students
- Participation of Students
e.g. ISPE I.A. stand at Pharmintec, here in Berlin
- cooperation in progress with AFI –
Associazione Farmaceutici dell'Industria –
an initiative to increase active participation from industry
- Speakers seminar CPA



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Working Groups



- Equipment Validation –
GCM Gruppo Convalida Macchine
- Result of the survey conducted with AFI produced the top 3 arguments of interest for launching working groups :
 - ⇒ Gestione elettronica dei documenti e dei processi
- electronic management of documentation & processes
 - ⇒ Sistemi computerizzati di Laboratorio
– laboratory computerised system
 - ⇒ Sicurezza delle informazioni - information security

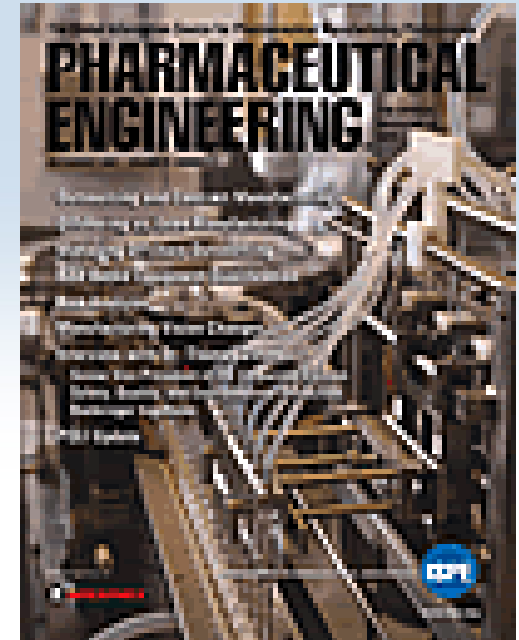


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GCM activities

- launched April 2006
- more than 20 members
- working meetings & Skype telecon
- seminar c/o Parma University on May 10th,
speakers: active components of the wg + lawyer + Sam Brooks (supplier cooperation) + AIFA (Italian authority)
- On line Exclusive Article, Pharmaceutical Engineering's
May/June 2007, Vol. 27 No. 3, "Risk Based Equipment Qualification: A user/Supplier Cooperative Approach



*Part 1 published on paper on **Pharmaceutical Engineering**
July/August 2007 (may be found at reception desk)*

*Part 2 with the specific recommendations for the life-cycle of a generic piece of equipment is being revised to take account of GAMP5 concepts, the new concepts and terminology in the revised C&Q Guide, as well as the recently approved ASTM standard **Pharmaceutical Engineering's** upcoming issue after GAMP5*



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GCM activities

1st article published

“Un approccio cooperativo tra utente e fornitore”
NCF

Notiziario Chimico Farmaceutico

May 2007



2nd article published

“Fornitori e Committenti: insieme per la gestione del ciclo di vita”

Notiziario Chimico Farmaceutico

June 2007



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Other activities of GAMP Italia

- Participation at GAMP Forum and GAMP European Steering Committee (Manchester October 2006, ... Manchester June 21st 2007)
- Cooperation with other Special Interest Groups:
 - JETT (Joint Equipment Transition Team) - templates URS, VP
 - Supplier Cooperation - e.g. workshop in Parma May 10th 2007
 - VPCS (Validation of Process Control Systems) - updating GPG
- 68 comments to GAMP 5 draft
- GAMP Italiano web pages on-line on ISPE web site
- Local discussion forum for information exchange:
<http://www.gampforum.it/> (anticipating E-community)



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Italian Affiliate events

- July 5th 2007

Meeting in Milan c/o Politecnico di Milano:

“pharmaceutical industries meet the University and the control agencies”

(languages: Italian & English)

to follow ISPE Night

- July 6th 2007 Factory Tour:

Istituto di Ricerche Biomediche Bellinzona (CH)

- 12th June 2007

Bologna – Pharmintech 2007

“Research, Development and Innovation in technology for pharmaceutical processing”



(documents available at www.gampit.com)

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Italian Affiliate upcoming events

- October 11th 2007 Conference on “Risk Management & Business Continuity in Life Science Mfg”
participation of BSI (focus on BS25999)
and BCI (Business Continuity Institute), in English
- October 12th 2007
Facility Tour c/o Kedrion Biopharmaceuticals in Bolognana (LU);
specializing in the development, production and distribution of
plasma derivatives.
- Conference on “Pharmaceutical Project e Risk Management” (co-
operation with CPA -*Chemical Pharmaceutical Association*- and PMI
Project Management Institute- SdC speech titled “Linea guida ICH Q9
(Risk Management) e Project management ”

(program published on ispe.org and EU informer)



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GAMP Italia upcoming events

- December 11th 2007

GAMP Steering Committee in Milan (afternoon)
ISPE Night to follow

- December 12th 2007

GAMP event in Milan:

(morning GAMP5; afternoon the results of the new initiatives)

(program published on ispe.org and EU informer)



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Grazie per l'attenzione!

www.gampforum.it



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