



EDPM Study Group Meeting Minutes – Sept. 25, 2013

Meeting minutes: **November 11, 2011**

Location: Farmaceutici Formenti, Lainate, Italy + remote web conference

Report author: Michele Gragnani, K2C Solutions

Attendees: Sandro De Caris, Consulente e Chairman GAMP Italia
Emanuele Rossi, Cosmo Pharmaceuticals
Michele Gragnani, K2C Solutions
Alessia Crivelli, Grunhental - Formenti
Manuela Pederzini, Grunhental - Formenti
Simona Trampetti, Grunhental - Formenti
Cristian Musazzi, Servitecno
Carlo Candotti, PQE
Pierluigi d'Emilio, S4BT (remote web conference)
Lorenzo Petronini, Adeodata
Filippo Savi, JM Consulting
Eustachio Nicoletti, Blulink (remote web conference)

Absent members: Michela Vianello, Datacheck
Augusto Fuchiciello, Indena SpA
Paolo De Bellis, Indena SpA
Francesca Merlini, Menarini
Stefano Zanobini, Menarini
Peirluigi De Rosa, Eon
Marco Torciani, LifeBee
Alessandro Cattaneo Promeditec s.r.l.
Elena Trincherio, Merck Serono
Francesco Fittipaldi, Servitecno
Giorgio Civaroli, CTP
Dario Ceccon, JM Consulting
Laura Luraghi, LB Research
Matteo Minelli, Grunhental - Formenti
Roberta Scuppa, Abbott
Sergio Dusci, ACS Dobfar
Silvia Bergamaschi, Grunhental - Formenti
Stefano Rampoldi, Centro Diagnostico Italiano
Daniela Boccanelli, Bristol Myers Squibb

Meeting Subject: as per the agenda already published on the website gampitalia.it:

1. Presentation of 2 different as-is / to-be Scenarios about Training Management;
2. Discussion about the possible content of EDPM Implementation Guide
3. Definition of rules, plan and roles for the production of the EDPM Implementation Guide



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Summary:

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2	DISCUSSION ABOUT THE POSSIBLE CONTENT OF EDPM IMPLEMENTATION GUIDE	3
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1 Presentation of As-Is / To-Be Scenarios for Training Management

- 1.1 Two short presentations of different As-Is/To Be scenario were planned, but only one has been presented by Pierluigi d'Emilio, (S4BT). The other one will be postponed because of the absence of the presenter (Daniela Boccanelli, Bristol Myers Squibb): even if not planned, a short video of one eLearning Solution was presented by Gragnani (K2C) just to provide some different example for approaching to an Electronic Training Management System.
- 1.2 The presentations have been followed by a discussion that has focused some relevant topics that should be better analyzed in the upcoming work of the group, including but not limited to:
 - Electronic survey/questionnaire and required possibility of user customizations
 - Extension of a training system: should it be limited to the training record, or training management? Something more, e.g. eLearning or Company Knowledge Mapping?
 - Different main subjects of a training (procedures, systems etc.) and associated need of customizations for each training category
 - Triggering events for training activities (change, deviation, CAPA etc.) and associated system requirements
 - Management of training documents and media and relationship with other possible process and systems (including other EDMS)

2 Discussion about the possible content of EDPM Implementation Guide

- 2.1 Sandro De Caris presented a draft index and template for EDPM Implementation Guide, based on what already presented, as a preliminary proposal by Michele Gragnani and Sandro De Caris in the previous meeting.
- 2.2 The template is "GAMP style", inspired to some existing guidelines: the main source of inspiration is the GAMP Operations Good Practice Guide, because it describes the main processes used to maintain system operation, and therefore covers many processes that are in common with the EDPM Implementation Guide. The two documents will have different contents and objectives, because we would like to mainly define the implementation project and not the operation process itself. Nonetheless there are elements in the GAMP GPG that can be useful for the implementation guide. There are several differences:
 - In the EDPM guide the process is intended as an example of the "to-be" process, and the description of the process should also include technical and functional aspects of the system. More than one process example could be shown, in case the specific process can be implemented in different ways.
 - In addition to the operation process, the EDPM guide should also describe the implementation project, including both business and compliance aspects (like data migration, use of electronic record and signatures, etc.).
 - The EDPM guide will probably cover in detail processes that are not covered by the GAMP GPG



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(e.g. the workflow for the management of SOP and other documents, the management of training activities etc.)

Similarities may include:

- The representation of the processes, using a flow chart and a narrative, visual aids to highlight important aspects (relationships with other processes, documents and electronic records, critical steps, etc.)
- Use of RACI tables to describe roles and responsibilities. Nonetheless, in our guideline we should also underline the project responsibilities, perhaps more than the operation ones.

- 2.2 The group would like to quickly produce a first draft of the guideline, with the definition of the main body contents and one first appendix as an example of the style that should be reused for all other appendixes. Gragnani and De Caris will drive the production of this first draft, with the possible collaboration of other team members. This initial job will be discussed and reviewed during the next meeting.
- 2.3 The writing of each appendix will be assigned to specific members of the study group, based on the professional experience and interest of the members. Each task team will carry out the job on each appendix independently, and results will be progressively presented to the entire Study Group for a common discussion and review.

3 Definition of rules, plan and roles for the production of the EDPM Implementation Guide

- 3.1 The next meeting date will take place in Milano (Grunenthal Formenti), with remote connections by a teleconference system: this meeting shall be postponed if the initial draft of the guideline will be not yet ready. Additional meetings among the members of each task team may occur in the meanwhile.

4 Summary of the planned tasks

The status of any Task below defined will be verified during the next meeting.

Meeting Date	Agenda Item #	Task	Responsible	Due date	Status
11/07/13	1.3	Explore the possibility to extend or transform the group in a GAMP SIG	ALL	3-6 months	The initiative will be reconsidered after the first completion of a draft EDPM guideline.
11/07/13	2.3	Promote the compilation of EDPM Survey that has been published in GAMP Italia website	ALL	Oct. 22, 2013	The initiative has been suspended, some possible upgrade will be discussed during the next meetings.
25/09/13	2	Definition of EDPM Implementation guide	ALL	6-9 months	In progress.



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Meeting Date	Agenda Item #	Task	Responsible	Due date	Status
07/11/13	3.1	EDPM Guideline, writing of a first draft	ALL	Nov. 4, 2013	
07/11/13	3.1	Next Meeting of EDPM Group	ALL	Nov. 4, 2013	