



## ***Local GAMP COP Charter: GAMP Benelux***

### **Part A: General Purpose**

#### **1. Introduction**

##### *Purpose*

[1.1] This document defines from a general point of view:

- ▶ the basic principles governing the GAMP organization
- ▶ the relation between a Local GAMP COP and the relevant GAMP regional organizations as well as with the Global GAMP COP Council
- ▶ the government and the activities of a Local GAMP COP
- ▶ the applicable rules regarding membership of a Local GAMP COP.

##### *Scope*

[1.2] The specific Local GAMP COP, where this charter applies to, is defined in Part B, [4.1].

##### *Supervising*

[1.3] The Local GAMP COP is supervised by the following organizations:

- ▶ GAMP Regional COP Steering Committee and Global GAMP COP Council (as defined in this Charter) from a technical and knowledge point of view
- ▶ Local ISPE affiliate(s) (formally the Local Affiliate Board) from an organizational point of view.

[1.4] If the Local GAMP COP does impact a geographical area where several Local ISPE Affiliates operate, more than one affiliate can take the organizational supervising responsibility.

[1.5] In order to avoid organizational conflict or competition (for example by organizing events or by contact with external organizations, e.g. university, associations, etc.), the Local GAMP COP has to inform all the concerned Local ISPE Affiliates about planned events and take note of their comments. Further, it is also essential to co-ordinate these activities according to the overall activities managed by the different ISPE offices.

##### *Approval*

[1.6] At the time of founding of the Local GAMP COP, this charter must be endorsed by the Global GAMP COP Council and approved by the GAMP Regional COP Steering Committee - represented by the Steering Committee chair, the relevant ISPE Affiliate board(s) – represented by the Affiliate chair(s) and the Affiliate board member(s)<sup>1</sup> liaising with the GAMP Regional COP Steering Committee.

[1.7] In case of major revisions, as defined in [1.9], the revised charter must be approved by the following body:

- ▶ GAMP Regional COP Steering Committee, represented by the Steering Committee chair
- ▶ the GAMP Local COP Steering Committee, represented by the local Steering Committee chair
- ▶ the ISPE Affiliate board(s), represented by the Affiliate chair(s) and the Affiliate board member(s) liaising with the GAMP Regional Steering Committee (can be the same person as the local Steering Committee chair).

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<sup>1</sup> It is recommended that the GAMP local Steering Committee chair is also member of the supervising ISPE Affiliate board.

[1.8] In case of minor revisions, as defined in [1.10], this charter does not need to be re-approved. The amendment must be approved by the local SC Chair and Vice-Chair.

### Content revision

[1.9] There are two types of revision concerning the content of this charter:

- ▶ Minor revisions based on amendment
- ▶ Major revisions corresponding to a new version of this charter.

[1.10] The update of [2.3], [2.6], [2.8], [2.9] and [2.10] according to the current development of the GAMP organization is considered as a minor revision of this charter.

## 2. Principles

### GAMP's objectives

[2.1] GAMP is a Community of Practice (COP) of the ISPE specifically devoted to the development, use and control of the use of computer systems, control systems, and intelligent instruments (henceforth called "computerized systems") the pharmaceutical, biopharmaceutical, medical device, or other related industry (henceforth called "industry" or "pharmaceutical industry").

[2.2] GAMP COP's aims are:

- ▶ to offer a discussion platform for the pharmaceutical industry, its product and service suppliers as well as for regulators
- ▶ where appropriate, to develop papers, articles or guidance regarding the achievement of regulatory requirements concerning computerised systems
- ▶ to support the industry and its suppliers by defining approaches to fulfill regulatory requirements concerning the regulatory compliance of computerised systems.

### Organizational structure

[2.3] **Fout! Verwijzingsbron niet gevonden.** shows the structure of the GAMP organization.

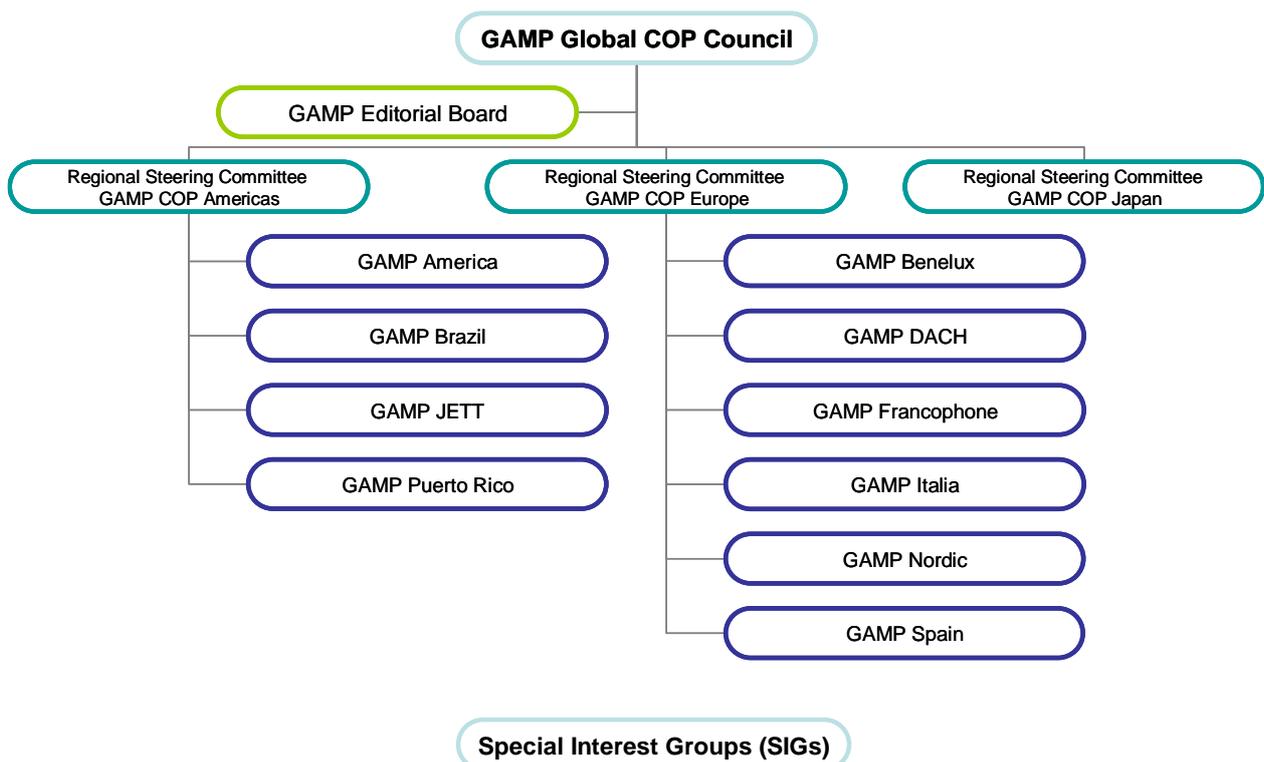


Figure 1

### **Global GAMP COP Council**

- [2.4] GAMP COP governing body with operating responsibility to *ISPE Community of Practice Council* and document delivery responsibility to *ISPE Technical Documents Executive Committee*. From the viewpoint of ISPE, the Global GAMP COP Council is the Steering Committee for the overall GAMP COP.
- [2.5] The Global GAMP COP Council is chaired preferably by a representative of the pharmaceutical industry.

### **GAMP Regional Steering Committees**

- [2.6] There are currently three GAMP organizational regions, each governed by a Regional Steering Committee:
- ▶ **GAMP COP Americas**
  - ▶ **GAMP COP Europe**
  - ▶ **GAMP COP Japan**
- [2.7] The regional GAMP Steering Committees report to the GAMP Council.

### **GAMP Local COP**

- [2.8] Within the Americas region, there are currently the following Local GAMP COPs, each governed by a local Steering Committee:
- ▶ **GAMP America**
  - ▶ **GAMP Brazil**
  - ▶ **GAMP JETT**
  - ▶ **GAMP Puerto Rico**
- [2.9] Within the European region, there are currently the following Local GAMP COPs, each governed by a local Steering Committee:
- ▶ **GAMP Benelux** for the geographical area: Belgium, The Netherlands and Luxemburg
  - ▶ **GAMP DACH**
  - ▶ **GAMP Francophone**
  - ▶ **GAMP Italy**
  - ▶ **GAMP Nordic**
  - ▶ **GAMP Spain**
- [2.10] Within the Japan region, there are currently no Local GAMP COPs

### 3. Local GAMP COP

#### *Local Steering Committee*

- [3.1] Each local GAMP COP is governed by a Steering Committee. This reports to the relevant regional Steering Committee and ultimately, to the GAMP Council.
- [3.2] It agrees and manages the local activities which could be:
- ▶ Organization of community meetings and conferences
  - ▶ Initiation and support of Local Task Teams (SIGs: Special Interest Group)
  - ▶ Maintaining locally an active GAMP presence; e.g. through web, “hotline”, etc.
  - ▶ Contact with ISPE external local organization, e.g. university.
- [3.3] Members can be employees regulated company, suppliers, academia, consultants, and regulators, with no more than two (2) representatives per legal entity of a company.
- [3.4] Ideally, a balance within the Steering Committee should be found between representatives of the **pharmaceutical industry** and supplier representatives.
- [3.5] The minimum size of the Steering Committee shall be five members.
- [3.6] Chair and Vice-Chair and other positions to be elected by majority vote of Local COP Steering Committee members and endorsed by GAMP Regional Steering Committee. The Steering Committee members are elected for a period of 2 years.
- [3.7] New Steering Committee members will be nominated by a current Steering Committee member. New Steering Committee members will join to the Steering Committee after acceptance by a majority of the SC.
- [3.8] The local Steering Committee should aim to meet four times the year. The minutes shall be submitted to the GAMP Regional Steering Committee.
- [3.9] In case of dispute, the local GAMP COP Steering Committee has to refer to the regional GAMP COP steering committee or (ultimately) the Global GAMP COP Council.

#### *Membership*

- [3.10] Membership in ISPE COPs is open to anyone, including ISPE members and non-members. Local GAMP COP Steering Committee members must be ISPE members; other local GAMP COP members are strongly encouraged to be ISPE member. Non-ISPE members will not have full access to the ISPE website.

#### *Activities*

- [3.11] The local GAMP COP Steering Committee defines the activities program taking into account suggestions of local GAMP COP members and according to the recommendations settled in [1.5].

#### *Principles*

- [3.12] Where possible, the activities of the local GAMP COP should involve the various players of the pharmaceutical regulated environment:
- ▶ Pharmaceutical industry
  - ▶ Product as well as service suppliers of the pharmaceutical industry
  - ▶ Regulators.
- [3.13] Since the constructive dialog between industry and regulator is one of the major reasons for the success of the GAMP initiative, local GAMP COP should encourage this dialog locally and give opportunity to regulator and industry for meeting and discussion without compromising the necessary regulator’s reserve and discretion.

### ***Community meetings and conferences***

- [3.14] The local GAMP COP organizes community meetings and conferences in accordance with the recommendation defined in [1.5]. Meetings could simply consist in “roundtables” where topics could be discussed and experience could be shared.
- [3.15] Community meetings and conferences shall follow the ethic rules of ISPE.

### ***Initiation of a SIG***

- [3.16] The setting up of new Special Interest Groups (SIGs) has to be approved by the GAMP COP Regional Steering Committee.
- [3.17] Typically, a request for a new SIG consists of a description (max. two pages) about the objectives, membership, and expected outputs of the task team.

### ***GAMP presence***

- [3.18] One of the important objectives of a local GAMP COP is to become a “point of contact” for all interested people such as, for example, industry, regulatory agency, suppliers, university and engineering school.
- [3.19] This presence could be multiple<sup>2</sup>:
- ▶ Mail- or phone-based “hotline”, including “E-discussions”
  - ▶ Web site
  - ▶ Participation to congress and exhibition.

### ***Web site***

- [3.20] If a Local GAMP COP web site does exist, this must follow the ISPE recommendation regarding “visual identity” and ethics.

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<sup>2</sup> *The proposed list is neither exhaustive nor mandatory.*

## Part B: Local GAMP COP

### 4. GAMP Benelux

#### *Scope*

- [4.1] This document applies specifically to the Local GAMP COP referred to as **GAMP Benelux** which represents the local GAMP community of practice for the countries Belgium (Be), the Netherlands (Ne) and Luxemburg (Lux).

#### *Supervising*

- [4.2] According to [1.3], the Local GAMP COP referred to as **GAMP Benelux** is formally supervised by the following organizations:
- ▶ GAMP Regional COP Steering Committee and Global GAMP COP Council
  - ▶ ISPE Netherlands Affiliate
  - ▶ ISPE Belgium Affiliate.

#### *Web site*

- [4.3] The Local GAMP COP referred to as **GAMP Benelux** maintain its own web site:
- ▶ [www.gamp5.nl](http://www.gamp5.nl)
  - ▶ [www.gamp-benelux.eu](http://www.gamp-benelux.eu)

## Part C

### 5. Approval

[5.1] After review by the GAMP Europe Regional Steering Committee and by members of the GAMP Council, this Charter has been approved according to [1.6] and [1.7] by:

<i>Date</i>	<i>Local ISPE Affiliate Chair (NI)</i>	<i>Date</i>	<i>Local ISPE Affiliate Chair (Be)</i>
			
		10 Dec 2014	
<i>Date</i>	<i>Local GAMP COP co-chair</i>	<i>Date</i>	<i>Local GAMP COP co-chair</i>

## Part D

### A Appendices

#### A1 Glossary

The following acronyms have been used in this document:

[A1.1]	<b>COP</b>	<i>Community of Practice</i>
[A1.2]	<b>GAMP</b>	<i>Good Automated Manufacturing Practice</i>
[A1.3]	<b>ISPE</b>	<i>International Society for Pharmaceutical Engineering</i>
[A1.4]	<b>SIG</b>	<i>Special Interest Group</i>

#### A2 Document versioning

The document version is identified according to the following scheme: “Version **x.yy[a-z]**”, where:

- ▶ “x” represents a major version number
- ▶ “yy” represents a minor version number.

A new major version is identified as “x.00”. Amendments to a major version – for example version 1.00 – are identified as “1.yy”. “yy” represents the amendment number.

Drafts of a future version of this document are identified as “0.yy.a-z”. For example “1.50.c” identifies the third draft of version “1.50”.

#### A3 Document history

Version	Date	Description
<b>1.00</b>	<b>Jan 13, 2009</b>	<b>Final version</b>
<b>1.01</b>	<b>Dec 08, 2014</b>	<b>Amendments to 1.8, 3.6 and 3.7</b>



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