

# Registration Form

Seminar no. 12 02 911.  
Milan - 15<sup>th</sup> February 2012

# Registration under

FAX: +39 02 95794435  
EMAIL: [temas-forum@quintiles.com](mailto:temas-forum@quintiles.com)

# Seminar



NAME \_\_\_\_\_

POSITION \_\_\_\_\_

COMPANY \_\_\_\_\_

ADDRESS \_\_\_\_\_

POSTAL CODE CITY COUNTRY

PHONE \_\_\_\_\_

FAX \_\_\_\_\_

EMAIL \_\_\_\_\_

## ■ Invoicing Data

COMPANY \_\_\_\_\_

VAT. No. \_\_\_\_\_

CODICE FISCALE (if different from VAT No.) \_\_\_\_\_

INVOICING ADDRESS \_\_\_\_\_

POSTAL CODE CITY COUNTRY

I would like to receive the invoice **ONLY** by mail according to the Italian R.M. n. 107 on 04/07/01 - (electronic invoicing submission)

EMAIL \_\_\_\_\_

## INFORMATION ON SAFEGUARDING OF SENSITIVE DATA

In compliance with Article 13 of Legislative Decree no. 196/2003, the Participant is informed that data obtained will be processed for purposes connected with the organization of the course and for the fulfillment of legally enforced obligations concerning the administrative and organizational management of the course. Sensitive data may also be used, subsequent to the Participant's permission, for statistical purposes and for the mailing of information on future commercial initiatives and new products, services and offers, both by the present Company and by its commercial partners. The participant's authorization is necessary for this specific option. If consent is not given the person concerned will NOT RECEIVE further information as described above.

The undersigned gives his/her consent to the processing of his/her sensitive data for the mailing of information on future initiatives

YES \_\_\_\_\_  
DATE SIGNATURE

The participant is further reminded that he/she may exercise his/her rights pursuant to Article 7 of Legislative Decree no. 196/2003 by writing to Temas S.r.l., Temas S.r.l. Unipersonale Cassina Plaza Edificio F, scala 2 - Via Roma, 108 20060 - Cassina De' Pecchi (MI).

## ■ Location - Milan

(The seminar venue will be announced in due time)

## ■ Fee for each participant

€ 890,00 + VAT 21%  
The fee includes didactic materials, lunch and two coffee breaks.

## ■ Special discount conditions

10% for the registration of 2 or more participants from the same company

## ■ Means of enrolment

Enrolment must be made by sending the form, duly completed by each participant, preferably **by fax** to the number **+39 02 95794435** or alternatively **by E-mail** [temas-forum@quintiles.com](mailto:temas-forum@quintiles.com)

**Submission of an enrolment form constitutes an undertaking to make payment of the related enrolment fee.**

## ■ Means of payment

The fee must be paid **prior to the date of the course** by money transfer to the bank B.N.L. Piazza S. Fedele 3 - 20121 Milano IBAN IT 18 D 01005 01600 000000005707 SWIFT/BIC: BNLITRR in the name of Temas S.r.l. (P. IVA [VAT registration no.] 12027810154), indicating **the number of the seminar and the name of the participant**. **Entry to the classroom will be permitted only subsequently to payment.**

## ■ Means of withdrawal

It is possible to cancel the attendance 15 days\* prior to the respective event for an administrative fee of € 50,00. For cancellations received from 14 to 7 days\* prior to the respective event half of the attendance fee will be charged. In all other cases the whole attendance fee must be paid unless another participant from the same company is provided. A change of participants must be communicated by fax or e-mail. \*Calendar days

## ■ Cancellation policy

Temas-Forum reserves the right to postpone or cancel the programmed course in the case that a minimum number of participants, for didactic purposes, is not reached, or in the case that organizational problems should arise. In the case of cancellation of the course, Temas S.r.l. will be only obliged to reimburse enrolment fees already paid, without further penalties. Temas-Forum reserves the right to modify the programme, the lecturers and/or the location of the course for reasons beyond its control.

## ■ For further information contact:

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web: [www.temasis.it](http://www.temasis.it)



# The use of herbs in medicinal products and food supplements



## Topics

- Traditional herbal medicinal products and traditional herbal food supplements: which regulations are applicable in Europe?
- Safety, quality, efficacy, indications/claims for medicinal products and food supplements in the EU
- Registration of an herbal medicinal product with traditional use procedure in different Countries
- Herbal active ingredients/extracts supply for use in medicinal products and food supplements

## Your Speakers

### Chairman

**Prof. Vittorio Silano**  
*Presidente del Comitato Scientifico EFSA*

### Dr. Valerio Bombardelli

*Regulatory Affairs*  
Indena S.p.A.

### Prof. Gioacchino Calapai

*Associato di Farmacologia e Tossicologia*  
Università di Messina - EMA HMPC Member

### Dr. Patrick Coppens

*Secretary-General of the European Botanical Forum*  
Brussels

### Dr. Ulrich Mathes

*Head of International Regulatory & Scientific Affairs*  
Dr. Willmar Schwabe GmbH & Co. KG

### Dr. Floriana Raso

*RA Manager & Pharmacovigilance Responsible*  
Loacker Remedica S.r.l.

*Temas-Forum invites everybody coming from the herbal products field to a meeting focused on the use of herbs in medicinal products and food supplements.*

## Who should attend?

The seminar addresses everybody working on herbal health products in the medicinal, food supplement and cosmetic fields coming from the following departments:

- Regulatory Affairs
- Research and Development
- Pharmaceutical Technology
- Manufacturing and Quality
- Toxicology
- Clinical
- Marketing

## About this seminar

The seminar aims to analyze the use of herbs in medicinal products and food supplements according to the legislation in force pointing out the differences between Italy and the other European countries. Starting with a necessary regulatory overview, we will discuss the safety, quality and efficacy aspects of both products. Two case studies will focus on the experience gleaned from the first authorization in Italy of an herbal medicinal product with traditional use procedure and on the supply of herbal active

ingredients/extracts for use in medicinal products and food supplements.

International Representatives of both pharmaceutical companies and Regulatory Authorities will be exchanging their experience and expertise and will help us to clarify the most critical aspects and open a debate on this interesting subject.

*The seminar will be quite useful for participants from all Countries who are interested in approaching the Italian market.*

**Attendance limited!**

## Waiver of liability

Temas shall not be liable to participants for any damage suffered by them during their participation in Temas-Forum courses except in cases of malice or gross negligence.

## Training events

Information on our training activities may be found at our web site [www.temasis.it](http://www.temasis.it).

## Seminar language

English/Italian.

A simultaneous translation service from English into Italian and vice versa will be provided during the course.

> 9.00 *Registration of participants*

> 9.30

## Chairman's introduction

*Seminar scope and purpose. Analysis of traditional herbal medicinal products and traditional herbal food supplements european market*

*Prof. Vittorio Silano*

> 9.45

## Traditional herbal medicinal products and traditional herbal food supplements: which regulations are applicable in Europe?

*Prof. Vittorio Silano*

> 10.15

## Herbal products: safety, quality, efficacy and indications for medicinal products in the EU

- Reference monographs
- Registration dossier requirements according to the different regulatory options
- Demonstrating well established use and traditional use
- EMA's activities

*Prof. Giocchino Calapai & Dr. Floriana Raso*

> 11.15 *Coffee break*

> 11.45

Herbal products: safety, quality, efficacy and claims for food supplements in the EU

- Regulatory framework
- Harmonised and local regulations
- Claims Regulation and practical problems

■ Herbal food supplements as novel foods

*Dr. Patrick Coppens*

> 13.00 *Discussion*

> 13.30 *Lunch*

> 14.45

## Case study. Herbal medicinal product's registration with traditional use procedure in different Countries

- Registration's route
- Difficulties met
- Different Countries = different positions
- First experience in marketing THMP products

*Dr. Ulrich Mathes*

> 15.15

## Case study. Herbal active ingredients/extracts supply for use in medicinal products and food supplements

- Regulatory requirements concerning the production of pharmaceutical and nutritional ingredients
- National peculiarities
- Two practical examples: from medicinal product to food supplement and back
- Is innovation possible?

*Dr. Valerio Bombardelli*

> 15.45

## Open discussion

*(Speakers and participants)*

> 17.00 *Seminar closing and farewell coffee*