

## 2 WAYS TO REGISTER

- **1 ONLINE:** <https://www.pda-it.org/TR65>
- **EMAIL:** [elena.baccalaro@congressiefiere.com](mailto:elena.baccalaro@congressiefiere.com)
- **EMAIL:** [dt-fiorentino@italfarmaco.com](mailto:dt-fiorentino@italfarmaco.com)

### 1 Your Contact Information

If this form is an update to a previously submitted form, please check here.

Mr.     Ms.     Dr.     Nonmember     I want to become a PDA Member. Please send me a subscription form.  
 PDA Member    ID Number

Name (Last, First, MI) \*

Job Title \*

Company \*  Department

Mailing Address

City  Postal Code

Country  Email \*

Business Phone  Fax

Substituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

### 2 Registration

No PDA membership included

All fees given in Euro and excluding VAT

#### Conference (21 October)

- PDA Member  400  
 Nonmember  500  
 New member  450

#### One-Day Workshop (22 October)

- Outsourcing, Technology Transfer, and CMO-Client Relationship  
 All Participants  100

#### Conference + Workshop (21-22 October)

- PDA Member  450  
 Nonmember  550  
 New member  500

#### EXCLUSIVE SPECIAL PRICE

- Conference + Workshop (21-22 October)  
 Only member of last course held in Florence on September 10  200

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation. PDA Italy has secured a limited number of rooms at a special group rate.

**Group Registration Discount** Register 5 colleagues for the conference at the same time and receive the 5th registration free. For more information on group discounts please contact Gaetano Fiorentino at [dt-fiorentino@italfarmaco.com](mailto:dt-fiorentino@italfarmaco.com) Other discounts cannot be applied.

**Discount for Exhibiting Companies** Please mark here if your company is an exhibitor to this event and you will receive the conference ticket at the special price of 800 Euro per ticket. No further discounts are applicable with this option (as PDA Membership Discount or Group Ticket discount). This special rate does not include one-year PDA membership.

### 3 Payment

**By Bank Transfer beneficiary:** PDA Italy Chapter  
 IBAN: IT55T010307194000002767926  
 BIC: PASCITMMPOG  
 Bank Address: Banca Monte dei Paschi di Siena, Agenzia di Poggibonsi, Loc. Salceto, 95-53036 Poggibonsi (SI)

### 4 Location

#### Hotel Villa La Vedetta

Via Michelangelo, 78  
 50125 Firenze (Italy)  
[www.villalavedettahotel.com](http://www.villalavedettahotel.com)

Posizionato nelle immediate vicinanze del Piazzale Michelangelo, a breve distanza dal Ponte Vecchio, VILLA LA VEDETTA gode di una vista mozzafiato sulla città di Firenze  
 Navetta gratuita, per il centro di Firenze (Ponte Vecchio), andata e ritorno, percorrenza 5 minuti.

Date

Mandatory Signature

**CONFIRMATION:** Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** You must have a written confirmation (including invoice) to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. Payment must be received or guaranteed by Purchase Order or credit card details on 1st day of event, at the very latest. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until prior to the start of the event. **REFUNDS: Refund requests must be sent to PDA ITALY.** If your written request is received on or before **16 October 2015**, you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Italy works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at [info-italy@pda.org](mailto:info-italy@pda.org) **DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

## MAKING IT EASIER FOR BOTH OF US

### 1 Please include your member ID number on registration form if available/known

If uncertain about your member ID number and/or your membership status, call or @ Mr. Gaetano Fiorentino.  
**+39 02 6443-3435** [dt-fiorentino@italfarmaco.com](mailto:dt-fiorentino@italfarmaco.com)

### 2 Do not send money in advance

Please wait until we send our invoice to you.  
It is helpful to reference our invoice number in your bank transfer details.

### 3 Complete and sign the event registration form

Please note the registration and cancellation policies at the bottom of the form.

### 4 Purchase Orders

Registration cannot be completed by sending Purchase Order alone. A Purchase Order is only accepted if a complete registration form is enclosed or follows very soon.

### 5 Please state the correct billing address on the registration form

This is particularly important if billing address and site address are different. Contact your accounting department for correct address and company name. There could be special requirements for accounting. Changes in the billing address (if induced by participating company) will be charged prior to the start of the event.

### 6 Confirmation of your registration

Bank transfers are confirmed upon receipt of full payment.

### 7 Refund/Credit Notes

Refunds to bank accounts can be done if payment had been done by bank transfer and the following details are provided:

**a) Name of your bank      b) IBAN number      c) Swift/BIC code**

### 8 Substitutions

If a participant is unable to attend, substitutions are welcome at any time. Changes are free of charge until prior to the start of the event.

### 9 For assistance contact: Gaetano Fiorentino, President PDA Italy

Tel: **+39 02 6443-3435**

Email: [dt-fiorentino@italfarmaco.com](mailto:dt-fiorentino@italfarmaco.com)

### 10 For assistance contact: Elena Baccalaro Executive Manager Centro Congressi Internazionale Italy

Tel: **+39 011 2446915**

Email: [Elena.baccalaro@centrocongressiefiere.com](mailto:Elena.baccalaro@centrocongressiefiere.com)

# THANK YOU FOR YOUR COOPERATION!

*Relatore: Mirko Gabriele - Technology Transfer Manager Patheon*

Head of the Technology Transfer Dep.t of the Ferentino site, coordinating the Technology Transfer Project Managers.

Responsible for transfer program of the site and project managers professional growing.

Member of the negotiation team for new projects to be transferred on site.

Leader IG PDA TT65 GROUP RAQAB

10 years of experience in pharma environment (R&D, analytical development, business management), pharmaceutical chemist by background with executive MBA.

The pharmaceutical industry is constantly engaged in transferring processes between organizations or locations; these transfers are critical to get product to market. The number of transfers is expected to increase as countries act on the need to manufacture drug products locally **(1)**. This activity is part of the normal lifecycle of a drug product, and it can range from very successful transfers to problematic ones, based on a myriad of factors. Among them are process and product robustness, the readiness of organizations to engage in transfer activities, availability of experts, and the timely execution of all the work needed to complete a transfer.

The ICH Q10 **(2)** guidance states that a transfer of technology is an integral part of its product lifecycle model and identifies it as an activity that must be executed under GMP given its relevance to commercial manufacturing and impact on product quality. This emphasis is justified due to the complexities surrounding transfers of technology.

Overall, technology transfer can be characterized as a phase in the pharmaceutical product lifecycle and requires considerations for specific areas to focus on when planning and executing transfers of technology between organizations.

## **Technology Transfer**

There are many definitions that describe the technology transfer process for pharmaceuticals. Approaching this process as only transferring information (documents, lists of process parameters, etc.), however, is not a technology transfer. Per ICH Q10 **(2)**, the objective of technology transfer is:

*"...to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realisation. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach and ongoing continual improvement."*

In summary, the goal is to transfer knowledge between organizations which will serve as the basis for a sustainable and controlled manufacturing of pharmaceutical products.

The process of transferring knowledge has recently received attention through the issuance of guidance documents that describe the expectations, approaches, and steps for executing transfers **(2-5)**. These documents offer valuable guidance on how to plan, manage and execute a transfer for a pharmaceutical product.

## **AGENDA 1<sup>st</sup> Day**

### **1. Welcome and introduction (09:00 – 10:00)**

- a. Attendees presentation
- b. Scope of the training
- c. Agenda for the day

### **2. Technology Transfer (10:00 – 11:00)**

- a. Definition
- b. Opportunities along product lifecycle
- c. TT process
- d. Prj management

### **3. Q/A Section (11:00 – 12:00)**

**LUNCH BREAK**

### **4. QRM in TT and QRM application (14:00 – 15:00)**

- a. PMCO program
- b. ICH Q9 brief introduction
- c. Why QRM in TT
- d. How QRM in TT
- e. TR 65

**COFFEE BREAK**

### **5. Technology Transfer Approaches - let's discuss and benchmark**

## **AGENDA 2<sup>nd</sup> Day**

### **1. IG Interest Group benefits (Round Table 09:30 - 17:00)**