

## Conference presentation and aims

Quality in the pharmaceutical industry is a must: we have the mission to discover, develop and manufacture drugs for sick people, so all our activities must implement the best levels of quality systems.

Indeed the quality process in the pharmaceutical industry started at the times of the "industrial boom of the '60s": GMP, GLP and finally GCP defined in clear terms the quality standards of our complex activities.

Now, it is time to consider the quality level of the education of professionals involved in drug development: this issue was already well considered by some pioneers, who established the first master or diploma courses in Pharmaceutical Medicine back in the '70s. However only in the last 20 years these courses have been established almost in every country with a significant tradition in drug development.

The IMI founded project named PharmaTrain, which lasted from 2009 to 2014, had the vision to harmonize these courses in the European Union: it was very successful in establishing the quality standards of education, and to identify several Centres of Excellence all over the European Union. In addition, it raised a global interest, so that in 2014 the PharmaTrain Federation was established, with the mission not only to continue in the harmonization process, but also to establish the title of Specialist in Medicines Development (SMD), a voluntary 4 years path to guarantee the correct implementation on the job of the principles acquired with the diploma title.

Our international conference aims at celebrating the first 40 years of IFAPP, a global Federation strongly devoted to education in Pharmaceutical Medicine, and to disseminate the culture of the SMD program, which will be implemented soon in Italy, Japan and other countries.

### SCIENTIFIC COMMITTEE

**Domenico Criscuolo** (SSFA)  
**Luciano M. Fuccella** (SSFA)  
**Gustavo Kesselring** (IFAPP)  
**Ingrid Klingmann** (PTF)  
**Honorio Silva** (IFAPP)  
**Peter Stonier** (PTF)

### ORGANIZING COMMITTEE

**Giuseppe Assogna** (SSFA)  
**Salvatore Bianco** (SSFA)  
**Caroline van Bruggen** (IFAPP)  
**Francesco De Tomasi** (SSFA)  
**Heinrich Klech** (PTF)  
**Gerfried Nell** (IFAPP)  
**Marco Romano** (SSFA)  
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# ADVANCING COMPETENT PROFESSIONALS IN MEDICINES DEVELOPMENT

## A PHARMATRIN – IFAPP – SSFA CONFERENCE



**ROME, 10 -11 JUNE, 2015**

**Nobile Collegio Chimico Farmaceutico – Via in Miranda 10**

## WEDNESDAY JUNE 10 MORNING

ARRIVAL OF GUESTS AND PARTICIPANTS

## WEDNESDAY JUNE 10 AFTERNOON

SESSION TITLE: **CELEBRATING THE FIRST 40 YEARS OF IFAPP**

CHAIRPERSONS: **Honorio Silva (IFAPP), Marco Romano (SSFA)**

|       |   |                            |
|-------|---|----------------------------|
| 14:00 | Introduction from the chairs                                    |                            |
| 14:10 | The history of IFAPP  | <b>Luciano M. Fuccella</b> |
| 14:30 | The development of Pharmatrain                                  | <b>Sam Salek</b>           |
| 14:50 | Back to the future-round table with some IFAPP Past Presidents: | <b>Domenico Criscuolo</b>  |

**Luciano M. Fuccella**  
**Gerfried Nell**  
**Johanna Schenk**  
**Peter Stonier**

16:00 TEA

16:30 IFAPP future strategies for competence development

|   |                             |
|---|-----------------------------|
| •Competencies in pharmaceutical medicine            | <b>Dominique Dubois</b>     |
| •Addressing expectations from National Associations | <b>Susanne Kienzle-Horn</b> |
| •Plans for 2015-2018 and ICPM 2016                  | <b>Gustavo Kesselring</b>   |
| •The role of the Faculty of Pharmaceutical Medicine | <b>Keith Bragman</b>        |

18:30 COCKTAIL

## THURSDAY JUNE 11 MORNING

SESSION TITLE: **EDUCATION IN PHARMACEUTICAL MEDICINE: PRESENT AND FUTURE**

CHAIRPERSONS : **Ingrid Klingmann (PTF), Gustavo Kesselring (IFAPP)**

|       |   |   |
|-------|---|---|
| 9:00  | Public and private partnerships to advance education in medicines development | <b>Mike Hardman</b>                                 |
| 9:20  | Pharmatrain: an EU initiative going global                                    | <b>Ingrid Klingmann</b>                             |
| 9:40  | The pharmatrain centres of excellence in Italy                                | <b>Pierluigi Navarra</b><br><b>Antonio Torsello</b> |
| 10:20 | The concept of specialist in medicines development                            | <b>Peter Stonier</b>                                |
| 10:40 | COFFEE  |   |
| 11:10 | Developing a global certification board                                       | <b>Heinrich Klech</b>                               |
| 11:30 | SMD implementation in Japan   | <b>Kyoko Imamura</b>                                |
| 11:50 | Medicines development education in low income countries                       | <b>Sandor Kerpel Fronius</b>                        |
| 12:10 | Competencies in clinical research: a global perspective                       | <b>Honorio Silva</b>                                |
| 12:30 | The CLIC project  | <b>Jean Marie Boeynaems</b>                         |
| 12:50 | DISCUSSION  |   |
| 13:30 | LUNCH   |   |

## THURSDAY JUNE 11 AFTERNOON

SESSION TITLE: **CERTIFICATION IN PHARMACEUTICAL MEDICINE AND CLINICAL RESEARCH**

CHAIRPERSONS: **Peter Stonier (PTF), Domenico Criscuolo (SSFA)**

|       |   |  |
|-------|---|--|
| 14:30 | The vision of regulators                                      | <b>Sergio Bonini (EMA)</b><br><b>Sandra Petraglia (AIFA)</b> |
| 15:20 | The vision of Italian pharmacologists                         | <b>Luca Steardo (SIF)</b>                                    |
| 15:50 | The vision of CROs  | <b>Mariapia Cirenei (AICRO)</b>                              |
| 16:10 | Perspectives from the Italian association of medical oncology | <b>Massimo Di Maio (AIOM)</b>                                |
| 16:30 | DISCUSSION  |  |
| 17:00 | CONCLUSIONS AND WRAP UP                                       | <b>FROM THE CHAIRS</b>                                       |

17:15 A BUS WILL LEAVE THE CONFERENCE VENUE FOR FIUMICINO AIRPORT (TRAVEL TIME : APPROXIMATELY 50 MINUTES)