



Associazione Farmaceutici Industria
Società Scientifica

2012 Annual Report

Mission and Goals

A.F.I. is the leading Italian scientific association of professionals working in the pharmaceutical and allied industries of Italy.

The main goals of A.F.I., as defined in its statutes, are:

- ✓ *to promote the scientific and professional development of the industrial pharmacists, encouraging high standards of education at undergraduate and postgraduate level*
- ✓ *to organise courses and conferences on scientific and technical subjects regarding all the industrial pharmaceutical fields*
- ✓ *to support other scientific initiatives for the promotion of the knowledge in the pharmaceutical area*
- ✓ *to maintain strict contacts with Health Authorities and to represent the position of its members on legislation matters*

2012 Activities

In 2012, A.F.I. organized conferences, seminars and training courses for the continuous professional development of its members, in agreement with the objectives of the Association.

Most of courses organised by A.F.I. received a positive assessment for credits in relation with the *ECM*, the Italian system of CE (Continuing Education) for professionals operating for the Health National Service.

1. Conferences and Seminars

- *"The pharmaceutical industry in Italy: a value for health, economy and employment", in collaboration with CRS, ADRITELF, TEFARCO (Milan, January, ½ day)*
- *"The safety and environment management system according to DLgs 231/01" in collaboration with CERTIQUALITY and SIAD (Pomezia, February, 1 day)*
- *"Cleaning validation: where are we?" (Rome, March, 1 day)*
- *"Methods for the toxicological characterization of chemical substances" (Milan, April, 1 day)*
- *"HPLC analysis: past, present and future" (Milan, April, 1 day)*
- *"The manufacture of highly potent active ingredients" in collaboration with ASCHIMFARMA- Association of Italian API manufacturers, (Milan, April, 1 day)*
- *"The contract manufacture of medicinal products" in collaboration with University of Padua (Padua, May, 1 day)*

- “The authorization of biocides” (Milan, June, 1 day)
- “The risk management in the pharmaceutical industry”(Milan, September, 1 day)
- “The clinical trials and the manufacture of IMPs” (Milan, November, 1 day)

2. Training Courses

- Six training sessions (one day each) organized with the support of EUROFINS/Biolab (Milan, February through November) on the following topics:
 - *ICH Q11*
 - *Biocides*
 - *Genotoxic impurities*
 - *The REACH procedure*
 - *Practical approach to pharmacological issues*
 - *Clinical investigations on medical devices*
- Five training sessions (two days each) organized with the support of TARTARI&Partners (Milan, January through November) on the following topics:
 - *Quality risk analysis*
 - *Process Robustness*
 - *Accelerated degradation analysis*
 - *Process validation*
 - *Statistical methods*
- Six training sessions (two days each) organized with the support of ACANTO (Milan, March through October) on “The business management of medical devices”
- Two training sessions (one day each) organized with the support of PTM Consulting (Milan, March and September) on the following topics:
 - *Know-how acquisition for business acceleration*
 - *Technology Transfer: from a need to an opportunity of improvement*
- “The application of the World Class methodology to Life Sciences”, organized with the support of BONFIGLIOLI Consulting (Milan, May, 1 day)
- “The international pharmaceutical legislation”, with the support of NFS-DBA (UK), (Rome, June, 1 day)
- Two training sessions (two days each) organized with the support of IRCCS –Pavia (Pavia, September) on the following topics:
 - *Pharmacokinetics and pharmacodynamics in Phase I studies*
 - *Clinical trials studies management*
- “Primary packaging and drug delivery trends for injectables”, with the support of NUOVA OMPI (Milan, December, 1 day)

3. Collaboration with Universities

Keeping a strict relationship with a few important Italian universities, A.F.I. contribute to the undergraduate and postgraduate education. Members of A.F.I. are regularly invited to give lessons to undergraduate students on selected subjects in order to make them aware of the industrial practical issues.

As far as postgraduate education is concerned, a few master courses are regularly organised every year, in co-operation with FARMINDUSTRIA (Association of Pharmaceutical Entrepreneurs) ,

TEFARCO (Association for Technical Innovation in the Pharma Sector) and C.R.S. (Controlled Release Society) Italian Chapter:

- Master in *“Pharmaceutical Technology and Regulatory Affairs”*, at the Universities of Parma, Pavia and Perugia (January- June 2012), 60 hrs
- Master in *“Industrial Pharmaceutical Technologies”* at the University La Sapienza- Rome (January-June 2012), 60 hrs
- Specialisation Course in *“Regulatory issues in medicinal products management”*, at the University of Milan (April- October 2012), 72 hrs
- Master in *“Pre-formulation, development and control of medicinal products”*, at the University of Pavia (March-September 2012), 120 hrs
- Master in *“Industrial Pharmaceutical Technologies”* at the University of Siena (March-June 2012), 60 hrs

4. Special Events

- The 52nd *Symposium* was organized in June 2012 with a presence of more than 1.000 participants. Representatives of Italian Health Authorities (AIFA), pharmaceutical entrepreneurs and trade associations were also present. During the three day symposium, conferences and workshops on various pharmaceutical issues were organized, inviting qualified speakers.
- On request of Italian Medicinal Agency (AIFA), *training course on GMP issues* (for a total of 16 days) were organised in Rome during 2012 for the inspectors of AIFA and ISS (Istituto Superiore di Sanità). The teachers of these courses were chosen among AFI members. In September and October, four visits to pharmaceutical plants (Sanofi, Eli Lilly, Abbott, BSP) were also organised for inspectors.
- A special conference on *“Quality, Inspections, Audits: experiences in the pharmaceutical industry”*, was organised with FARMINDUSTRIA in Rome (October 2012)
- *“6th Meeting of the Qualified Persons”*, with the participation of Italian Medicinal Agency (AIFA) representatives (Rome, November, 1 day)
- *“3rd Meeting of Regulatory Affairs Managers”*, held in Rome, 1 day, in December 2012
- A special conference on *“The medicinal gases: how to manage in community pharmacies”*, addressed to community pharmacists at the COSMOFARMA exhibition, held in Rome, in May 2012
- Annual meeting with the representatives and officers of Italian Medicinal Agency (AIFA) was held to review the main Italian regulatory issues of the year (Rome, December, ½ day).

5. Working Groups

The activity of AFI is based on the working groups which are open to all its members.

The groups are set up according to the activity of the Committees (which report to the board) and are managed on a voluntary basis. Working groups meet regularly during the year.

6. Publications

As a result of the working group activity, technical documents are generated and a few of them are published.

In 2012, the 7th volume of the *“AFI GMPs Guidance”* was published and presented to the annual symposium.

Technical documentation was prepared and distributed at each training course or conference.

Reports about events are regularly published on *N.C.F. (Notiziario Chimico Farmaceutico)*, a magazine which is circulated to most professionals of the pharmaceutical industry of Italy.

Organization

Members Total Count: **570 industrial pharmacists**

President Name and E-Mail: **prof Alessandro Rigamonti** (alessandro.rigamonti@afiscientifica.it)

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Piero Iamartino/March 2013