



Associazione Farmaceutici Industria  
Società Scientifica

## Annual Report 2016

<b>Foundation</b>	1960	
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<b>Membership</b>	595 Industrial Pharmacists	

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### Goals

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

The goals of A.F.I. are as follows:

- ✓ 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 seminars 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

## **2016 Activities**

In 2016 A.F.I. organized conferences, seminars and training courses for the continuous professional development of its members, in agreement with the goals 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.

A few events organized by others organizations have been sponsored by A.F.I. after a careful evaluation and formal approval by the A.F.I. Board of Directors.

### **1. Conferences and Workshops**

January 2016

- “*Production Innovation and Value: the Role of the Pharmaceutical Industry*” (Milan, 1/2 day)

March 2016

- “*The Pharmaceutical Excipients: the new regulation*” (Milan, 1 day)
- “*The GDPs and Medicine Counterfeiting*” (Florence, 1 day)

April 2016

- “*The Evolution of GMPS for APIs: Regulatory Impact on API Users*”, in collaboration with ASCHIMFARMA (Italian Association of API Manufacturers), (Milan, 1 day)
- “*Serialization and Traceability: Two Steps for Patient Safety and Quality Compliance*”, in collaboration with ISPE Italy and PHARMINTECH, (Bologna, 1/2 day)
- “*Data Integrity: How to Ensure Integrity of Data in the Pharmaceutical Area*” (Milan, 1 day)
- “*The non Profit Clinical Trials*” in collaboration with the University of Milan (Milan, 1 day)

## May 2016

- *“The Pharmaceutical Quality in Industry: Patient Safety and Industrial Competition”* in collaboration with the University of Perugia (Perugia, ½ day)
- *“The Role and the Management of the Pharmaceutical Production”* , in collaboration with the University of Perugia (Perugia, ½ day)
- *The Evolution of the QP”*, in collaboration with University of Padua (Padua, ½ day)

## June 2016

- *“Clinical trials in neurology”*, in collaboration with POLICLINICO DEZZA, (Milan, 1 day)
- *“Innovation Drive by Smart Manufacturing and Industry 4.0”*, sponsoring Pfizer Italy, Ascoli Piceno (Ascoli Piceno, 1 day)

## September 2016

- *“Gene and Cell Therapy in Italy: Excellence from Research to Production and Clinical Practice”* in collaboration with ASSOBIOTEC (Italian Association of Biotechnology), (Milan, 1 day)

## October 2016

- *“Data Integrity: How to Ensure Integrity of Data in the Pharmaceutical Area”* (Rome, 1 day)
- *“Clinical Trials in Oncology: Italy and Lombardy Region, an example”* in collaboration with Regione Lombardia (Milan, 1 day)

## November 2016

- *“The Strictly Controlled Conditions in Chemical Manufacture”* (Milan, 1 day)
- *“The Preparation of Radiopharmaceuticals”*, (Milan, 1 day)

## December 2016

- *“Innovative Pharmaceutical Technologies: as We Started in Pavia 45 Years Ago”*, in collaboration with the Universities of Pavia and Milan (Milan, 1 day)

## **2. Training Courses**

February 2016

- *“GMPs of Medicinal Products: a Basic Course”*, in collaboration with University of Milan (Milan, 2 days)

March 2016

- *“Design of Experiments for Analytical Methods Development”*, sponsoring Tartari&Pratners (Milan, 2 day)
- *“How to Face an Audit”*, sponsoring Tartari&Partners (Milan, 1 day)

April 2016

- *“Granulation and Tableting for Drug Products and Food Supplements”*, in collaboration with University of Milan (Milan, 2 days)
- *“Chemiometrics: Statistical and Multivariate Statistical Methods for Chemists”*, sponsoring Tartari&Partners (Milan, 4 days)
- *Elemental Impurities and Primary Packaging”*, sponsoring NEOTRON (Modena, 1 day)

June 2016

- *“Granulation and Tableting for Drug Products and Food Supplements”*, in collaboration with University of Milan (Milan, 2 days)

July 2016

- *“Medical Devices: form design to market”* in collaboration with the University of Turin (Turin, 1 day)

October 2016

- *Updating on The International Pharmaceutical Legislation”*, sponsoring NSF (Milan, 1 day)

### **3. Master and Specialization Courses by Universities**

Keeping a strict relationship with a few important Italian universities, A.F.I. contributes 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, members of A.F.I. are regularly invited as teachers at master courses, which are organized every year, in co-operation with other associations.

In 2016, members of A.F.I. were involved in the following two events:

- Master (second level) in “*Pharmaceutical Technology and Regulatory Affairs*”, with the support of TEFARCO, at the Universities of Parma, Pavia and Perugia (February - September )
- Master (second level) in “*Industrial Pharmaceutical Technologies*”, with the support of FARMINDUSTRIA, at the University La Sapienza - Rome (January - June)
- Specialisation Course on “*Pharmaceutical Logistics*”, at the University of Padua (May - November)

### **4. Special Events**

- The **56th Symposium** was held on 8-10 June 2016, having the title: “*Evolution in the Pharmaceutical Sector: Radical Changes in the Drug Supply Chain*”. About 1.000 participants attended this event. Representatives of Italian Health Authorities (AIFA), pharmaceutical entrepreneurs and trade associations were invited. During the three day symposium, conferences and workshops on various pharmaceutical issues were organized, inviting qualified speakers.
- “**6<sup>th</sup> National Meeting of Regulatory Affairs Experts**”, with the participation of Italian Medicinal Agency (AIFA) representatives, was held in Rome on February 24th, for discussing the hot topics in the application of national and European legislation.
- “**10<sup>th</sup> National Meeting of the Qualified Persons**”, with the participation of Italian Medicinal Agency (AIFA) representatives, was held in Rome on December 2<sup>nd</sup>, for discussing the hot topics about the role and responsibilities of the QP in Italy.

### **5. Working Groups**

All activities of AFI are on voluntary basis, which is funded on working groups dealing with different disciplines of the pharmaceutical area.

The groups are set up according to the activity of the Committees (which report to the board) and are managed by group leaders. Working groups meet regularly and submit to the board their proposals of workshops, training courses, seminars.

Most of the activities of the working groups are reported on the AFI website.

## **6. Publications**

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

In June 2016, the 12<sup>th</sup> book of the “**AFI - GMPs Guidance**” was issued and presented to the annual symposium.

At each training course or workshop, technical documentation is prepared and distributed to participants .

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.

***Piero lamartino***

**Member of the AFI Board of Directors - EIPG Delegate**

6<sup>th</sup> May 2017