



Associazione Farmaceutici Industria  
Società Scientifica

From knowledge  
to digitalization  
for competitiveness  
of the health industry



Palacongressi • Entrance A  
Via della Fiera, 23 • Rimini (Italy)

PROGRAMME

## SYMPOSIUM COMMITTEES

### SCIENTIFIC COMMITTEE

- **Giorgio Bruno** - AFI President
- **Alberto Bartolini** - AFI - CIT
- **Maurizio Battistini** - AFI - EIPG
- **Massimo Beccaria** - AFI - Advice Pharma Group
- **Paolo Caliceti** - AFI - University of Padua
- **Carla Caramella** - AFI - University of Pavia
- **Matteo Cerea** - AFI - University of Milan
- **Bice Conti** - AFI - SITELF
- **Lorenzo Cottini** - AFI - Evidence Health
- **Roberto de Luca** - AFI
- **Pierfelice Ferrari** - AFI
- **Andrea Gazzaniga** - AFI - University of Milan
- **Piero Iamartino** - AFI - EIPG
- **Ilaria Maruti** - AFI - Astrazeneca
- **Paola Minghetti** - AFI Vice-president - University of Milan
- **Alessandra Molin Zan** - AFI - Zentiva Italia
- **Maria Luisa Nolli** - AFI - NCNbio
- **Andrea Oliva** - AFI - Viatris
- **Laura Patrucco** - AFI - PRINEOS
- **Massimo Pedrani** - AFI - Mogon Pharmaceuticals
- **Lino Pontello** - AFI
- **Anna Ponzianelli** - AFI - Moderna
- **Mauro Rainoni** - AFI - Cooper Consumer Health
- **Floriana Raso** - AFI
- **Alessandro Regola** - AFI Vice-president
- **Stefano Salmaso** - CRS - University of Padua
- **Francesca Selmin** - AFI - University of Milan

### ORGANIZING COMMITTEE

- **Giorgio Bruno** - AFI President
- **Emiliano Celli** - New Aurameeting

### DISSERTATION COMMITTEE

#### **Coordinator:**

- **Carla Caramella** - AFI - University of Pavia

#### **Members:**

- **Marco Adami** - AFI
- **Nicola Realdon** - AFI - University of Verona
- **Francesca Selmin** - AFI - University of Milan

### POSTER COMMITTEE

#### **Coordinator:**

- **Giovanni Boccardi** - AFI

#### **Members:**

- **Bice Conti** - AFI - SITELF
- **Antonio Danese** - Communication and Press Relations - DV Informatica
- **Monica Gunetti** - AFI - Bambino Gesù Children's Hospital
- **Maria Luisa Nolli** - AFI - NCNbio
- **Alessandro Regola** - AFI Vice-president

### ORGANIZING SECRETARIAT

- **Alessandra Artesi** - AFI
- **Aldo Bernuzzi** - New Aurameeting
- **Mariangela Del Vecchio** - AFI
- **Bianca Mazzucco** - New Aurameeting
- **Cindy Paganoni** - New Aurameeting
- **Elena Pelosi** - New Aurameeting
- **Greta Zani** - New Aurameeting



## MEETING POINTS

AFI expresses its sincere gratitude to the prominent and prestigious Societies that have contributed once again to the organization of this annual Symposium, providing participants with comprehensive information on specific activities.

N. STAND	AZIENDA ESPOSITRICE
109	AAF INTERNATIONAL
133	ABAR
26	ABC FARMACEUTICI
77	ACOTEC MANGINI TURNKEY DIVISION
2	ADEODATA
80-81	ADIUTO - Bluenext
45	AKKODIS ITALY
113	ALCHEMY
138	ALFATESTLAB
119-120	ALIPHARMA
5	ALTEN Italia
82	ALTERGON ITALIA
79	AMARIS CONSULTING
65	AM INSTRUMENTS
52	AMITA HEALTH CARE
104	Analysis
36-53	ANTARES VISION GROUP
29	ANTON PAAR ITALIA
87	ARITHMOS
73	ASGENIA
126	AZELIS
21	B&D ITALIA
127	BRAM-COR
19	BURKERT ITALIA SPA
72	C&P Engineering
143	CAI
18	CAMST - Life Science Solutions
69	CAPSULIT
67	CHEMSAFE
86	CO.RA.
8	COMECER
33	CSV Life Science Group
37-38	CYTIVA
146	D.O.C. - DOCUMENTATION ORGANIZATION AND CONSULTANCY
58	DDA Quality Development For Industries
36-53	DE LAMA
135	DHL Supply Chain Italy
84	DI RENZO REGULATORY AFFAIRS
142	DMX Pharma
141	DYNAMIC FORWARDING INTERNATIONAL
89	ECOLAB
54	ELLAB
19	EMERSON
27	EN-COM
98	ENDRESS+HAUSER ITALIA
55	EUREKA InfoMed
149-150-151	Eurofins BioPharma Product Testing Italy
149-150-151	Eurofins Healthcare Assurance
149-150-151	Eurofins PSS Insourcing Solutions®
149-150-151	Eurofins Regulatory & Consulting Services Italy
149-150-151	Eurofins Medical Device Services
15	EUROMED PHARMA SERVICES
107	EURPACK
116	EUSOFT
48	EVIDENZE HEALTH
103	EXCiPACT / IPEC Europe
25	FARMADATI ITALIA
36-53	Farmo Res
49	FARMOL HEALTH CARE
7	Fine Foods & Pharmaceuticals
60-61	FLARER
20	Grafibox Sud
145	Gruppo SASI
90-91	HONEYWELL Life Sciences
44	I.G.B.
110	IBD
154-155	IMA

## MEETING POINTS

108	INDENA
153	INN Lifes
80-81	INPHARMATIC - Bluenext
152	IQVIA
34	ITALIANA SERVIZI
115	JRS Rettenmaier Italia
148	JSB Solutions
129-140	KÖRBER
105	KYMOS GROUP
40	LabAnalysis Process Pharma
39	LABOTICS ITALIA
9-10	LabWare
130	LAETUS
64	LifeBee   Digitalizing Life Science
100	LIVES INTERNATIONAL
131	LS Academy
93-94	MAASI Enterprises
3	MAKING LIFE
22-23	MARCHESINI GROUP
12	MASTERFILTER
136	MEDICAL AFFAIRS CONSULTING
99	Merck Life Science
59	NEOTRON TESTING LAB
77	NICOMAC EUROPE
137	NORDTEST
6	NTT DATA
106	O.M.A.R.
134	OLD PHARMA International
132	OMRON
124	ORISE
57	P.B.L.
63	PEC – Pharma Education Center
125-144	PHA.SE. ENGINEERING & COMPLIANCE SERVICES
71	Pharma D&S
62	PHARMA PARTNERS a PALLADIO GROUP brand
50	Pharmadule Morimatsu AB
92	PRC TICINUM LAB
88	PRINEOS
74-75	PTM Consulting
97	PVS
30-31	QSGROUP
117	QStep
95-96	QUALIMETRIX
156	QUASCENTA PTE. ITD.
14	RATTIINOX
11	RECIPHARM ITALIA
106	ROFARMA ITALIA
42	S.C.F. Studio di Consulenza Farmacologica
51	S4BT
145	SafetyDrugs
112	SAUERMANN ITALIA
22-23	SEA VISION
41	SERVICE PHARMA CHEMICAL & FOOD
101	SIEMENS
47	SOITRA
97	SOLTECH
35	SOTAX
68	STERIGENICS
118	STERILINE
139	SWAN Analitica
78	TEAM mastery
28	Tecniche Nuove - Notiziario Chimico Farmaceutico
111	TEMA SINERGIE
147	TRUFFINI & REGGE' FARMACEUTICI
85	UNIVAR SOLUTIONS
114	UNIVERSAL PACK
70	VAISALA
121	VIEW SCIENCE
36-53	VIS VIVA
83	WAB-GROUP®
123	ZETA
128	ZETA FARMACEUTICI GROUP

## From knowledge to digitalization for competitiveness of the health industry

**The 64<sup>th</sup> AFI Symposium on "From knowledge to digitalization for competitiveness of the health industry" will take place as usual at the Palacongressi of Rimini from 11<sup>th</sup> to 13<sup>th</sup> June 2025.**

In recent years, the healthcare industry has undergone a profound transformation due to the advent of digitization. The integration of such technologies into the processes of different industries in the sector has the potential to revolutionize the way patient services are delivered, improving efficiency, accessibility and quality of care.

We are therefore witnessing the evolution of traditional knowledge through digitization, which is also a key factor in improving the competitiveness of the sector.

Doctors, researchers and health professionals rely on years of study and experience to diagnose diseases, develop treatments and improve care. Continuous education and updating skills are essential to stay abreast of new scientific discoveries and best practices. Digitization makes it possible to collect, store, and analyze huge volumes of data more efficiently, data that become immediately available where it is most needed, such as for timely and personalized diagnosis and treatment. Thus, a paradigm shift is occurring in the way knowledge is collected, shared, and applied in the health sector, thanks in part to new technologies that can be applied such as artificial intelligence (AI) and machine learning, the Internet of Things (IoT), and blockchain, which are transforming the way in which data is managed, improving the accuracy of diagnoses and optimizing treatments.

In this context, telemedicine services and new types of medical devices have been developed, such as wearables, that enable real-time monitoring of the patient's health, with a more effective chronic disease management and continuous remote control.

In addition, digitization fosters collaboration among hospitals, laboratories, pharmaceutical companies and other healthcare stakeholders through integrated systems, useful for sharing information quickly and safely, improving care coordination and accelerating research.

However, it should be remembered that investment in digital skills training, aimed at the staff involved, is a fundamental prerequisite to ensure that the health industry can take full advantage of all potential benefits.

This transition from traditional knowledge to digitization is thus transforming the entire healthcare supply chain, making it more efficient, competitive, and future-oriented, with significant improvement for access and quality of medical treatments.

The concepts of "knowledge and digitization," which give the 64<sup>th</sup> Symposium its title, will permeate all sessions.

This edition of the AFI Symposium will include **18 Scientific Sessions, 2 Keynote Lectures**, numerous side events, including the **Poster Session, Corporate Workshops**, in-person on Wednesday morning and digital, featuring authoritative speakers from the Industry, Universities, Institutions and Trade Associations.

The Symposium will begin Wednesday afternoon with a speech by Giorgio Bruno, AFI president. This will be followed by the three sessions scientific sessions on Sustainability, Innovation and Clinical Research.

Thursday morning will feature sessions on **HTA, Regulatory, Quality, Biotech, Special Productions, PVV** and **Poster**, during which participants will be allowed to showcase the results of their projects, ending with an award ceremony for the best posters, which will still remain on display throughout the Symposium in the dedicated area.

Thursday afternoon will feature the **Keynote Lecture**, by Roberto Burioni, Ordinary Professor of Microbiology and Virology at the University Vita-Salute San Raffele di Milano, followed by the sessions Medical Devices, Supply Chain, Pharmacovigilance, AFI/SITELF Pharmaceutical Sciences and CRS – SITELF.

To conclude, Friday morning will feature the last four sessions on **Production, Digital Health, Raw Materials** and **Social Trends and Phenomena** in the **Pharmaceutical Supply Chain**.

## WEDNESDAY 11<sup>TH</sup> JUNE

09.00 – 13.00	Registration of Symposium Participants
09.00 – 10.00	Registration of Workshop Participants (at the entrance of workshop rooms - 1st floor)
10.00 – 12.30	<b>Workshop</b> ( <i>free admission subject to mandatory registration</i> )
<b>Sala del Borgo</b>	• <b>AM Instruments:</b> Beyond compliance: strategies and innovation to face Annex 1's challenges
<b>Sala della Marina 2</b>	• <b>Bonfiglioli Consulting in collaboration with expert.ai:</b> Digital, data, intelligence: how to bring the pharmaceutical industry into the future
<b>Sala della Marina 1</b>	• <b>Eurofins BioPharma Product Testing Italy:</b> Innovation and new technologies in microbiology: The frontier of "Rapid Methods"
<b>Sala del Faro</b>	• <b>Eurofins Medical Device Services:</b> Medical devices – Contaminants on trial: a matter of manufacture?
<b>Sala del Parco 1</b>	• <b>FTR ADVISOR:</b> Are we in possession of "quality" clinical data relevant to the intended purpose of our medical device? Means to obtain them in the pre/post market
<b>Sala del Parco 2</b>	• <b>PTM CONSULTING:</b> The necessary change of pace to integrate combination products in the pharmaceutical industry
13.30	<b>Inauguration of the 64<sup>th</sup> AFI Symposium at the entrance of the exhibition area</b>
12.30 – 14.00	<i>Welcome lunch</i>
14.00 – 15.00	• Giorgio Bruno – AFI President
<b>Sala del Tempio</b>	<b>Welcome and Opening of the Symposium</b>

**Poster Session:** posters will be displayed in the lobby of Sala dell'Arco and be always available during the all the Symposium days.

## TECHNICAL AND SCIENTIFIC SESSIONS

15.15 – 19.00	• SESSION I – ENERGY AND SUSTAINABILITY
<b>Sala del Castello 1</b>	<b>New compliances and real-life cases in the sustainability of the pharmaceutical world: challenges and opportunities</b>
15.15 – 18.45	• SESSION II – INNOVATION
<b>Sala del Tempio</b>	<b>From 4.0 to 5.0: a guideline and some practical examples</b>
15.15 – 18.45	• SESSION III – CLINICAL RESEARCH
<b>Sala del Castello 2</b>	<b>Digitalization, decentralization, Real World Evidence: how to make Italy and Europe competitive in the field of clinical research</b>
20.00	<b>WHITE&amp;BLUE Beach Party</b> <b>at the Beach of Grand Hotel Rimini</b> <b>in collaboration with</b>

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## THURSDAY 12<sup>TH</sup> JUNE

- |  |   |
|--|---|
| <p>09.00 – 11.00<br/><b>Sala del Tempio</b></p>      | <ul style="list-style-type: none"> <li>• SESSION IV – HTA<br/><b>HTA Regulation from JCA to Full HTA in Italy</b></li> </ul>  |
| <p>11.30 – 13.00<br/><b>Sala del Tempio</b></p>      | <ul style="list-style-type: none"> <li>• SESSION V – REGULATORY<br/><b>Package leaflet digitalization: Where we stand and future perspectives</b></li> </ul>  |
| <p>09.00 – 13.00<br/><b>Sala del Castello 2</b></p>  | <ul style="list-style-type: none"> <li>• SESSION VI – QUALITY<br/><b>Evolution of the Pharmaceutical Quality System for the continuity of business and the prevention of drugs shortages</b></li> </ul>   |
| <p>09.00 – 13.00<br/><b>Sala del Castello 1</b></p>  | <ul style="list-style-type: none"> <li>• SESSION VII – BIOTECH<br/><b>The new frontiers of Advanced Therapies: from production to delivery</b></li> </ul>   |
| <p>09.00 – 11.00<br/><b>Sala dell'Arco</b></p>       | <ul style="list-style-type: none"> <li>• SESSION VIII – SPECIAL PRODUCTIONS<br/><b>Digital innovation in the research field, development and management of special productions: opportunities and challenges</b></li> </ul>   |
| <p>11.30 – 13.30<br/><b>Sala dell'Arco</b></p>       | <ul style="list-style-type: none"> <li>• SESSION IX – PATIENT VOICE &amp; VALUE (PVV)<br/><b>Evolution of the VALUE BASED HEALTHCARE supported by the patient voice for an "ad personam" health system, through the assistance of digital technology as well</b></li> </ul> |
| <p>12.30 – 14.30<br/><b>Foyer Sala dell'Arco</b></p> | <ul style="list-style-type: none"> <li>• POSTER SESSION<br/><b>An area dedicated to oral poster presentations. One of the authors will be next to their poster to answer any questions from participants about the work presented.</b></li> </ul>                           |
| <p>12.30 – 14.00</p>                                 | <p><i><b>Working lunch</b></i></p>  |
| <p>14.00 – 15.00<br/><b>Sala del Tempio</b></p>      | <ul style="list-style-type: none"> <li>• Roberto Burioni – University Vita-Salute San Raffaele di Milano<br/><b>Keynote Lecture</b> (free admission)<br/><b>Viruses and Pandemics</b></li> </ul>  |
| <p>15.15 – 18.45<br/><b>Sala del Tempio</b></p>      | <ul style="list-style-type: none"> <li>• SESSION X – MEDICAL DEVICES<br/><b>Innovation and application of the new technologies for substance-based Medical Devices in the field of MDR</b></li> </ul>   |
| <p>15.15 – 18.45<br/><b>Sala del Castello 1</b></p>  | <ul style="list-style-type: none"> <li>• SESSION XI – SUPPLY CHAIN<br/><b>Criticalities and opportunities within drugs distribution</b></li> </ul>  |
| <p>15.15 – 18.45<br/><b>Sala del Castello 2</b></p>  | <ul style="list-style-type: none"> <li>• SESSION XII - PHARMACOVIGILANCE<br/><b>Educational materials: an efficient management in the digital era</b></li> </ul>  |
| <p>15.15 – 17.15<br/><b>Sala dell'Arco</b></p>       | <ul style="list-style-type: none"> <li>• SESSION XIII – PHARMACEUTICAL SCIENCES (AFI/SITELF)<br/><b>Research and development of new therapeutical approach in gastroenterology: clinical, pharmacological and social aspects</b></li> </ul>                                 |
| <p>17.15 – 19.45<br/><b>Sala dell'Arco</b></p>       | <ul style="list-style-type: none"> <li>• SESSION XIV – CRS/SITELF<br/><b>Functional and innovative pharmaceutical excipients</b></li> </ul>   |
| <p>20.00</p>   | <p><i><b>Gala Dinner of the Symposium at the Grand Hotel Rimini in collaboration with</b></i></p>   |



## FRIDAY 13<sup>TH</sup> JUNE

09.00 – 13.00

**Sala del Tempio**

- SESSION XV – PRODUCTION  
**2025 Production: news and future developments**

09.00 – 13.15

**Sala del Castello 1**

- SESSION XVI – DIGITAL HEALTH  
**How the pharmaceutical industry is evolving with the introduction of technology such as AI and digital medical devices**

09.30 – 11.15

**Sala del Castello 2**

- SESSION XVII – RAW MATERIALS  
**Market and criticalities of API and excipients' management**

09.30 – 13.00

**Sala dell'Arco**

- SESSION XVIII (*free admission*)  
**Trends and social phenomena in the drugs' supply chain**

13:00 – 14:30

***Working lunch***

## From knowledge to digitalization for competitiveness of the health industry

- |               |   |
|---------------|---|
| 09.00 - 13.00 | • Registration of Symposium Participants  |
| 09.00 - 10.00 | • Registration of Workshop Participants<br>(at the entrance of workshop rooms - 1st floor)        |
| 10.00 - 12.30 | • <b>Workshop</b>   |
| 13.00         | • <b>Inauguration of the 64<sup>th</sup> AFI Symposium at the entrance of the exhibition area</b> |
| 12.30 - 14.00 | • <i>Working lunch</i>  |

## WORKSHOP PROGRAMME

**Free admission subject to mandatory registration within Tuesday 10th June.  
Please, use the following link:**

**[CLICK HERE](#)**

*Participation in workshops does not entitle to admission to the Symposium scientific sessions.*

Coordinator: **Alessandro Regola - AFI Vice-president**

- |               |   |
|---------------|---|
| 09.00 - 10.00 | • <b>Registration of the Workshop participants (at the entrance of the meeting rooms)</b>   |
| 10.00 - 12.30 | • <b>Sala del Borgo</b><br>Workshop organized by <b>AM Instruments</b><br><i>Beyond compliance: strategies and innovation to face Annex 1's challenges</i>  |
| 10.00 - 12.30 | • <b>Sala della Marina 2</b><br>Workshop organized by <b>Bonfiglioli Consulting in collaboration with expert.ai</b><br><i>Digital, data, intelligence: how to bring the pharmaceutical industry into the future</i>                 |
| 10.00 - 12.30 | • <b>Sala della Marina 1</b><br>Workshop organized by <b>Eurofins BioPharma Product Testing Italy</b><br><i>Innovation and new technologies in microbiology: The frontier of "Rapid Methods"</i>                                    |
| 10.00 - 12.30 | • <b>Sala del Faro</b><br>Workshop organized by <b>Eurofins Medical Device Services</b><br><i>Medical devices – Contaminants on trial: a matter of manufacture?</i>   |
| 10.00 - 12.30 | • <b>Sala del Parco 1</b><br>Workshop organized by <b>FTR ADVISOR</b><br><i>Are we in possession of "quality" clinical data relevant to the intended purpose of our medical device? Means to obtain them in the pre/post market</i> |
| 10.00 - 12.30 | • <b>Sala del Parco 2</b><br>Workshop organized by <b>PTM CONSULTING</b><br><i>The necessary change of pace to integrate combination products in the pharmaceutical industry</i>  |
| 12.30 - 14.00 | • <i>Working lunch</i>  |

14.00 - 15.00  
**Sala del Tempio**

- Giorgio Bruno – AFI President  
**Welcome and Opening of the Symposium**

**Technical and scientific sessions**

## SESSION I

### NEW COMPLIANCES AND REAL-LIFE CASES IN THE SUSTAINABILITY OF THE PHARMACEUTICAL WORLD: CHALLENGES AND OPPORTUNITIES

#### Sala del Castello 1

- 15.15 - 15.30      **Presentation of GdS Energy & Sustainability**
- Pierfelice Ferrari – AFI
- Moderator:**      • Pierfelice Ferrari – AFI
- 15.30 - 16.10      **Future CSRD, ESRS fulfillment/implementation borne by companies with particular reference to double materiality**
- Ettore Piantoni – CEN and CENELEC – JTC14
- 16.10 - 16.30      **2024 ERA (Environmental Risk Assessment) revision and its implementation in the drug industry**
- Ivo Caldera – AFI
  - Piero Iamartino – AFI – EIPG
- 16.30 - 17.15      **Coffee break**
- 17.15 - 17.45      **Carbon net zero (purpose 1, 2 and 3), sustainability goals and case studies of Chiesi group**
- Elisa Bandini – Chiesi Farmaceutici
- 17.45 - 18.15      **Carbon net zero and net nature positive: sustainability goals and case studies of GSK group**
- Ilaria Lo Presti – Glaxosmithkline
- 18.15 - 18.45      **Reducing environmental impact in the production of pharmaceutical active principles – The experience of European project LIFE GREENAPI in Angelini Pharma**
- Anna Codazzi – Angelini Pharma
  - Tommaso Iacoangeli – Angelini Pharma
- 18.45 - 19.00      **Discussion and end of session**
- 20.00      **WHITE&BLUE Beach Party at the Beach of Grand Hotel Rimini in collaboration with**

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14.00 - 15.00  
**Sala del Tempio**

- Giorgio Bruno – AFI President  
**Welcome and Opening of the Symposium**

Technical and scientific sessions

## SESSION II

### FROM 4.0 TO 5.0: A GUIDELINE AND SOME PRACTICAL EXAMPLES

**Sala del Tempio**

15.15 - 15.20

**Welcome address and introduction to the session**

- Alberto Bartolini – AFI – CIT

**Moderator:**

- Alberto Bartolini – AFI – CIT

15.20 - 16.00

**GUIDELINE PRESENTATION FOR THE USE OF NEW TECHNOLOGIES**

**Introduction**

- Alberto Bartolini – AFI – CIT
- **4.0 New Technologies**
- Paola Martini – AFI – Takeda Manufacturing Italia
- **Cyber Security e Data Protection**
- Gian Paolo Baranzoni – AFI
- **GAMP 5 second edition**
- Sandro de Caris – GAMP Italia

16.00 - 17.00

**EXAMPLES OF AI PRACTICAL IMPLEMENTATION**

**Digitization in support of knowledge - The human at the center**

- Maria Paravani – Seingim Life Science
- Riccardo Vaccina – Aenova Group
- **A Deep-Learning Approach to Predict Optical Density at 600 Nanometers**
- Franca Cattani – Dompé Farmaceutici
- Giovanna Scaramuzzino – Orise
- **AI and ML, new opportunities for performance improvement in pharmaceutical production**
- Claudio Ernesto, Mario Manzati – Clabiotech
- Joerg Tautrim – Lean Institute
- **Transition 5.0 plan - Supporting enterprises digital and energy conversion**
- Fedele Pini – AFI – Seingim Life Science
- Enrico Russo – Italfarmaco

17.00 - 17.30

**Coffee break**

17.30 - 18.30

**Panel themes discussion**

**Moderator:**

- Alberto Bartolini – AFI – CIT

**Panelists:**

- Gian Paolo Baranzoni – AFI
- Sandro de Caris – GAMP Italia
- Marco Paolo Fulfaro – AIFA (*pending confirmation*)
- Giampiero Lorenti – EMA (*pending confirmation*)
- Paola Martini – AFI – Takeda Manufacturing Italia
- Lino Pontello – AFI
- Alessandro Regola – AFI Vice-president

18.30 - 18.45

**Discussion and end of session**

20.00

**WHITE&BLUE Beach Party at the Beach  
of Grand Hotel Rimini in collaboration with**

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14.00 - 15.00  
Sala del Tempio

- Giorgio Bruno – AFI President  
**Welcome and Opening of the Symposium**

Technical and scientific sessions

## SESSION III

### DIGITALIZATION, DECENTRALIZATION, REAL WORLD EVIDENCE: HOW TO MAKE ITALY AND EUROPE COMPETITIVE IN THE FIELD OF CLINICAL RESEARCH

Sala del Castello 2

15.15 -15.25

#### **Welcome address and introduction to the session**

- Guido Fedele – AFI
- Ilaria Maruti – AFI – Astrazeneca

**Elements for a greater attractiveness of Italy and Europe in clinical trials: how to promote the inclusion and management of patients in clinical trials**

**Moderator:**

- Ilaria Maruti – AFI – Astrazeneca

15.25 - 16.30

#### **Panel discussion**

- Simona Berardi Vilei – Swissmedic
- Liana de Plasencia Mascuñana – Evidenze Clinical Research
- Fabrizio Forini – AICRO
- Sandra Petraglia – AIFA (*pending confirmation*)
- Francesca Vaccari – AFI

16.30 - 17.15

#### **Coffee break**

**Real World Data and technological innovations: evolving trends in drugs development and medical devices/IVD**

**Moderators:**

- Lorenzo Cottini – AFI – Evidenze Health
- Noemi Porrello – AFI – Roche

17.15 - 17.45

#### **The value of health data and new technologies in the continuum of care**

- Matteo Della Porta – IRCCS Clinical Institute Humanitas(*pending confirmation*)

17.45 - 18.30

#### **Panel discussion with:**

- Sara Cazzaniga – AFI – IQVIA
- Valeria Glorioso – Confindustria DM
- Caterina Golotta – Assobiotec
- Farmindustria Representative (*pending confirmation*)
- Health Ministry Representative (*pending confirmation*)

18.30 - 18.45

#### **Discussion and end of session**

20.00

**WHITE&BLUE Beach Party at the Beach  
of Grand Hotel Rimini in collaboration with**

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## SESSION IV

### HTA REGULATION FROM JCA TO FULL HTA IN ITALY

#### Sala del Tempio

- 09.00 – 09.10      **Welcome address and introduction to the session**
- Paola Minghetti – AFI Vice-president – University of Milan
- 09.10 – 09.20      **Institutional greetings: The voice of Institutions**
- Francesco Saverio Mennini – Health Ministry – University of Rome Tor Vergata
- Moderators:**
- Simona Montilla – AIFA (*pending confirmation*)
  - Anna Ponzianelli – AFI – Moderna
- 09.20 – 09.35      **Europe and HTA Regulation: 12th January 2025 and then?**
- Marco Marchetti – age.na.s
- 09.35 – 09.50      **AIFA and HTA Regulation: from EU to AIFA evaluation**
- Pierluigi Russo – AIFA (*pending confirmation*)
- 09.50 – 10.00      **Q&A**
- 10.00 – 10.45      **Panel discussion**
- Moderator:**
- Anna Ponzianelli – AFI – Moderna
- Panelists:**
- Valeria Fava – Cittadinanzattiva
  - Walter Marrocco – FIMMG, CSE
  - Simona Montilla – AIFA (*pending confirmation*)
  - Giandomenico Nollo – SIHTA President
  - Carlo Riccini – Farindustria
- 10.45 – 11.00      **Discussion and end of session**
- 11.00 – 11.30      **Coffee break**

## SESSION V

### PACKAGE LEAFLET DIGITALIZATION: WHERE WE STAND AND FUTURE PROSPECTIVES

#### Sala del Tempio

- 11.30 - 11.50      **Introduction of the session**
- Alessandra Molin Zan – AFI – Zentiva Italia
- 11.40 - 12.00      **EMA pilot project**
- Margherita Parziale – AIFA (*pending confirmation*)
- 12.00 - 12.20      **Overview of the ePIL implementation in Europe in anticipation of the new Pharmaceutical legislation**
- Elena Tedeschi – AFI – Teva Italia
  - Elena Verrengia – AFI – Bayer
- 12.20 - 12.40      **Results of the citizens survey to comprehend the use of the package leaflet and its digitalization**
- Claudia Calò – AFI – Chiesi Italia
  - Martina Perini – AFI – Roche
- Moderator:**      • Maria Elena Trovati – AFI – Amgen
- 12.40-13.00      **Panel discussion “The evolution of the package leaflet: opportunities and challenges of the digitization process - Confrontation of opinions” with:**
- Paolo Abrate – SIFO
  - Salvatore Bauleo – FIMMG Bologna
  - Luciano Diomedi – FOFI – Ordine Farmacisti di Macerata
  - Valeria Fava – Cittadinanzattiva
  - Margherita Parziale – AIFA (*pending confirmation*)
- 12.30 - 14.00      **Working lunch**

## SESSION VI

### EVOLUTION OF THE PHARMACEUTICAL QUALITY SYSTEM FOR THE CONTINUITY OF BUSINESS AND THE PREVENTION OF DRUGS SHORTAGES

#### Sala del Castello 2

- 09.00 - 09.10      **Introduction of the session**
- Alessandro Regola – AFI Vice-president
- Moderators:**
- Giovanni Boccardi – AFI
  - Alessandro Regola – AFI Vice-president
- 09.10 - 09.40      **Are GMP compliance and business continuity two sides of the same coin? How risk assessment can foster efficient synergy**
- Gabriele Bellatorre – AFI
  - Devis Lamberti – MITIM Recipharm
- 09.40 - 10.10      **Risk Management and Guaranteeing the Continuity of Supplies**
- Silvia Sanzone – Galenica Senese
  - Tania Perfetti – Ingenus Pharmaceuticals
- 10.10 - 10.40      **US FDA speech on programme "Quality Management Maturity"**
- Panelist to be determined
- 10.40 - 11.10      **Coffee Break**
- Moderators:**
- Marco Adami – AFI
  - Lino Pontello – AFI
- 11.10 - 11.40      **Production processes optimization: in continuous quality as key to success**
- Claudia Bianchi Carnevale – AFI – Pfizer
  - Francesca Speroni – AFI – PTM Consulting
- 11.40 - 12.10      **Regulatory compliance and business continuity: a shared path between workshops, MAH and regulatory agencies**
- Sara Bellini – AFI – Chiesi Italia
  - Francesca Berti – AFI – Eli Lilly Italia
  - Mariagrazia Marzorati – AFI – Thea Farma
- 12.10 - 12.40      **AIFA Speech on "Shortages"**
- Domenico Di Giorgio – AIFA (*pending confirmation*)
- 12.40 - 13.00      **Discussion and end of session**
- 12.30 - 14.00      **Working lunch**



## SESSION VII

### THE NEW FRONTIERS OF ADVANCED THERAPIES: FROM PRODUCTION TO DELIVERY

#### Sala del Castello 1

- 09.00 – 09.05      **Welcoming**
- Marica Nobile – Assobiotech
  - Maria Luisa Nolli – AFI – NCNbio
  - Sara Vignati – AFI – AFTI
- Moderator:**      • Maria Luisa Nolli – AFI – NCNbio
- 09.05 – 09.50      **Keynote lecture – Drugs overview for gene therapy: from development to commerce**
- Alessandro Aiuti – IRCCS Ospedale San Raffaele
- 09.50 – 10.10      **Use of in vivo lentiviral vectors**
- Alessio Cantore – SR-Tiget
- 10.10 – 10.30      **Manufacturing of the future**
- Filippo Begarani – PBL
  - Monica Gunetti – AFI – Bambino Gesù Children's Hospital
- 10.30 – 11.00      **The new frontiers of Decentralized Production for Advanced Therapies products**
- Marco Paolo Fulfaro – AIFA (*pending confirmation*)
- 11.00 – 11.30      **Coffee Break**
- 11.30 – 11.50      **CAR model supply chain by Gilead / Kite**
- Andrea Quadrio – AFI – Gilead / Kite
- 11.50 – 12.10      **Case history: Nemo project experience with Zolgesma**
- Beatrice Berti – Fondazione Policlinico Universitario Agostino Gemelli IRCCS
- 12.10 – 12.40      **Panel discussion: "Decentralization of the CART production: new production strategy"**
- Moderators:**      • Stefano Baila – AFI – Eurofins-Biolab  
                             • Monica Gunetti – AFI – Bambino Gesù Children's Hospital
- Panelists:**      • Beatrice Berti – Fondazione Policlinico Universitario Agostino Gemelli IRCCS  
                             • Valentina Fonsato – 2i3T – University of Turin  
                             • Marco Paolo Fulfaro – AIFA (*pending confirmation*)  
                             • Claudia Maldini – Miltenyi Biotec  
                             • Andrea Quadrio – AFI – Gilead / Kite  
                             • Anna Silvani – AFI – Gilead  
                             • Cristina Zanini – IWT Pharma
- 12.50 – 13.00      **Discussion and end of session**
- 12.30 – 14.30      **Working lunch**

## SESSION VIII

### DIGITAL INNOVATION IN THE RESEARCH FIELD, DEVELOPMENT AND MANAGEMENT OF SPECIAL PRODUCTIONS: OPPORTUNITIES AND CHALLENGES

Sala dell'Arco

- Moderators:**
- Marilena Carazzone – AFI
  - Floriana Raso – AFI

#### HERBAL MEDICINES

- 09.00 – 09.20      **Computational techniques for the study of medical plants**
- Giorgio Cappellucci – SIFIT
- 09.20 – 09.40      **Innovative techniques of drug discovery applied to natural substances**
- Jean-Luc Wolfender – University of Geneva

#### RADIOPHARMACEUTICALS

- 09.40 – 10.00      **Digital technology and Artificial Intelligence in medical image analysis**
- Jan Wolber – GE HealthCare Pharmaceutical Diagnostics UK
- 10.00 – 10.20      **PET Radiopharmaceuticals preparation and management: current state and future implementations**
- Manuela Monti – IRCCS Istituto Romagnolo per lo studio dei tumori "Dino Amadori" IRST
  - Anna Tolomeo – Itelpharma

#### MEDICINAL GASES

- 10.20 – 10.40      **Digitization of the medicinal oxygen production process: application of software with AI for logistic scheduling, remote control of tanks and primary stations**
- Stefania Mariani – Assogastecnici – Sol Group
- 10.40 – 11.00      **Panel Discussion**

- Moderator:**
- Floriana Raso – AFI

- Panelists:**
- Alessandro Assisi – AIFA (*pending confirmation*)
  - Lorella Chiappinelli – AIFA (*pending confirmation*)
  - Giorgio Cappellucci – SIFIT
  - Andrea Fieschi – Assogastecnici
  - Manuela Monti – IRCCS Istituto Romagnolo per lo studio dei tumori "Dino Amadori" IRST
  - Anna Tolomeo – Itelpharma

- 12.30 – 14.00      **Working lunch**

## SESSION IX

### EVOLUTION OF THE VALUE BASED HEALTHCARE SUPPORTED BY THE PATIENT VOICE FOR AN "AD PERSONAM" HEALTH SYSTEM, THROUGH THE ASSISTANCE OF DIGITAL TECHNOLOGY AS WELL

#### Sala dell'Arco

- Moderators:**
- Simona Aloe – AFI – Daiichi Sankyo Italia
  - Laura Patrucco – AFI – PRINEOS
- 11.30 – 11.45      **Human Value Based Healthcare – HVBH and case studies**
- Maria Rosaria Natale – Your Business Partner
- 11.45 – 12.40      **Panel discussion: The value of a VBH model combined with the patient voice for an "ad personam" patient journey. The floor to the Stakeholders**
- Moderators:**
- Simona Aloe, Maria Rosaria Natale – AFI – Daiichi Sankyo Italia
  - Laura Patrucco – AFI – PRINEOS
  - Monica Calamai – ASP Crotone – Community Donne Protagoniste in Sanità
  - Marco Greco – EPF
  - Tiziana Pia Latiano – AIOM
  - Giandomenico Nollo – SIHTA
  - Teresa Petrangolini – ALTEMS – Catholic University of the Sacred Heart
  - Annalisa Scopinaro – UNIAMO
  - Relatore da definire – F.A.V.O.
- 12.40 – 12.50      **Digital design thinking approach in support of HVBH – Digital innovation in HTA**
- Roberta Gilardi – G. Gravity – Associazione Scientifica Sanità Digitale ASSD
- 12.50 – 13.20      **Talk Show: The value of a VBH model combined with the patient voice for an "ad personam" patient journey. The floor to the Stakeholders**
- Moderators:**
- Simona Aloe – AFI – Daiichi Sankyo Italia
  - Laura Patrucco – AFI – PRINEOS
- Panelists:**
- Massimo Beccaria – AFI – Advice Pharma
  - Luisa De Stefano – AFI – Roche
  - Alessandra Ferrari – AFI – Fondazione IRCCS Policlinico San Matteo
  - Anna Ponzianelli – AFI – Moderna
  - Francesca Rollo – AFI – DOC GENERICI
- 13.20 – 13.30      **Discussion and end of session: Take Home Messages**
- 12.30 – 14.00      **Working lunch**

#### Foyer Sala dell'Arco

An area dedicated to oral poster presentations. One of the authors will be next to their poster to answer any questions from participants about the work presented.

14.00 - 15.00  
**Sala del Tempio**

- Keynote Lecture: "Viruses and Pandemics"**  
• Roberto Burioni – University Vita-Salute San Raffaele di Milano

## SESSION X

### INNOVATION AND APPLICATION OF THE NEW TECHNOLOGIES FOR MEDICAL DEVICES MADE FROM SUBSTANCES IN THE FIELD OF MDR

**Sala del Tempio**

- 15.15 - 15.25      **Welcome address and introduction to the session**  
• Paola Minghetti – AFI Vice-president – University of Milan
- Moderators:**  
• Maria Grazia Leone – Health Ministry  
• Marcella Marletta – University Campus Bio-Medico, Rome
- 15.25 - 15.50      **Institutional Greetings Confindustria Dispositivi Medici**  
• Guido Beccagutti – Confindustria Dispositivi Medici
- 15.50 - 16.15      **Medical devices – Legislative changes and future scenarios**  
• Alessandra Basilisco – Health Ministry
- PANEL DISCUSSION OPENING WITH THE NOTIFIED BODIES ALONG-SIDE THE PARTECIPATION OF:**
- Daniele Bollati – IMQ
  - Paolo Dentis – Eurofins TECH
  - Alessia Frabetti – KIWA CERMET ITALIA
  - Sara Gianellini – ITALCERT
  - Pietro Iannì – CERTIQUALITY
  - Roberta Marcoaldi – Italian National Institute of Health
  - Chiara Novi – TUV Rheinland
  - Tatiana Vignudelli – Ente Certificazione Macchine
- 16.15 - 16.35      **Clinical data collection and submission for legacy devices certification in MDR; data collection and acceptance strategies**  
• Lorenzo Cottini – AFI – Evidenze Health
- 16.35 - 17.20      **Coffee break**
- 17.20 - 17.40      **Combined products: synergies and interactions between companies and authorities**  
• Sveva Sanzone – AFI – Biogen Italia
- 17.40 - 18.10      **Innovative MD – The experience of Certification in MDR**  
• Antonella Mamoli – AFI – IBSA
- 18.10 - 18.20      **AI and substance-based MD – Risks and Benefits**  
• Tiziana Pecora – AFI
- 18.20 - 18.45      **Discussion and end of session**  
• Mauro Rainoni – AFI – Cooper Consumer Health
- 20.00      **Gala Dinner of the Symposium at the Grand Hotel Rimini in collaboration with**  **tecniche nuove**

14.00 - 15.00  
**Sala del Tempio**

- Keynote Lecture: "Viruses and Pandemics"**  
• Roberto Burioni – University Vita-Salute San Raffaele di Milano

## SESSION XI

### CRITICALITIES AND OPPORTUNITIES WITHIN DRUGS DISTRIBUTION

#### Sala del Castello 1

- 15.15 - 15.30      **Welcome address and introduction to the session**  
• Roberto de Luca – AFI – University of Padua

- Moderators:**  
• Alberto Bartolini – AFI – CIT  
• Roberto de Luca – AFI – University of Padua

- 15.30 - 16.00      **Biotech and "Orphan" drugs' supply chain**  
• Maria Luisa Nolli – AFI – NCNbio

- 16.00 - 16.30      **Supply chain traceability for the patient safety**  
• Alberto Bartolini – AFI – CIT

16.30 - 17.15      **Coffee break**

- 17.15 - 17.35      **Logistic Operator's criticalities**  
• Michele Pochettino – H.Essers

- 17.35 - 17.55      **Wholesale distributor's criticalities**  
• Andrea Frettoli – CEF – Cooperative Esercenti Farmacia

- 17.55 - 18.15      **Conveyor's criticalities and opportunities**  
• Ilaria Aloe – EDF

- 18.15 - 18.25      **Integrated traceability**  
• Gian Paolo Baranzoni – AFI

18.25 - 18.45      **Discussion and end of session**

20.00      **Gala Dinner of the Symposium at the  
Grand Hotel Rimini in collaboration with**



14.00 - 15.00  
**Sala del Tempio**

- Keynote Lecture: "Viruses and Pandemics"**  
• Roberto Burioni – University Vita-Salute San Raffaele di Milano

## SESSION XII

### EDUCATIONAL MATERIALS: AN EFFICIENT MANAGEMENT IN THE DIGITAL ERA

**Sala del Castello 2**

15.15 - 15.30

**Introduction of the session**

- Anna Rosa Marra – AIFA (*pending confirmation*)

**Moderator:**

- Andrea Oliva – AFI – Viatrix

15.30 - 16.00

**AIFA's point of view**

- Giovanni Diana – AIFA (*pending confirmation*)

16.00 - 16.30

**AFI Project: "Rethinking Safety Communication"**

- Matteo Monti, Maria Signorelli – AFI – Roche

16.30 - 17.00

**Coffee break**

17.00 - 17.30

**Trade associations' involvement: double interview**

- Serena Dominici – SIFO
- Annalisa Scopinaro – UNIAMO

17.30 - 18.30

**Panel discussion**

**Moderator:**

- Andrea Oliva – AFI – Viatrix
- Giovanni Diana – AIFA (*pending confirmation*)
- Simonetta Palazzini – A.U.S.L. Romagna
- Vincenza Panzarella – AFI – Gilead Sciences
- Giovanna Pescatore – Farmindustria
- Milena Sirtori – Eupati
- Romina Tulimiero – Egualea

18.30 - 18.45

**Discussion and end of session**

- Andrea Oliva – AFI – Viatrix

20.00

**Gala Dinner of the Symposium at the  
Grand Hotel Rimini in collaboration with**



14.00 - 15.00  
Sala del Tempio

- Keynote Lecture: "Viruses and Pandemics"**  
• Roberto Burioni – University Vita-Salute San Raffaele di Milano

## SESSION XIII

### RESEARCH AND DEVELOPMENT OF NEW THERAPEUTICAL APPROACH IN GASTROENTEROLOGY: CLINICAL, PHARMACOLOGICAL AND SOCIAL ASPECTS

Sala dell'Arco

- 15.15 - 15.25      **Welcome address and introduction to the session**  
• Carla Caramella – AFI – University of Pavia
- Moderators:**
- Paolo Caliceti – AFI – SITELF – University of Padua
  - Matteo Cerea – AFI – SITELF – University of Milan
  - Andrea Gazzaniga – AFI – University of Milan
- 15.25 - 15.40      **Gastrointestinal tract pathologies: drugs, trends, therapies, and perspectives**  
• Massimo Pedrani – AFI – Mogon Pharmaceuticals
- 15.40 - 16.00      **Pharmacological needs in gastroenterology: old drugs and new necessities**  
• Edda Battaglia – ASL T04
- 16.00 - 16.30      **Pancreatic enzyme replacement therapy in the treatment of pancreatic exocrine insufficiency. Clinical and regulatory pathway**  
• Marco Anelli, Massimo Latino – 4S4P
- 16.30 - 16.45      **Eosinophilic esophagitis: a new medical need?**  
• Salvatore Agostino Giammillari – AFI – DMX Pharma
- 16.45 - 17.05      **Oral drug delivery for the treatment of gastrointestinal pathologies**  
• Anastasia Foppoli – AFI – University of Milan
- 17.05 - 17.15      **Discussion and end of session**
- 20.00      *Gala Dinner of the Symposium at the Grand Hotel Rimini in collaboration with*  **tecniche nuove**

14.00 - 15.00  
**Sala del Tempio**

**Keynote Lecture: "Viruses and Pandemics"**  
• Roberto Burioni – University Vita-Salute San Raffaele di Milano

## SESSION XIV

### FUNCTIONAL AND INNOVATIVE PHARMACEUTICAL EXCIPIENTS

**Sala dell'Arco**

17.15 - 17.20

**Introduction of the session**

- Bice Conti – AFI – SITELF – University of Pavia
- Stefano Salmaso – CRS Italy Chapter President – University of Padua

**Moderators:**

- Bice Conti – AFI – SITELF – University of Pavia
- Stefano Salmaso – CRS Italy Chapter President – University of Padua

17.20 - 17.40

**Introduction**

- Laura Rampi – Croda

**High purity excipients for solubility and bioavailability enhancement**

- William Small – Croda

17.40 - 18.00

**Lipid excipients: the key to improve solubility and intestinal permeation of poorly soluble drugs**

- Héloïse Imbault – Gattefossé

18.00 - 18.20

**Sustainable and conventional excipients: balancing innovation and performance**

- Francesco Puoci – Università della Calabria

18.20 - 18.40

**Excipienti PEGilati**

- Paolo Caliceti – AFI – SITELF – University of Padua

18.40 - 19.00

**Regulatory aspects of pharmaceutical excipients**

- Maria Vitocolonna – AIFA (*pending confirmation*)

19.00 - 19.20

**Panel discussion with every panelist**

19.20 - 19.45

**CRS Italy Chapter Annual Meeting**

20.00

**Gala Dinner of the Symposium at the  
Grand Hotel Rimini in collaboration with**





## SESSION XV

### 2025 PRODUCTION: NEWS AND FUTURE DEVELOPMENTS

#### Sala del Tempio

- 09.00 - 09.05      **Introduction of the session**
- Lino Pontello – AFI
- Moderators:**
- Lino Pontello – AFI
  - Vittorio Tonus – AFI
- 09.05 - 09.25      **Computer supports for the integrated factory: experiences on drugs and APIs manufacturing**
- Emilia Imbriani – Aschimfarma – Angelini Pharma
  - Annarita Zacchilli – AFI – Angelini Pharma
- 09.25 - 09.55      **Criteria for establishing a Cross Control Contamination Strategy in non-sterile medicinal facilities**
- Alessandro Zenoni – AFI – IBSA
- 09.55 - 10.25      **Operational aspects of Italian serialization**
- Panelist to be defined
- 10.25 - 10.45      **Discussion and questions on the first part of the morning speeches**
- 10.45 - 11.30      **Coffee break**
- Moderators:**
- Luciano Gambini – AFI
  - Francesca Selmin – AFI – University of Milan
- 11.30 - 11.50      **The risk analysis for IMP production in manufacturing facilities**
- Sebastiano Carangelo – AFI – Evotec
  - Claudio Pagano – AFI – Evotec
- 11.50 - 12.20      **Elements of Quality by Design from the early stages of a complex injectable drug development**
- Marinella Capuzzi – AFI – Italfarmaco
  - Silvia Piersanti – PTM Consulting
- 12.20 - 12.50      **Experimental injectable products based on lipid nanoparticles: study and development**
- Giovanni Ghezzi – Thermo Fisher Scientific
  - Umberto Romeo – CordenPharma
- 12.50 - 13.00      **Discussion and end of session**
- 13.00 - 14.30      **Working lunch**

## SESSION XVI

### HOW THE PHARMACEUTICAL INDUSTRY IS EVOLVING WITH THE INTRODUCTION OF TECHNOLOGY SUCH AS AI AND DIGITAL MEDICAL DEVICES

#### Sala del Castello 1

- 09.00 - 09.15      **Introduction of the session**
- Massimo Beccaria – AFI – Advice Pharma
  - Elisa Stefanini – AFI – Portolano Cavallo Law Office
- Moderators:**
- Massimo Beccaria – AFI – Advice Pharma
  - Elisa Stefanini – AFI – Portolano Cavallo Law Office
- 09.15 - 09.35      **Overview of the Italian digital system in healthcare: from AI to big-data**
- Enrico Caiani – Politecnico di Milano
- 09.35 - 09.55      **Criteria for the definition of Integrating digital health into the strategies of a global pharmaceutical company**
- Monica Lispi – Merck
- 09.55 - 10.15      **Innovation applied to drug distribution in clinical trials field: the Palladio Group case study**
- Gabriele Molari – AFI – Palladio Group
- 10.15 - 10.45      **Italian digital health: diffusion and future prospects, data from Politecnico di Milano's observatory**
- Chiara Sgarbossa – Politecnico di Milano
- 10.45 - 11.30      **Coffee break**
- Moderators:**
- Sara Cazzaniga – AFI – IQVIA
  - Stefania Cercone – Jazz Pharmaceuticals
- 11.30 - 11.50      **Why secondary reuse of data: the MUSA case study**
- Ernesto Damiani – University of Milan
- 11.50 - 12.10      **Use of digital medical devices: the RTA case study**
- Laura Liberati – Sanofi
- 12.10 - 12.20      **Italy's first digital therapy for obesity: where are we now?**
- Laura Lazzarotti – Theras Group
- 12.20 - 12.40      **Strategy and implementation of a digital therapy from a pharmaceutical industry: Polifarma's Quark project**
- Andrea Bracci – Polifarma
- 12.40 - 13.00      **Innovation processes in a large company: Astrazeneca case study**
- Valeria Lovato – AFI – Astrazeneca
- 13.00 - 13.15      **Discussion and end of session**
- 13.00 - 14.30      **Working lunch**

## SESSION XVII

### MARKET AND CRITICALITIES OF API AND EXCIPIENTS' MANAGEMENT

#### Sala del Castello 2

- 09.30 - 09.35      **Introduction of the session**
- Piero Iamartino – AFI – EIPG
- Moderator:**      • Piero Iamartino – AFI – EIPG
- 09.35 - 09.55      **The future turmoil in the API world**
- Marcello Fumagalli – CPA
- 09.55 - 10.15      **Critical drug shortages in Europe: the Critical Medicine Act and the perspective of API manufacturers**
- Pierfrancesco Morosini – Aschimfarma
- 10.15 - 10.35      **API supply chain and key factors of drug shortages**
- Maurizio Battistini – AFI – EIPG
- 10.35 - 10.55      **Using the Formalized Risk Assessment to secure the excipient supply chain**
- Iain Moore – IPEC Europe
- 10.55 - 11.15      **AIFA Speech**
- Ufficio GMP API Speaker (*pending confirmation*)
- 11.15 - 11.45      **Coffee break**

## SESSION XVIII

### TRENDS AND SOCIAL PHENOMENA IN THE DRUGS' SUPPLY CHAIN

Sala dell'Arco

#### FIRST SECTION

##### **Diversity Pills: Gender Equality and Inclusion in the Evolution of the Pharmaceutical Industry.**

The world is changing, and the pharmaceutical industry must evolve with it! Gender equality and inclusion are not only about women, but also about men and all the diversity that enriches our field. From scientific research to decision-making roles, how can we overcome stereotypes and biases to build more equitable and innovative workplaces? Through case studies, best practices and an open debate with industry experts, we will explore how to value all skills and perspectives, creating a future where talent is the only true criterion for success.

09.30 - 09.40

##### **Introduction of the session**

- Paola Minghetti – AFI Vice-president – University of Milan

09.40 - 09:55

##### **Presentation**

- Alessandro Libero Lorini – AFI – Boiron

09.55 - 11.00

##### **Panel discussion**

##### **Moderator:**

- Paola Minghetti – AFI Vice-president – University of Milan

##### **Panelists:**

- Maria Lisa Platania – Incrementum Factory
- Rosa Sant'Angelo – A.U.S.L Romagna
- Olimpia Alessandra Zuliani – AFI – HBA – Daiichi Sankyo Italia

11:00 - 11:30

##### **Coffee break**

#### SECOND SECTION

##### **Women and startups in life science: a winning combination**

Recent editions of the AFI Symposium have included highly successful sessions regarding Start-ups in the pharma/device/HealthCare world and sessions on the contribution of women in the pharma world. It was decided to combine these two topics that are considered to be of enormous importance to the success of successful projects. What contribution and added value can women provide in relation to start-ups in HealthCare?

In this session, practical cases will be presented and the two topics will be explored jointly.

11.30 - 11.40

##### **Introduction of the session**

- Lorenzo Cottini – AFI – Evidence Health
- Maria Luisa Nolli – AFI – NCNbio

11.40 - 11.55

##### **Presentation**

- Relatore da definire

11.55 - 12.50

##### **Panel discussion**

##### **Moderators:**

- Lorenzo Cottini – AFI – Evidence Health
- Maria Luisa Nolli – AFI – NCNbio

##### **Panelists:**

- Panelists to be defined

12.50 - 13.00

##### **Discussion and end of session**

13.00 - 14.30

##### **Working lunch**

### THURSDAY 12<sup>TH</sup> JUNE - GALA DINNER AT GRAND HOTEL RIMINI

#### Luigi Cavenaghi Award

This Award was established by Dr Maria Luisa Nolli in memory of Dr Luigi Cavenaghi for young researchers and is given to the best poster presented at the Symposium.

### POSTER

The **64<sup>th</sup> AFI Symposium** includes the presentation of posters about original research on topics that are relevant for the entire pharmaceutical supply chain, from chemically-synthesized drugs to biotech products to advanced therapies. The topics covered are design, development, innovative solutions in quality control and quality assurance, manufacturing, intellectual property protection, clinical trials, regulatory affairs and therapeutic use.

A Q&A session is scheduled to allow participants to discuss with the authors of the posters. The most interesting and innovative poster selected by a Committee of Experts appointed by AFI will be awarded a prize of € 1,000 established by Dr. Maria Luisa Nolli, co-founder of NCNbio, in memory of Dr. Luigi Cavenaghi, former president of the company. A certificate acknowledging their special scientific contribution will be awarded to the posters ranked second and third.

**The award ceremony will take place in the evening on Thursday 12<sup>th</sup> June at the Grand Hotel Rimini, during the Gala Dinner.**

The poster submission form and the abstract template must be received **no later than 15<sup>th</sup> May 2025** (firm deadline) using the form that can be filled in at the following address:

<https://simposio.afiscientifica.it/eventi-e-formazione/poster-2025/>

**For further information, please contact Dr. Giovanni Boccardi**  
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Tel. +39 02 4045361 - +39 02 4047375 - Fax +39 02 48717573  
e-mail: [segreteria@afiscientifica.it](mailto:segreteria@afiscientifica.it)

The Poster Committee will review the abstracts received, verify that they come with a statement attesting that the research work has never been published before and approve or reject their eligibility for presentation at the Symposium.

The Authors of accepted posters will be notified and invited to register for the Symposium, along with any contributors; **this registration is free of charge and mandatory** for organizational purposes and grants access to the exhibition area, participation in the 2 Keynote Lecture, the SESSION XVIII "Trends and social phenomena in the drugs' supply chain" and the Poster Session.

**[CLICK HERE for online registration](#)**

**However, access to the Scientific Sessions is subject to a fee and requires registration to the Symposium.**

**[CLICK HERE for online paid registration](#)**

Accepted posters will remain on display in the lobby of the Sala dell'Arco until the end of the Symposium. Abstracts of accepted posters will be published in the Symposium Proceedings and be available online on the Symposium website.

On **12<sup>th</sup> June**, from 12:30 to 14.30, one of the Authors must be present next to their poster to answer any questions from participants about their work.

## RECIPHARM ITALIA AWARD

Recipharm Italia, a leading CDMO, promotes with Italian university the award for the best dissertation on **"Quality by Design (QbD) in the development and control of sterile pharmaceutical forms"**.

The award aims to strengthen the link between the academic world and the industry, offering an opportunity to young people who are finishing their studies. The two best entries, selected by a jury of experts from both industry and academia backgrounds, will be awarded with a monetary recognition prize and a certificate of merit.

**The award ceremony will take place in the evening on Thursday 6th June at the Grand Hotel Rimini, during the Gala Dinner, a special occasion to celebrate the achieved results and foster networking among industry leaders.**

For further information, please contact the AFI Secretariat by sending an e-mail to: [segreteria@afiscientifica.it](mailto:segreteria@afiscientifica.it)

Participants should send in their dissertations. In the case of undergraduate candidates, their preliminary version will be also accepted.

**The two best papers will receive a prize in the amount of €500.00/CAD, which will be bestowed during the AFI Symposium.**



### TIME

- **By 28th of April 2025**, submission of dissertations, written in Italian, to the AFI secretariat via e-mail [segreteria@afiscientifica.it](mailto:segreteria@afiscientifica.it)
- **By 26th of May**, dissertations evaluation from the Commission
- **By 12th of June 2025**, award ceremony at the Grand Hotel in Rimini during the Gala Dinner
- Recipharm will be glad to host the winners

## GENERAL INFORMATION

### SCIENTIFIC SECRETARIAT

#### AFI

Viale D. Ranzoni, 1 - 20149 MILAN (Italy)

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[segreteria@afiscientifica.it](mailto:segreteria@afiscientifica.it)

Opening hours: 13.30 - 17.30 from Monday to Friday

[www.afiscientifica.it](http://www.afiscientifica.it)

### ORGANIZING SECRETARIAT

#### NEW AURAMEETING S.r.l.

Via Rocca D'Anfo, 7 - 20161 MILAN (Italy)

Ph. +39 02 66203390

Fax +39 02 45486457

[eventi@newaurameeting.it](mailto:eventi@newaurameeting.it)

Opening hours: 09.00 - 17.30 from Monday to Friday

[www.newaurameeting.it](http://www.newaurameeting.it)

## REGISTRATION FEES

	Until 13 <sup>th</sup> May		After 13 <sup>th</sup> May	
	VAT EXCLUDED	22% VAT INCLUDED	VAT EXCLUDED	22% VAT INCLUDED
<b>AFI, AFTI, CRS, SITELF Members</b>	€ 850,00	€ 1.037,00	€ 1.050,00	€ 1.281,00
<b>Non Members</b>	€ 1.100,00	€ 1.342,00	€ 1.200,00	€ 1.464,00
<b>Public Bodies, Universities, University Hospital, Community Hospitals, Ministries</b> (excluding working lunches, WHITE&BLUE Beach Party and Gala Dinner)	€ 400,00	€ 488,00	€ 450,00	€ 549,00
<b>Daily fee</b> (for registration to one of the three Symposium days, excluding WHITE&BLUE Beach Party and Gala Dinner)	€ 600,00	€ 732,00	€ 650,00	€ 793,00
<b>Daily fee for Public Bodies, University, University Hospitals, Community Hospitals, Ministries</b> (for registration to one of the three Symposium days, excluding WHITE&BLUE Beach Party and Gala Dinner)	€ 250,00	€ 305,00	€ 250,00	€ 305,00

### THE REGISTRATION FEE INCLUDES

- Access to the Scientific Sessions and the exhibition area
- Congress proceedings and documents
- Three working lunches (not included in the fees for Public Bodies)
- Four coffee breaks
- WHITE&BLUE Beach Party on 11<sup>th</sup> June (not included in the daily fee and the fee for Public Bodies)
- Gala Dinner on 12<sup>th</sup> June (not included in the daily fee and the fee for Public Bodies)

**50% of the fee will be refunded for CANCELLATIONS received no later than 17<sup>th</sup> May 2025. No refunds will be given after that date.**

**Online registration must be completed by 31<sup>st</sup> May 2025**

**[CLICK HERE](http://simposio.afiscientifica.it/)**

**For further information, please visit the website <http://simposio.afiscientifica.it/>**

### HOTEL BOOKING


New Aurameeting offers a selection of hotel deals for the days of the Symposium; hotel fees include a **shuttle service** from the selected Hotel to the Palacongressi of Rimini and back running from the beginning and the end of the sessions of the Symposium.

**[Download the hotel reservation form](#)**

**to be sent by 17<sup>th</sup> May 2025 to:**

[eventi@newaurameeting.it](mailto:eventi@newaurameeting.it)

# TIMETABLE

	<b>Wednesday 11<sup>th</sup> June</b> <b>14.00 - 19.00</b>	<b>Thursday 12<sup>th</sup> June</b> <b>09.00 - 13.30</b>	<b>Thursday 12<sup>th</sup> June</b> <b>14.00 - 19.45</b>	<b>Friday 13<sup>th</sup> June</b> <b>09.00 - 13.15</b>
<b>SALA DEL TEMPIO</b>	<b>14.00 – 15.00</b> <b>WELCOME AND OPENING OF THE SYMPOSIUM</b>	<b>09.00 – 11.00</b> <b>SESSION IV</b> HTA Regulation from JCA to Full HTA in Italy	<b>14.00 – 15.00</b> <b>Keynote Lecture</b> Viruses and Pandemics	<b>09.00 – 13.00</b> <b>SESSION XV</b> 2025 Production: news and future developments
	<b>15.15 – 18.45</b> <b>SESSION II</b> From 4.0 to 5.0: a guideline and some practical examples	<b>11.30 – 13.00</b> <b>SESSION V</b> Package leaflet digitalization: Where we stand and future perspectives	<b>15.15 – 18.45</b> <b>SESSION X</b> Innovation and application of the new technologies for substance-based Medical Devices in the field of MDR	
<b>SALA DEL CASTELLO 1</b>	<b>15.15 – 19.00</b> <b>SESSION I</b> New compliances and real-life cases in the sustainability of the pharmaceutical world: challenges and opportunities	<b>09.00 – 13.00</b> <b>SESSION VII</b> The new frontiers of Advanced Therapies: from production to delivery	<b>15.15 – 18.45</b> <b>SESSION XI</b> Criticalities and opportunities within drugs distribution	<b>09.00 – 13.15</b> <b>SESSION XVI</b> How the pharmaceutical industry is evolving with the introduction of technology such as AI and digital medical devices
<b>SALA DEL CASTELLO 2</b>	<b>15.15 – 18.45</b> <b>SESSION III</b> Digitalization, decentralization, Real World Evidence: how to make Italy and Europe competitive in the field of clinical research	<b>09.00 – 13.00</b> <b>SESSION VI</b> Evolution of the Pharmaceutical Quality System for the continuity of business and the prevention of drugs shortages	<b>15.15 – 18.45</b> <b>SESSION XII</b> Educational materials: an efficient management in the digital era	<b>09.30 – 11.15</b> <b>SESSION XVII</b> Market and criticalities of API and excipients' management
<b>SALA DELL'ARCO</b>		<b>09.00 – 11.00</b> <b>SESSION VIII</b> Digital innovation in the research field, development and management of special productions: opportunities and challenges	<b>15.15 – 17.15</b> <b>SESSION XIII</b> Research and development of new therapeutical approach in gastroenterology: clinical, pharmacological and social aspects	<b>09.30 – 13.00</b> <b>SESSION XVIII</b> Trends and social phenomena in the drugs' supply chain
		<b>11.30 – 13.30</b> <b>SESSION IX</b> Evolution of the VALUE BASED HEALTHCARE supported by the patient voice for an "ad personam" health system, through the assistance of digital technology as well	<b>17.15 – 19.45</b> <b>SESSION XIV</b> Functional and innovative pharmaceutical excipients	
<b>FOYER SALA DELL'ARCO</b>		<b>12.30 – 14.30</b> <b>POSTER SESSION</b>		



**Scientific Secretariat**

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Associazione Farmaceutici Industria  
Società Scientifica

