

From knowledge to digitalization for competitiveness of the health industry



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

**PROGRAMME** 

#### SYMPOSIUM COMMITTEES



#### SCIENTIFIC COMMITTEE

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- Alberto Bartolini AFI CIT
- Maurizio Battistini AFI EIPG
- Massimo Beccaria AFI Advice Pharma Group
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- Pierfelice Ferrari AFI
- Andrea Gazzaniga AFI University of Milan
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- 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
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- 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
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- Emiliano Celli New Aurameeting

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#### Coordinator:

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#### Members:

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Giovanni Boccardi - AFI

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

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- Aldo Bernuzzi New Aurameeting
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- 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
	ABC FARMACEUTICI
26 77	ACOTEC MANGINI TURNKEY DIVISION
2	ADEODATA
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45	AKKODIS ITALY
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18	CAMST - Life Science Solutions
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15	EUROMED PHARMA SERVICES
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48	EVIDENZE HEALTH
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25	FARMADATI ITALIA
36-53	Farmo Res
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7	Fine Foods & Pharmaceuticals
60-61	FLARER Cysfibay Cud
20 145	Grafibox Sud
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## **MEETING POINTS**

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105	KYMOS GROUP
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39	LABOTICS ITALIA
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130 64	LifePea   Digitalizing Life Science
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3	MAKING LIFE
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12	MASTERFILTER
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99 59	Merck Life Science
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132	OMRON
124	ORISE
57	P.B.L.
63 125-144	PEC - Pharma Education Center
71	PHA.SE. ENGINEERING & COMPLIANCE SERVICES 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
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95-96	QStep QUALIMETRIX
156	QUASCENTA PTE. ITD.
14	RATTIINOX
11	RECIPHARM ITALIA
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51	S4BT
145	SafetyDrugs SALEDMANN ITALIA
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41	SERVICE PHARMA CHEMICAL & FOOD
101	SIEMENS
47	SOITRA
97	SOLTECH
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# From knowledge to digitalization for competitiveness of the health industry

The 64th AFI Symposium on "From knowledge to digitalization for competitiveness of the health industry" will take place as usual at the Palacongressi of Rimini from 11th to 13th 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 64th 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 start on Wednesday afternoon with a speech by Giorgio Bruno, AFI President, followed by the Keynote speech by Lucio Poma, Nomisma Chief Economist, who will focus on the theme: 'Shifts in the healthcare world'. 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>™</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	Workshop (free admission subject to mandatory registration)	
Sala del Borgo	AM Instruments: Beyond compliance: strategies and innovation to face Annex 1's challenges	
Sala della Marina 2	• Bonfiglioli Consulting in collaboration with expert.ai: Digital, data, intelligence: how to bring the pharmaceutical industry into the future	
Sala della Marina 1	<ul> <li>Eurofins BioPharma Product Testing Italy: Innovation and new technologies in microbiology: The frontier of "Rapid Methods"</li> </ul>	
Sala del Faro	• Eurofins Medical Device Services: Medical devices — Contaminants on trial: a matter of manufacture?	
Sala del Parco 1	• FTR ADVISOR: Are we in possesion of "quality" clinical data relevant to the intended purpose of our medical device? Means to obtain them in the pre/post market	
Sala del Parco 2	• PTM CONSULTING: The necessary change of pace to integrate combination products in the pharmaceutical industry	
13.30	Inauguration of the 64 $^{\rm th}$ AFI Symposium at the entrance of the exhibition area	
12.30 - 14.00	Welcome lunch	
14.00 - 15.00 <b>Sala del Tempio</b>	<ul> <li>Giorgio Bruno – AFI President</li> <li>Welcome and Opening of the Symposium</li> </ul>	

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

Lucio Poma – Nomisma Chief Economist

Shifts in the healthcare world

**Keynote Speech** 

#### **TECHNICAL AND SCIENTIFIC SESSIONS**

15.15 – 19.00 Sala del Castello 1	SESSION I – ENERGY AND SUSTAINABILITY  New compliances and real-life cases in the sustainability of the pharmaceutical world: challenges and opportunities
15.15 – 18.45 <b>Sala del Tempio</b>	SESSION II – INNOVATION From 4.0 to 5.0: a guideline and some practical examples

15.15 - 18.45• SESSION III – CLINICAL RESEARCH Digitalization, decentralization, Real World Evidence: how to make Italy and Europe competitive in the field of clinical re-Sala del Castello 2 search

20.00

WHITE&BLUE Beach Party > bluenext << adjuto > at the Beach of Grand Hotel Rimini in collaboration with



#### THURSDAY 12<sup>™</sup> JUNE

09.00 - 11.00 **Sala del Tempio**  SESSION IV – HTA
 HTA Regulation from JCA to Full HTA in Italy

11.30 - 13.00 **Sala del Tempio** 

SESSION V – REGULATORY
 Package leaflet digitalization: Where we stand and future perspectives

09.00 - 13.00 Sala del Castello 2 • SESSION VI – QUALITY

Evolution of the Pharmaceutical Quality System for the continuity of business and the prevention of drugs shortages

09.00 - 13.00 Sala del Castello 1 SESSION VII – BIOTECH

The new frontiers of Advanced Therapies: from production to delivery

09.00 - 11.00 **Sala dell'Arco** 

SESSION VIII – SPECIAL PRODUCTIONS

Digital innovation in the research field, development and management of special productions: opportunities and challenges

11.30 - 13.30 Sala dell'Arco • SESSION IX - PATIENT VOICE & VALUE (PVV)

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

12.30 - 14.30 **Foyer Sala dell'Arco** 

POSTER SESSION

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.

12.30 - 14.00

Working lunch

14.00 - 15.00 **Sala del Tempio** 

 Roberto Burioni – University Vita-Salute San Raffaele di Milano Keynote Lecture (free admission)
 Viruses and Pandemics

15.15 - 18.45 **Sala del Tempio** 

SESSION X — MEDICAL DEVICES

Innovation and application of the new technologies for substance-based Medical Devices in the field of MDR

15.15 - 18.45 **Sala del Castello 1**  • SESSION XI — SUPPLY CHAIN

Criticalities and opportunities within drugs distribution

15.15 – 18.45 **Sala del Castello 2**  SESSION XII - PHARMACOVIGILANCE

Educational materials: an efficient management in the digital era

15.15 – 17.15 **Sala dell'Arco**  SESSION XIII – PHARMACEUTICAL SCIENCES (AFI/SITELF)

 Percarch and development of new therapeutical approximation.

Research and development of new therapeutical approach in qastroenterology: clinical, pharmacological and social aspects

17.15 – 19.45 **Sala dell'Arco** 

• SESSION XIV - CRS/SITELF

Functional and innovative pharmaceutical excipients

20.00

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





#### **GENERAL PROGRAMME**

#### FRIDAY 13<sup>™</sup> JUNE

09.00 - 13.00 **Sala del Tempio** 

09.00 - 13.15 Sala del Castello 1

09.30 - 11.15 Sala del Castello 2

09.30 - 13.00 Sala dell'Arco

13:00 - 14:30

• SESSION XV – PRODUCTION 2025 Production: news and future developments

• SESSION XVI — DIGITAL HEALTH

How the pharmaceutical industry is evolving with the introduction of technology such as AI and digital medical devices

- SESSION XVII RAW MATERIALS

  Market and criticalities of API and excipients' management
- SESSION XVIII (free admission)
   Trends and social phenomena in the drugs' supply chain

Working lunch



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

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

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

WEDNESDAY 11<sup>™</sup> JUNE • AFTERNOON



- Giorgio Bruno AFI President Welcome and Opening of the Symposium
- Lucio Poma Nomisma Chief Economist Keynote Speech
  Shifts in the healthcare world

**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	<ul> <li>2024 ERA (Environmental Risk Assesment) revision and its implementation in the drug industry</li> <li>Ivo Caldera – AFI</li> <li>Piero lamartino – AFI – EIPG</li> </ul>
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 lacoangeli – 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



14.00 - 15.00 Sala del Tempio · Giorgio Bruno - AFI President Welcome and Opening of the Symposium

· Lucio Poma - Nomisma Chief Economist

Kevnote Speech

Shifts in the healthcare world

Technical and scientific sessions

### **SESSION II**

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

#### Sala del Tempio

Welcome address and introduction to the session 15.15 - 15.20

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

Al and ML, new opportunities for performance improvement in pharmaceutical production

Claudio Ernesto Mario Manzati – AFI – 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

> bluenext << adjuto :





- Giorgio Bruno AFI President Welcome and Opening of the Symposium
- Lucio Poma Nomisma Chief Economist Kevnote Speech Shifts in the healthcare world

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

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

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

> bluenext << adjuto >



## **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:	<ul> <li>Simona Montilla – AIFA (pending confirmation)</li> <li>Anna Ponzianelli – AFI – Moderna</li> </ul>
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:	<ul> <li>Valeria Fava – Cittandinanzattiva</li> <li>Walter Marrocco – FIMMG, CSE</li> <li>Simona Montilla – AIFA (pending confirmation)</li> <li>Giandomenico Nollo – SIHTA President</li> <li>Carlo Riccini – Farmindustria</li> </ul>
10.45 - 11.00	Discussion and end of session
11.00 - 11.30	Coffee break





## 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	<ul> <li>EMA pilot project</li> <li>Margherita Parziale – AIFA (pending confirmation)</li> </ul>
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 Gastello 2
09.00 - 09.10	Introduction of the session  • Alessandro Regola — AFI Vice-president
Moderators:	<ul> <li>Giovanni Boccardi – AFI</li> <li>Alessandro Regola – AFI Vice-president</li> </ul>
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 — AFI — MITIM Recipharm
09.40 - 10.10	Risk Management and Guaranteeing the Continuity of Supplies <ul> <li>Silvia Sanzone – AFI – Galenica Senese</li> <li>Tania Perfetti – AFI – Ingenus Pharmaceuticals</li> </ul>
10.10 - 10.40	US FDA speech on programme "Quality Management Maturity" • Panelist to be determined
10.40 - 11.10	Coffee Break
Moderators:	<ul> <li>Marco Adami – AFI</li> <li>Lino Pontello – AFI</li> </ul>
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





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

09.00 - 09.05	Welcoming  • Marica Nobile — Assobiotec  • 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:	<ul> <li>Stefano Baila – AFI – Eurofins-Biolab</li> <li>Monica Gunetti – AFI – Bambino Gesù Children's Hospital</li> </ul>
Panelists:	<ul> <li>Beatrice Berti – Fondazione Policlinico Universitario Agostino Gemelli IRCCS</li> <li>Valentina Fonsato – 2i3T – University of Turin</li> <li>Marco Paolo Fulfaro – AIFA (pending confirmation)</li> <li>Claudia Maldini – AFI – Miltenyi Biotec</li> <li>Andrea Quadrio – AFI – Gilead / Kite</li> <li>Anna Silvani – AFI – Assobiotec</li> <li>Cristina Zanini – IWT Pharma</li> </ul>
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:	<ul> <li>Marilena Carazzone – AFI</li> <li>Floriana Raso – AFI</li> </ul>
	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 – AFI – IRCCS Istituto Romagnolo per lo studio dei tumori "Dino Amadori" IRST  • Anna Tolomeo – AFI – 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:	<ul> <li>Alessandro Assisi – AIFA (pending confirmation)</li> <li>Marco Biagi – Università degli Studi di Parma</li> <li>Lorella Chiappinelli – AIFA (pending confirmation)</li> <li>Giorgio Cappellucci – SIFIT</li> <li>Andrea Fieschi – Assogastecnici</li> <li>Manuela Monti – AFI – IRCCS Istituto Romagnolo per lo studio dei tumori "Dino Amadori" IRST</li> <li>Anna Tolomeo – AFI – Itelpharma</li> </ul>
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	<ul> <li>Human Value Based Healthcare – HVBH and case studies</li> <li>Maria Rosaria Natale – Your Business Partner</li> </ul>			
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:	<ul> <li>Simona Aloe – AFI – Daiichi Sankyo Italia</li> <li>Maria Rosaria Natale – Your Business Partner</li> <li>Laura Patrucco – AFI – PRINEOS</li> </ul>			
	<ul> <li>Monica Calamai – ASP Crotone – Community Donne Protagoniste in Sanità</li> <li>Marco Greco – EPF</li> <li>Tiziana Pia Latiano – AIOM</li> <li>Giandomenico Nollo – SIHTA</li> <li>Teresa Petrangolini – ALTEMS – Catholic University of the Sacred Heart</li> <li>Annalisa Scopinaro – UNIAMO</li> <li>Relatore da definire – F.A.V.O.</li> </ul>			
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:	<ul> <li>Simona Aloe – AFI – Daiichi Sankyo Italia</li> <li>Laura Patrucco – AFI – PRINEOS</li> </ul>			
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 Dispostivi Medici			
15.50 - 16.15	Medical devices – Legislative changes and future scenarios <ul> <li>Alessandra Basilisco – Health Ministry</li> </ul>			
	PANEL DISCUSSION OPENING WITH THE NOTIFIED BODIES ALONG- SIDE THE PARTECIPATION OF:			
	<ul> <li>Daniele Bollati – IMQ</li> <li>Paolo Dentis – Eurofins TECH</li> <li>Alessia Frabetti – KIWA CERMET ITALIA</li> <li>Sara Gianellini – ITALCERT</li> <li>Pietro Iannì – CERTIQUALITY</li> <li>Roberta Marcoaldi – Italian National Institute of Health</li> <li>Chiara Novi – TUV Rheinland</li> <li>Tatiana Vignudelli – Ente Certificazione Macchine</li> </ul>			
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	Al 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			



THURSDAY 12™ JUNE • AFTERNOON

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**

15.15 - 15.30	Welcome address and introduction to the session Roberto de Luca – AFI – University of Padua
	<ul> <li>Alberto Bartolini – AFI – CIT</li> <li>Roberto de Luca – AFI – University of Padua</li> </ul>
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 – Viatris			
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 — Viatris			
	<ul> <li>Giovanni Diana – AIFA (pending confirmation)</li> <li>Simonetta Palazzini – A.U.S.L Romagna</li> <li>Vincenza Panzarella – AFI – Gilead Sciences</li> <li>Giovanna Pescatore – Farmindustria</li> <li>Milena Sirtori – Eupati</li> <li>Romina Tulimiero – Egualia</li> </ul>			
18.30 - 18.45	Discussion and end of session  • Andrea Oliva – AFI – Viatris			
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 per spectives  Massimo Pedrani – AFI – Mogon Pharmaceuticals			
15.40 - 16.00	Pharmacological needs in gastroenterology: old drugs and new necessities  Edda Battaglia — ASL TO4			
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			



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:	<ul> <li>Bice Conti – AFI – SITELF – University of Pavia</li> <li>Stefano Salmaso – CRS Italy Chapter President – University of Padua</li> </ul>
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	• 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:	<ul><li>Lino Pontello – AFI</li><li>Vittorio Tonus – AFI</li></ul>
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:	<ul> <li>Luciano Gambini – AFI</li> <li>Francesca Selmin – AFI – University of Milan</li> </ul>
	The sight analysis for IAAD and decking in accompany to sitting
11.30 - 11.50	<ul> <li>The risk analysis for IMP production in manufacturing facilities</li> <li>Sebastiano Carangelo – AFI – Evotec</li> <li>Claudio Pagano – AFI – Evotec</li> </ul>
11.30 - 11.50 11.50 - 12.20	Sebastiano Carangelo – AFI – Evotec
	<ul> <li>Sebastiano Carangelo – AFI – Evotec</li> <li>Claudio Pagano – AFI – Evotec</li> <li>Elements of Quality by Design from the early stages of a complex injectable drug development</li> <li>Marinella Capuzzi – AFI – Italfarmaco</li> </ul>
11.50 - 12.20	<ul> <li>Sebastiano Carangelo – AFI – Evotec</li> <li>Claudio Pagano – AFI – Evotec</li> <li>Elements of Quality by Design from the early stages of a complex injectable drug development</li> <li>Marinella Capuzzi – AFI – Italfarmaco</li> <li>Silvia Piersanti – PTM Consulting</li> <li>Experimental injectable products based on lipid nanoparticles: study and development</li> <li>Giovanni Ghezzi – Thermo Fisher Scientific</li> </ul>
11.50 - 12.20 12.20 - 12.50	<ul> <li>Sebastiano Carangelo – AFI – Evotec</li> <li>Claudio Pagano – AFI – Evotec</li> <li>Elements of Quality by Design from the early stages of a complex injectable drug development</li> <li>Marinella Capuzzi – AFI – Italfarmaco</li> <li>Silvia Piersanti – PTM Consulting</li> <li>Experimental injectable products based on lipid nanoparticles: study and development</li> <li>Giovanni Ghezzi – Thermo Fisher Scientific</li> <li>Umberto Romeo – CordenPharma</li> </ul>



## **SESSION XVI**

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

09.00 - 09.15	Introduction of the session  • Massimo Beccaria – AFI – Advice Pharma  • Elisa Stefanini – AFI – Portolano Cavallo Law Office
Moderators:	<ul> <li>Massimo Beccaria – AFI – Advice Pharma</li> <li>Elisa Stefanini – AFI – Portolano Cavallo Law Office</li> </ul>
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:	<ul> <li>Sara Cazzaniga – AFI – IQVIA</li> <li>Stefania Cercone – Jazz Pharmaceuticals</li> </ul>
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





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

09.30 - 09.35	Introduction of the session • Piero lamartino – AFI – EIPG
Moderator:	• Piero lamartino – AFI – EIPG
09.35 - 09.55	The future turmoil in the API world  • Marcello Fumagalli – AFI – CPA
09.55 - 10.15	Critical drug shortages in Europe: the Critical Medicine Act and the perspective of API manufacturers • Pierfrancesco Morosini – Aschimfarma President
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  • lain 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

• 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 Startups 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 – Evidenze Health

Maria Luisa Nolli – AFI – NCNbio

11.40 - 11.55 **Presentation** 

· Relatore da definire

11.55 - 12.50 **Panel discussion** 

Moderators: • Lorenzo Cottini – AFI – Evidenze 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 12TH 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**th **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>st</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 AFI - Viale D. Ranzoni, 1 - 20149 Milano Tel. +39 02 4045361 - +39 02 4047375 - Fax +39 02 48717573 e-mail: 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 12th 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:  $\underline{segreteria@afiscientifica.it}$ 

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
- 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) Ph. +39 02 4045361 - +39 02 4047375 Fax +39 02 48717573

segreteria@afiscientifica.it

Opening hours: 13.30 - 17.30 from Monday to Friday

www.afiscientifica.it

#### **ORGANIZING SECRETARIAT**

**NEW AURAMEETING S.r.I.** 

Via Rocca D'Anfo, 7 - 20161 MILAN (Italy) Ph. +39 02 66203390 Fax +39 02 45486457

eventi@newaurameeting.it

Opening hours: 09.00 - 17.30 from Monday to Friday 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
AFI, AFTI, CRS, SITELF Members	€ 850,00	€ 1.037,00	€ 1.050,00	€ 1.281,00
Non Members	€ 1.100,00	€ 1.342,00	€ 1.200,00	€ 1.464,00
Public Bodies, Universities, University Hospital, Community Hospitals, Ministries (excluding working lunches, WHITE&BLUE Beach Party and Gala Dinner)	€ 400,00	€ 488,00	€ 450,00	€ 549,00
Daily fee (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
Daily fee for Public Bodies, University, University Hospitals, Community Hospitals, Ministries (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 11th 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 17th May 2025. No refunds will be given after that date.

Online registration must be completed by 31th May 2025
CLICK HERE

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 17th May 2025 to:

eventi@newaurameeting.it



SIMPOSIO AFI	Wednesday 11 <sup>th</sup> June 14.00 - 19.00	Thursday 12 <sup>th</sup> June 09.00 - 13.30	Thursday 12th June 14.00 - 19.45	Friday 13 <sup>th</sup> June 09.00 - 13.15	
SALA DEL TEMPIO	14.00 – 15. 00 WELCOME AND OPENING OF THE SYMPOSIUM  * Keynote Speech Shifts in the healthcare world	09.00 – 11.00 SESSION IV HTA Regulation from JCA to Full HTA in Italy  14.00 – 15.00 Keynote Lecture Viruses and Pandemics		09.00 – 13.00 SESSION XV 2025 Production: news	
DEL	15.15 – 18.45 SESSION II From 4.0 to 5.0: a guideline and some practical examples	11.30 – 13.00 SESSION V Package leaflet digitalization: Where we stand and future perspectives	15.15 – 18.45 SESSION X Innovation and application of the new technologies for substance-based Medical Devices in the field of MDR	and future developments	
SALA DEL CASTELLO 1	15.15 – 19.00 SESSION I New compliances and real-life cases in the sustainability of the pharmaceutical world: challenges and opportunities	09.00 – 13.00 SESSION VII The new frontiers of Advanced Therapies: from production to delivery	15.15 – 18.45 SESSION XI Criticalities and opportunities within drugs distribution	09.00 – 13.15 SESSION XVI How the pharmaceutical industry is evolving with the introduction of technology such as AI and digital medical devices	
SALA DEL CASTELLO 2	15.15 – 18.45 SESSION III Digitalization, decentralization, Real World Evidence: how to make Italy and Europe competitive in the field of clinical research	09.00 – 13.00 SESSION VI Evolution of the Pharmaceutical Quality System for the continuity of business and the prevention of drugs shortages	15.15 – 18.45 SESSION XII Educational materials: an efficient management in the digital era	09.30 – 11.15 SESSION XVII Market and criticalities of API and excipients' management	
.L'ARCO		09.00 – 11.00 SESSION VIII Digital innovation in the research field, development and management of special productions: opportunities and challenges	15.15 – 17.15 SESSION XIII Research and development of new therapeutical approach in gastroenterology: clinical, pharmacological and social aspects	09.30 – 13.00 SESSION XVIII	
SALA DELL'ARCO		11.30 – 13.30 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	17.15 – 19.45 SESSION XIV Functional and innovative pharmaceutical excipients	Trends and social phenomena in the drugs' supply chain	
FOYER SALA DELL'ARCO		12.30 – 14.30 POSTER SESSION			

# Associazione Farmaceutici Industria Società Scientifica

AFI SYMPOSIUM RIMINITI-12-13 J U N E 2 0 2 5

Scientific Secretariat

AFI

Viale D. Ranzoni, 1 - 20149 MILAN (Italy) Ph. +39 02 4045361 - +39 02 4047375 Fax +39 02 48717573 segreteria@afiscientifica.it

www.afiscientifica.it

Organizing Secretariat
NEW AURAMEETING S.r.I.
Via Rocca D'Anfo, 7 - 20161 MILAN (Italy)
Ph. +39 02 66203390
Fax +39 02 45486457
eventi@newaurameeting.it
www.newaurameeting.it



