



Associazione Farmaceutici Industria  
Società Scientifica

# 63°

AFI SYMPOSIUM  
RIMINI 5<sup>TH</sup> · 6<sup>TH</sup> · 7<sup>TH</sup>  
JUNE 2024



## PROGRAMME

**The main  
challenges  
for the  
Healthcare  
Industry:  
Research,  
Innovation,  
Sustainability**

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

## SYMPOSIUM COMMITTEES

**SCIENTIFIC COMMITTEE**

- Giorgio Bruno - AFI President
- Marco Adami - AFI
- Alberto Bartolini - AFI - CIT
- Maurizio Battistini - AFI - EIPG
- Massimo Beccaria - AFI - Advice Pharma Group
- Carla Caramella - AFI - University of Pavia
- Marilena Carazzone - AFI
- Bice Conti - AFI - SITELF
- Antonio Conto - AFI - Chemsafe
- Lorenzo Cottini - AFI - Evidenze Health
- Roberto De Luca - AFI
- Guido Fedele - AFI
- Pierfelice Ferrari - AFI
- Andrea Gazzaniga - AFI - University of Milan
- Piero Iamartino - AFI - EIPG
- Paola Minghetti - AFI Vice-President - University of Milan
- Alessandra Molin Zan - AFI - Zentiva Italia
- Maria Luisa Nolli - AFI - NCNbio
- Andrea Oliva - AFI - Viatris
- Massimo Pedrani - AFI - Mogon Pharmaceuticals
- Lino Pontello - AFI
- Anna Ponzianelli - AFI - Moderna
- Mauro Rainoni - AFI - Meda Pharma
- 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 Padua
- Francesca Selmin - AFI - University of Milan

**POSTER COMMITTEE****Coordinator:**

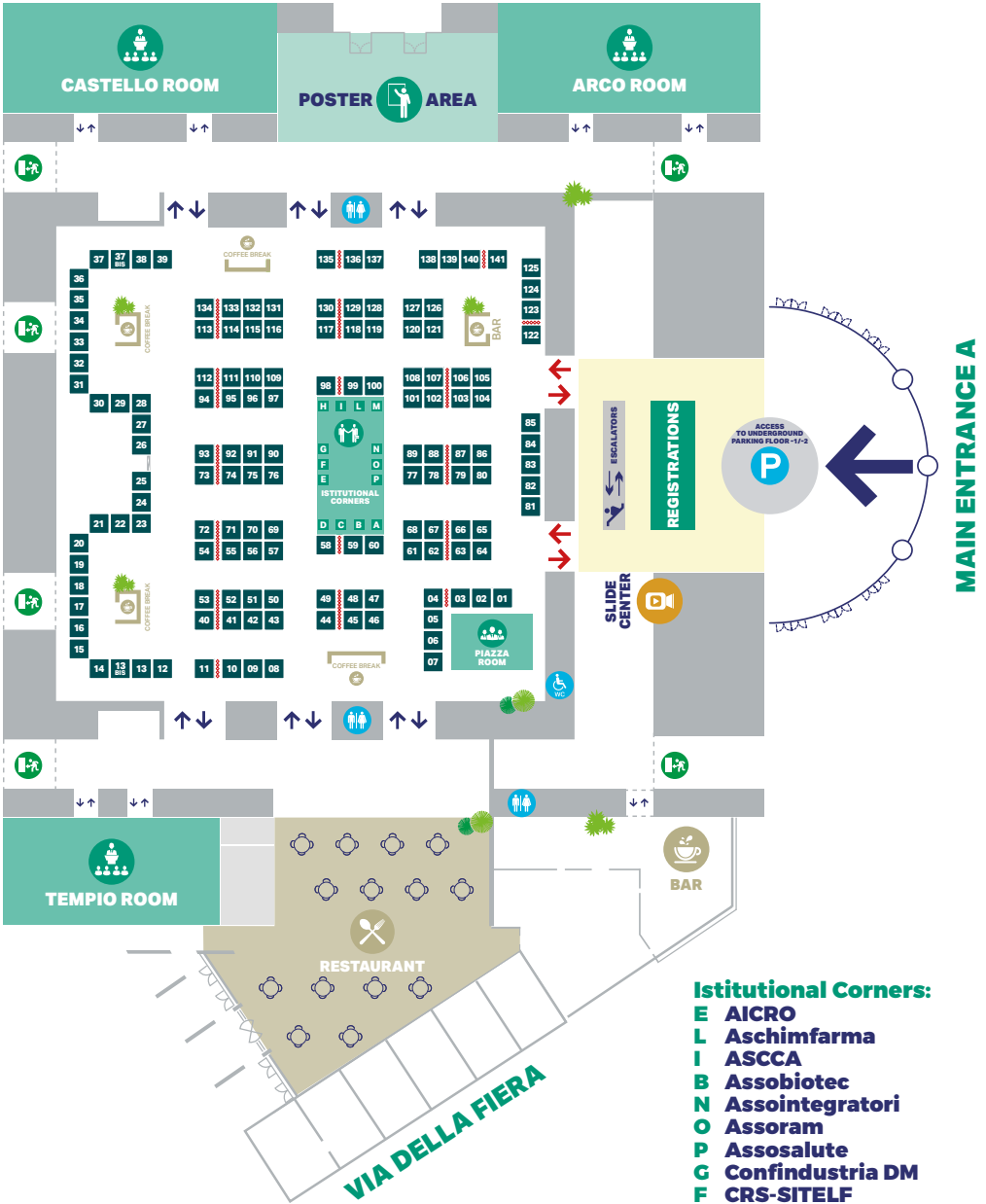
- Giovanni Boccardi - AFI

**Members:**

- Antonio Danese - AFI Communication and Press Relations - DV Informatica
- Carla Caramella - AFI - University of Pavia
- Monica Gunetti - AFI - Bambino Gesù Children's Hospital
- Maria Luisa Nolli - AFI - NCNbio
- Alessandro Regola - AFI Vice-President

**ORGANIZING SECRETARIAT**

- Sandra Del Vecchio - AFI - New Aurameeting
- Aldo Bernuzzi - New Aurameeting
- Cindy Paganoni - New Aurameeting
- Elena Pelosi - New Aurameeting
- Greta Zani - New Aurameeting



**Istitutional Corners:**

- E** AICRO
- L** Aschimfarma
- I** ASCCA
- B** Assobiotec
- N** Assointegratori
- O** Assoram
- P** Assosalute
- G** Confindustria DM
- F** CRS-SITELF
- M** Egualia
- A** Farminindustria
- D** ISPE Italy Affiliate
- C** Omeopresse
- H** PDA Italy Chapter

## 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.

**STAND NO. EXHIBITOR**

120	ABAR
31	ABC FARMACEUTICI
16	ACOTEC MANGINI TURNKEY DIVISION
121	AKKODIS ITALY
114	ALFATEST - strumentazione scientifica
109-110	ALIPHARMA
37bis	ALTEN ITALIA
68	ALTERGON ITALIA
72	AM INSTRUMENTS
57	AMITA HEALTH CARE
92	Analysis
29	ANALYTICAL CONTROL DE MORI
27	ARITHMOS
88	ASEPTCONN AG
116	ASGENIA
93	AZELIS
18	B&D ITALIA
2	BIOCLASS
38	BIOMAPAS
69	BLUENEXT - ADIUTO
74	C&P ENGINEERING - A product Life Group Company
53	CAI - Commissioning Agents Italy
66	CANNON ARTES
80	CAPSULIT
87	Cencora - World Courier
64	CHEMSAFE
132	CLARISCIENCE
51 - 52	CLEANROOM ITALIA
63	CO.RA.
11	COMECER
4	CONTENT GROUP
126 - 127	CROlife
37	CSV LIFE SCIENCE GROUP
136 - 137	CYTIVA
33	D.O.C. - DOCUMENTATION ORGANIZATION AND CONSULTANCY
76	DI RENZO REGULATORY AFFAIRS
84	ECOLAB
15	E INSTRUMENTS GROUP
54	ELLAB
3	EMGI
135	EMME 3
91	ENDRESS+HAUSER ITALIA
35	EUROCLONE
138-139-140	Eurofins BioPharma Product Testing Italy
138-139-140	Eurofins Healthcare Assurance
138-139-140	Eurofins PSS Insourcing Solutions®
138-139-140	Eurofins Regulatory & Consulting Services Italy
39	EUROMED PHARMA SERVICES
98	EURPACK
97	EUSOFT
61	EVIDENZE HEALTH
32	Farmo Res
47	FARMOL HEALTH CARE
67	FEDEGARI AUTOCLAVI
79	Fine Foods & Pharmaceuticals N.T.M.
40 - 41	FLARER
103	FUTURA - L
115	GALILEO RESEARCH
23	Grafibox Sud
94	Gruppo SASI
62	HONEYWELL
113	HSG ENGINEERING
20	I.G.B.
119	IBD
123-124	IMA
118	INDENA

# MEETING POINTS

010101  
100101  
010101  
010101

83	INNLIFES
13	INPHARMATIC
106	IQVIA Solutions Italy
108	JRS Rettenmaier Italia
70	JSB Solutions
48-49	Körber Pharma Software
24-25	KYDEA
117	KYMOS GROUP
77	LabAnalysis Process Pharma
14	LABORATOIRE HUCKERT'S INTERNATIONAL
8 - 9	LabWare
1	LB Research
43 - 50	LifeBee
26	LIVES INTERNATIONAL
71	LP Pharma
99	LS Academy
10	MAASI Enterprises
125	MAKINGLIFE
95-96	MARCHESINI GROUP
102	MIPHARM
107	m-Squared Consulting
89	NEOTRON
36	NERI LABELS
58	NEUMO
17	NICOMAC EUROPE
22	NORDTEST
1	Nubilaria ACTide®
42	OFF. MECC. RONCHI - KIKUSUI EUROPE
105	OLD PHARMA International
75	PEC - PHARMA EDUCATION CENTER - A product Life Group Company
134	PEMFLOW ITALIA
73	PHARMA D&S - A product Life Group Company
100	PHARMA PARTNERS a PALLADIO GROUP brand
111	PHARMAPROCESS
60	PHA.SE. ENGINEERING & COMPLIANCE SERVICES
86	PRC TICINUM LAB
82	PRINEOS
13bis	PROMOFLUID
56	PTM Consulting
90	PVS
6	QStep
129 - 130	QUALIMETRIX
30	RATTIINOX
12	RECIPHARM ITALIA
122	ROCKWELL AUTOMATION
101	ROFARMA ITALIA
78	ROMACO
94	SafetyDrugs
133	SAPIO SCIENCES
46	SAUERMANN ITALIA
128	SEA Vision
59	SEINGIM LIFE SCIENCE
7	SERVICE PHARMA CHEMICAL & FOOD
45	SERVITECNO
5	S-IN Soluzioni Informatiche
90	SOLTECH
81	STERIGENICS
131	STERILINE
28	SWAN Analitica
21	TEAM mastery
19	Technobis Crystallization Systems
34	Tecniche Nuove - Notiziario Chimico Farmaceutico
141	TEMA SINERGIE
85	Univar Solutions
104	UNIVERSAL PACK
44	VEGA ITALIA
65	WAB-GROUP®
112	ZETA
55	ZETA FARMACEUTICI GROUP

## The main challenges for the Healthcare Industry: Research, Innovation, Sustainability

**The 63<sup>th</sup> AFI Symposium on “The main challenges for the Healthcare Industry: Research, Innovation and Sustainability” will take place as usual at the Palacongressi of Rimini from 5th to 7th June 2024.**

The Healthcare Industry is a crucial cornerstone of the Italian economy and aims to ensure the health and well-being of the population, while generating added value and jobs. This is an interdisciplinary, complex, and dynamic economic sector with a wide range of activities, such as research, development, production of medicines and medical devices, clinical trials, distribution, and marketing. From a business perspective, it is a very competitive sector, where innovation, built on sound scientific and technological bases, plays an essential role, as does the ability to sustain medium-long term investments. From a social and professional point of view, this sector offers equal opportunities to both men and women in all job roles, including top-management positions.

In this pivotal moment marked by the rise of artificial intelligence technologies and digital therapies, the healthcare sector will have to face numerous new challenges and opportunities in the near future. Besides the increasing demand for healthcare products and services, driven by an ageing population, we are faced with a growing need to integrate diverse scientific disciplines and foster a robust innovation culture, thus seizing this opportunity to contribute to sustainable development and environmental protection. The adoption of more efficient and environment-friendly technologies and production processes can significantly help this sector become more environmentally sustainable. Not only does this approach fulfil current needs, but can also become a reference framework for the benefit of all.

It is therefore essential that we continue to invest in research and development, encouraging collaboration between companies, universities, research centres and public institutions. Such efforts will not only create new talents, but also foster new innovation networks and the dissemination of best practices on both national and international scales.

This is the context in which the 63<sup>th</sup> AFI Symposium will take place with 19 Scientific Sessions, 2 Keynote Lectures (Dr. Marcello Cattani, Sen. Elena Cattaneo) and many satellite events featuring eminent speakers from the industry, universities institutions and trade associations.

The Symposium will begin on Wednesday afternoon with a speech by the AFI President, Giorgio Bruno, to be followed by the **Keynote Lecture** held by the President of Farmindustria, Marcello Cattani, who will focus on the main topic discussed this year. This opening session will be followed by the **scientific sessions**, focusing on areas of significant interest. The **Energy and Sustainability** session will delve into the diverse facets of sustainability as applied to the pharmaceutical sector. The following sessions will be devoted to the **Supply Chain, Packaging Materials and Digital Health**, while the closing session on **Start-ups** aims to promote a culture that recognizes and promotes innovative ideas across this sector from research labs to market access.

On Thursday the morning session will start with the **Keynote Lecture** “There is no care without research” held by Sen. Elena Cattaneo. The next sessions will be on **Clinical Research**, focusing on “Innovation and Sustainability”, **Quality, HTA, and Deblistering**, ending with the **Piazza delle Donne**.

The afternoon sessions will be on **Environmental Risk Assessment** focusing on the conventional approach and the prospects related to the new European directive, **AFI-SITELF Pharmaceutical Sciences, Biotech, Pharmacovigilance, Medical Devices, Advertising and Medical and Scientific Information in the Era of Digital Technologies** and **CRF-SITELF**.

Friday will start with a session on **Parenterals** and continue with a session on **Innovation** focused on Artificial Intelligence, Process Digitalization and 4.0 GAMP 5 Validation and Qualification 2nd edition. The Symposium will end with the sessions on **APIs** and **Specialty Products**.

As usual, the **Poster** session will allow participants to showcase the results of their projects.

## WEDNESDAY 5<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)
10.00 - 12.30	<b>Workshop (free admission subject to mandatory registration)</b>
<b>Sala del Borgo 1</b>	• <b>AM Instruments:</b> Overcoming the Challenges of Annex 1: Optimization of Material Transfer Processes into Controlled Environments
<b>Sala del Borgo 2</b>	• <b>FUJIFILM:</b> Choosing the correct BET methodology
<b>Sala del Faro</b>	• <b>CHEMSAFE:</b> Clinical evidence and innovation in the evaluation of medical devices
<b>Sala della Marina 1</b>	• <b>EUROFINS:</b> Extractables & Leachables: updates on the regulation and challenges for the future
<b>Sala della Marina 2</b>	• <b>ONOBLO:</b> Let's build solutions! Let's use LEGO® bricks to overcome barriers between Quality, Production and Logistics
<b>Sala del Parco 1</b>	• <b>LIFEBEE, PHARMA D&amp;S and PRODUCTLIFE GROUP:</b> The perfect recipe for sustained Compliance and Efficiency through Digital Transformation
<b>Sala del Lavatoio</b>	• <b>PTM CONSULTING:</b> Quality risk management: how about moving beyond the FMEA?
<b>Sala del Parco 2</b>	• <b>S-IN SOLUZIONI INFORMATICHE:</b> Production processes: innovative solutions for impurity detection and evaluation and integrated information management
13.00	<b>Inauguration of the 63<sup>th</sup> AFI Symposium at the entrance of the exhibition area</b>
12.30 - 14.00	<b>Working lunch</b>
14.00 - 15.00	• Giorgio Bruno - AFI President <b>Welcome and Opening of the Symposium</b>
<b>Sala del Castello</b>	• Marcello Cattani - Farindustria President <b>KEYNOTE LECTURE</b> <b>The challenges for the Healthcare Industry: research, innovation and sustainability</b>

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

## TECHNICAL AND SCIENTIFIC SESSIONS

15.00 - 19.00	• SESSION I - ENERGY AND SUSTAINABILITY <b>Sustainability projects in the pharmaceutical sector</b>
<b>Sala del Castello</b>	
15.00 - 19.00	• SESSION II - SUPPLY CHAIN <b>The supply chain... work in progress</b>
<b>Sala del Tempio</b>	
17.00 - 19.00	• SESSION III - PACKAGING MATERIALS <b>Packaging materials: manufacturing and applications</b>
<b>Sala dell'Arco</b>	
15.00 - 17.00	• SESSION IV - DIGITAL HEALTH <b>Synergies and innovation in the healthcare sector: the rise of artificial intelligence technologies and digital therapies</b>
<b>Sala della Piazza</b>	
17.30 - 19.00	• SESSION ON START-UPS <b>Life sciences Italian strategy for innovation revolution</b>
<b>Sala della Piazza</b>	
20.00	<b>WHITE&amp;BLUE Beach Party at the Beach of Grand Hotel Rimini in collaboration with</b>



THURSDAY 6<sup>TH</sup> JUNE

- 09.00 - 10.00  
**Sala del Castello**
- Senator Elena Cattaneo  
**KEYNOTE LECTURE**  
**There is no care without research**
- 10.00 - 13.00  
**Sala del Castello**
- SESSION V - CLINICAL RESEARCH  
**The future of clinical research: innovation and sustainability**
- 10.00 - 13.00  
**Sala del Tempio**
- SESSION VI - QUALITY  
**Special quality systems**
- 10.00 - 13.00  
**Sala dell'Arco**
- SESSION VII - HTA  
**The HTA regulation is around the corner, what are the next steps? Europe and Italy among developers, stakeholders, and the Agency**
- 11.30 - 13.00  
**Sala della Piazza**
- WOMEN-IN-PHARMA FORUM  
**Women in manufacturing in the Pharma - Biotech sector**
- 12.30 - 13.30  
**Sala della Marina 1<sup>st</sup> floor**
- SESSION VIII - DEBLISTERING  
**Preparation of one-dose packages in pharmacies: risks and opportunities**
- 12.30 - 14.30  
**Lobby 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 - 14.30
- Working lunch**
- 14.00 - 15.00  
**Sala del Castello**
- SESSION IX - ENVIRONMENTAL RISK ASSESSMENT  
**Environmental risk assessment (ERA) of medicinal products. The conventional approach and the prospects related to the new European human medicine directive**
- 14.00 - 16.30  
**Sala della Marina 1<sup>st</sup> floor**
- SESSION X - PHARMACEUTICAL SCIENCES (AFI/SITELF)  
**Research, development of new approaches to diabetes treatment**
- 14.30 - 18.30  
**Sala del Tempio**
- SESSION XI - BIOTECH  
**CAR-T therapies: from recent past to near future**
- 14.30 - 16.30  
**Sala dell'Arco**
- SESSION XII - PHARMACOVIGILANCE  
**Pharmacovigilance and quality: when a quality complaint impacts patient health**
- 15.00 - 18.30  
**Sala del Castello**
- SESSION XIII - MEDICAL DEVICES  
**Synergies and innovation in the healthcare sector: the role of medical devices**
- 16.30 - 18.30  
**Sala dell'Arco**
- SESSION XIV - ADVERTISING AND PROMOTION IN THE HEALTHCARE  
**Advertising and medical and scientific information: rules and opportunities**
- 16.30 - 18.45  
**Sala della Marina 1<sup>st</sup> floor**
- SESSION XV - CRS/SITELF  
**Interaction of modified release drug delivery systems with primary packaging materials: critical issues and new characterization techniques**
- 20.00
- Gala Dinner of the Symposium at the Grand Hotel Rimini**



## FRIDAY 7<sup>TH</sup> JUNE

09.00 - 13.00

**Sala del Castello**

- SESSION XVI - PARENTERALS  
**Parenteral and lyophilized drug manufacturing: challenges and solutions according to Annex 1**

09.00 - 13.00

**Sala del Tempio**

- SESSION XVII - INNOVATION  
**An overview of Technological Innovation between the present and the near future**

09.00 - 11.00

**Sala dell'Arco**

- SESSION XVIII - APIs  
**Role of APIs in the new European Regulation**

11.00 - 13.00

**Sala della Piazza**

- SESSION XIX - SPECIALTY PRODUCTS  
**Innovation in specialty products**

13.00 - 14.30

**Working lunch**

## THE MAIN CHALLENGES FOR THE HEALTHCARE SECTOR: RESEARCH, INNOVATION, SUSTAINABILITY

- 09.00 - 13.00
  - 09.00 - 10.00
  - 10.00 - 12.30
  - 13.00
  - 12.30 - 14.00
- Registration of Symposium Participants
  - Registration of Workshop Participants
  - **Workshop**
  - **Inauguration of the 63<sup>th</sup> AFI Symposium at the entrance of the exhibition area**
  - **Working lunch**

## WORKSHOP PROGRAMME

**Free admission subject to mandatory registration within Tuesday 5<sup>th</sup> June.  
Please, use the following link:**

**[CLICK HERE](#)**

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

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

- 09.00 - 10.00
  - **Registration of the participants at the entrance of the meeting rooms**
- 10.00 - 12.30
  - **Sala del Borgo 1**  
Workshop organized by **AM Instruments:**  
*Overcoming the Challenges of Annex 1: Optimization of Material Transfer Processes into Controlled Environments*
- 10.00 - 12.30
  - **Sala del Borgo 2**  
Workshop organized by **FUJIFILM:**  
*Choosing the correct BET methodology*
- 10.00 - 12.30
  - **Sala del Faro**  
Workshop organized by **CHEMSAFE:**  
*Clinical evidence and innovation in the evaluation of medical devices*
- 10.00 - 12.30
  - **Sala della Marina 1**  
Workshop organized by **EUROFINS:**  
*Extractables & Leachables: aggiornamenti regolatori e sfide per il futuro*
- 10.00 - 12.30
  - **Sala della Marina 2**  
Workshop organized by **ONOBLO:**  
*Let's build solutions! Let's use LEGO® bricks to overcome barriers between Quality, Production and Logistics*
- 10.00 - 12.30
  - **Sala del Parco 1**  
Workshop organized by **LIFEBEE, PHARMA D&S e PRODUCTLIFE GROUP:**  
*The perfect recipe for sustained Compliance and Efficiency through Digital Transformation*
- 10.00 - 12.30
  - **Sala del Lavatoio**  
Workshop organized by **PTM CONSULTING:**  
*Quality risk management: how about moving beyond the FMEA?*
- 10.00 - 12.30
  - **Sala del Parco 2**  
Workshop organized by **S-IN SOLUZIONI INFORMATICHE:**  
*Production processes: innovative solutions for impurity detection and evaluation and integrated information management*
- 12.30 - 14.00
  - **Working lunch**

14.00 - 15.00

**Sala del Castello**

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

- Marcello Cattani – Farindustria President

**KEYNOTE LECTURE****The challenges for the Healthcare Industry: research, innovation and sustainability**

15.00 - 19.00

**Technical and scientific sessions****SESSION I****SUSTAINABILITY PROJECTS IN THE PHARMA SECTOR****Sala del Castello**

15.00 - 15.05

**Presentation of the Energy and Sustainability Working Group**

- Pierfelice Ferrari – AFI

**Moderator:**

- Pierfelice Ferrari – AFI

15.05 - 15.25

**Results of the 2023 Survey****The ecological transition as a joint effort as a joint effort. Sharing knowledge and experiences: the importance of sector benchmarks**

- Giorgio Amato, Pier Angelo Galligani – AFI – Techniconsult Group

15.25 - 15.45

**The regulation in force and the next compliance requirements****The regulatory framework and the next sustainability-related compliance requirements**

- Enrico Brena – Federchimica

15.45 - 16.15

**Sustainability in the pharmaceutical sector****How to implement a corporate culture that understands the promotion of ethical business practices, social responsibility, diversity, and inclusion**

- Alfredo Lombardi – HR Executive Consultant

16.15 - 17.00

**Coffee break**

17.00 - 17.20

**PRO-ECO project: a circular economy project to turn wastes from the production of live biotherapeutic products ( LBP) into resources**

- Giancarla Dondi – Proge Farm

17.20 - 17.40

**The “green” roadmap of an Analytical Development lab**

- Lorena Antonelli – AFI – Angelini Pharma

17.40 - 18.00

**Safety as an essential element of sustainability**

- Ivo Caldera – AFI

18.00 - 18.20

**High-containment areas: design and monitoring**

- Michele Grassi – AFI – Techniconsult Group

18.20 - 18.40

**Unveiling of monography “La sfida della sostenibilità per l’industria farmaceutica” (The sustainability challenge for the pharmaceutical industry)**

- Ivo Caldera – AFI

18.40 - 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 Castello**

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

- Marcello Cattani – Farindustria President

**KEYNOTE LECTURE****The challenges for the Healthcare Industry: research, innovation and sustainability**

15.00 - 19.00

**Technical and scientific sessions****SESSION II****THE SUPPLY CHAIN... WORK IN PROGRESS****Sala del Tempio**

15.00 - 15.10

**Welcome address and introduction to the session**

- Alberto Bartolini – AFI – CIT
- Roberto de Luca – AFI – University of Padua

**Moderators:**

- Alberto Bartolini – AFI – CIT
- Roberto de Luca – AFI – University of Padua

15.10 - 15.25

**Pharmaceutical serialization: implications for the pharmaceutical sector**

- Alberto Bartolini – AFI – CIT

15.25 - 15.45

**Drug management in hospital pharmacies: critical issues and goals**

- Diego Lauritano – Sant'Orsola Hospital Bologna

15.45 - 16.05

**Transporting medicines by air: stakeholders, complexity, situation**

Marco Del Giudice – MdC

16.05 - 16.15

**Cold chain: processes and related enabling technologies**

Alberto Bartolini – AFI – CIT

16.15 - 16.40

**Products for advanced therapies**

- Monica Gunetti – AFI – Bambino Gesù Children's Hospital

16.40 - 17.20

**Coffee break**

17.20 - 18.00

**Sustainability in drug distribution: waste reduction and delivery optimization**

- Silvano Firmo – Gruppo Comifar

18.00 - 18.40

**Panel discussion with:**

- ADF Salute – Raffaele Testa
- Assoram – Alfredo Sassi
- Egualea – Adriano Pietrosanto
- Farindustria – Luca Paoles
- Speaker from the Ministry of Health (*to be confirmed*)
- Official Pharmacy Association Provinces of Milan, Lodi, Monza Brianza – Francesco Camaleri
- SIFO – Marcello Pani

18.40 - 19.00

**Discussion and end of session**

20.00

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

14.00 - 15.00

**Sala del Castello**

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

- Marcello Cattani – Farindustria President

**KEYNOTE LECTURE****The challenges for the Healthcare Industry: research, innovation and sustainability**

15.00 - 19.00

**Technical and scientific sessions****SESSION III****PACKAGING MATERIALS: MANUFACTURING AND APPLICATIONS****Sala dell'Arco**

17.00 - 17.05

**Welcome address and introduction to the session**

- Alessandro Regola – AFI Vice-President

**Moderators:**

- Alessandro Regola – ViceAFI President
- Piero Iamartino – AFI – EIPG

17.05 - 17.25

**Overview of control and use requirements for primary and secondary packaging materials in pharmaceutical manufacturing**

Angela Federica Pinto – AFI – Bayer Healthcare Manufacturing

17.25 - 17.45

**Manufacturing of alufoil for drug blisters**

- Claudio Algarotti – Aluberg

17.45 - 18.05

**Manufacturing processes for elastomeric closures classified as primary packaging**

- Cesare Cameran – Datwyler Pharma Packaging Italy

18.05 - 18.25

**Tubular glass vials and bottles: state of the art of Manufacturing and Quality Control**

- Luca Carnelli – Soffieria Bertolini

18.25 - 18.45

**Pharmaceutical secondary packaging: Production and Quality Guarantee**

- Roberto Masciambruni – DDA

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 Castello**

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

- Marcello Cattani – Farindustria President

**KEYNOTE LECTURE****The challenges for the Healthcare Industry: research, innovation and sustainability**

15.00 - 19.00

**Technical and scientific sessions****SESSION IV****SYNERGIES AND INNOVATION IN THE HEALTHCARE SECTOR:  
THE RISE OF ARTIFICIAL INTELLIGENCE TECHNOLOGIES  
AND DIGITAL THERAPIES****Sala della Piazza**

15.00 - 15.10

**Welcome address and introduction to the session**

- On. Simona Loizzo – Member of the Italian Parliament

**Moderators:**

- Massimo Beccaria – AFI – Advice Pharma
- Elisa Stefanini – AFI – Portolano Cavallo Studio Legale

15.10 - 15.30

**Business models associated to digital therapies**

- Marco Gorini – AFI – AstraZeneca

15.30 - 15.50

**The impact of digital therapies in Italy: the point of view of doctors and patients**

- Chiara Sgarbossa – Politecnico di Milano

15.50 - 16.10

**Data, digital therapies, and AI: how to regulate this field**

- Silvia Stefanelli – AFI – Studio legale Stefanelli & Stefanelli

16.10 - 16.30

**The digital caregiver**

- Laura Patrucco – AFI – Alfasigma

16.30 - 16.50

**Artificial intelligence and digital technologies: impact on research and current status**

- Sara Cazzaniga – AFI – IQVIA

16.50 - 17.00

**Discussion and end of session**

20.00

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

14.00 - 15.00

**Sala del Castello**

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

- Marcello Cattani – Farindustria President

**KEYNOTE LECTURE**

**The challenges for the Healthcare Industry: research, innovation and sustainability**

15.00 - 19.00

**Technical and scientific sessions****SESSION ON START-UPS****LIFE SCIENCES ITALIAN STRATEGY FOR INNOVATION REVOLUTION****Sala della Piazza**

17.30 - 17.40

**Introduction to the session**

- Lorenzo Cottini – AFI – Evidenze Health
- Manuela Monti – AFI – IRST Technology Transfer Office
- Maria Luisa Nolli – AFI – NCNbio

**Moderators:**

- Lorenzo Cottini – AFI – Evidenze Health
- Manuela Monti – AFI – IRST Technology Transfer Office

17.40 - 17.50

**The skills for the future: Biotechnologies, Training and Value of Contamination**

- Gianluigi de Gennaro – Centro d'Eccellenza per l'Innovazione e la Creatività, Università degli Studi di Bari Aldo Moro

17.50 - 18.00

**From research to access – new Public Private alliances**

- Mauro Racaniello – Farindustria

18.00 - 18.10

**The strength of networks - PerfeTTO: the “Network Italiano Life Science” of hospital and university technology transfer offices**

- Luca Battistelli, Paola Burioli – IRST Technology Transfer Office

18.10 - 18.30

**SESSION on start-ups**

18.30 - 18.50

**Panel discussion: Key Innovation players of innovation ecosystems****Moderators:**

- Paola Burioli – IRST Technology Transfer Office
- Manuela Monti – AFI – IRST Technology Transfer Office
- Nicoletta Amodio - Cluster Nazionale Alisei
- Michele Longhi - Deloitte
- Simone Valorani – Scientifica

18.50 - 19.00

**Discussion and end of session**

20.00

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

**phase**

9.00 - 10.00	• Senator Elena Cattaneo <b>KEYNOTE LECTURE</b> <b>There is no care without research</b>
10.00 - 18.45	<b>Technical and scientific sessions</b>
12.30 - 14.30	<b>Poster SESSION</b>

## SESSION V

### THE FUTURE OF CLINICAL RESEARCH: INNOVATION AND SUSTAINABILITY

#### Sala del Castello

10.00 - 10.15	<b>Introduction of the session</b> • Lorenzo Cottini – AFI – Evidenze Health • Guido Fedele – AFI
	<b>Part I</b>
<b>Moderators:</b>	• Ilaria Maruti – AFI – Astrazeneca • Francesca Vaccari – AFI – Chiesi Farmaceutici • Marco Zibellini – Farmindustria
10.15 - 10.35	<b>sustainability: state of the art of Decentralised Clinical Trials</b> • Fabrizio Forini – AICRO President
10.35 - 10.55	<b>The decentralized approach: a strategy to reduce the carbonfootprint of clinical trials</b> • Marisa Minetti – Chiesi Farmaceutici
10.55 - 11.10	<b>Discussion</b>
11.10 - 11.45	<b>Coffee break</b>
	<b>Part II</b>
<b>Moderators:</b>	• Lorenzo Cottini – AFI – Evidenze Health • Sandra Petraglia – AIFA ( <i>to be confirmed</i> ) • Sergio Scaccabarozzi – AFI – ARITHMOS
11.45 - 12.05	<b>The Ethical Committees one year after their reorganization: limits and opportunities</b> • Carlo Tomino – AFI – CET Lazio 5 President – San Raffaele University Hospital, Rome
12.05 - 12.25	<b>Patient management in clinical trials: sustainability and decentralization, environmental and economic impact. The perspective of the clinical center</b> • Alessandra Ferrari – AFI – IRCCS Policlinico S. Matteo Foundation
12.25 - 12.45	<b>Community pharmacies and clinical trials: possible contact point in RWE and decentralized interventional trials</b> • Corrado Giuia – SIFAC
12.45 - 13.00	<b>Discussion and end of session</b>
13.00 - 14.30	<b>Working lunch</b>



9.00 - 10.00	• Senator Elena Cattaneo <b>KEYNOTE LECTURE</b> <b>There is no care without research</b>
10.00 - 18.45	<b>Technical and scientific sessions</b>
12.30 - 14.30	<b>Poster SESSION</b>

## SESSION VI

### SPECIAL QUALITY SYSTEMS

#### Sala del Tempio

10.00 - 10.05	<b>Introduction of the session</b> • Alessandro Regola - AFI Vice-President
<b>Moderators:</b>	• Giovanni Boccardi - AFI • Alessandro Regola - AFI Vice-President
10.05 - 10.25	<b>Non-EU import/distribution of APIs and medicinal products: quality requirements and regulatory framework</b> • Paola Stefanelli - AFI - MIAT
10.25 - 10.45	<b>API and medicinal product warehousing and transport: features and issues of the quality system</b> • Maria Briganti - Essers Italia
10.45 - 11.05	<b>The ISO 9001 system applied to medical gas primary production</b> • Lorenzo Messa - Assogastecnici - SOL
11.05 - 11.40	<b>Coffee Break</b>
11.40 - 12.00	<b>GCP-GLP-GMP: similarities and differences between three quality systems intended to ensure patient safety</b> • Luciano Gambini - AFI
12.00 - 12.20	<b>GMP Quality Management System in the Production of Advanced Therapy Medicinal Products (ATMPs)</b> • Monica Gunetti - AFI - Bambino Gesù Children's Hospital
12.20 - 12.50	<b>AIFA Speaker (to be confirmed)</b>
12.50 - 13.00	<b>Discussion and end of session</b>
13.00 - 14.30	<b>Working lunch</b>

9.00 - 10.00 <b>Sala del Castello</b>	• Senator Elena Cattaneo <b>KEYNOTE LECTURE</b> <b>There is no care without research</b>
10.00 - 18.45	<b>Technical and scientific sessions</b>
12.30 - 14.30	<b>Poster SESSION</b>

## SESSION VII

### THE HTA REGULATION IS AROUND THE CORNER, WHAT ARE THE NEXT STEPS? EUROPE AND ITALY AMONG DEVELOPERS, STAKEHOLDERS AND THE AGENCY

#### Sala dell'Arco

10.00 - 10.05	<b>Welcome</b> <ul style="list-style-type: none"><li>• Paola Minghetti - AFI Vice-President- University of Milan</li></ul>
10.05 - 10.15	<b>Introduction of the session</b> <ul style="list-style-type: none"><li>• Massimo Cavaliere - AFI - Euraconsult</li><li>• Anna Ponzianelli - AFI - Moderna</li></ul>
<b>Moderators:</b>	<ul style="list-style-type: none"><li>• Massimo Cavaliere - AFI - Euraconsult</li><li>• Anna Ponzianelli - AFI - Moderna</li></ul>
10.15 - 10.35	<b>The HTA Regulation... ready, steady, go: the perspective of the Coordination Group and the Member States</b> <ul style="list-style-type: none"><li>• Marco Marchetti - AGENAS</li></ul>
10.35 - 10.55	<b>The HTA Regulation and the perspective of the NHS</b> <ul style="list-style-type: none"><li>• Francesco Saverio Mennini - Ministry of Health</li></ul>
10.55 - 11.15	<b>The HTA regulation and AIFA: where do we stand?</b> <ul style="list-style-type: none"><li>• Pierluigi Russo - AIFA (<i>to be confirmed</i>)</li></ul>
11.15 - 12.00	<b>Coffee Break</b>
12.00 - 12.50	<b>Panel discussion: HTA between Oncologists and ATMPs and then?</b>
<b>Moderator:</b>	<ul style="list-style-type: none"><li>• Anna Ponzianelli - AFI - Moderna</li></ul>
<b>Panelists:</b>	<ul style="list-style-type: none"><li>• Valeria Fava - Cittadinanzattiva</li><li>• Giovanni Giuliani - AFI- Roche</li><li>• Walter Marrocco - CSE</li><li>• Paola Minghetti - AFI Vice-President - University of Milan</li><li>• Simona Montilla - AIFA (<i>to be confirmed</i>)</li><li>• Carlo Riccini - Farindustria</li></ul>
12.50 - 13.00	<b>Discussion and end of session</b>
13.00 - 14.30	<b>Working lunch</b>

9.00 - 10.00	• Senator Elena Cattaneo
<b>Sala del Castello</b>	<b>KEYNOTE LECTURE</b> <b>There is no care without research</b>
10.00 - 18.45	<b>Technical and scientific sessions</b>
12.30 - 14.30	<b>Poster SESSION</b>

## WOMEN-IN-PHARMA FORUM

### WOMEN IN MANUFACTURING IN THE THE PHARMA - BIOTECH SECTOR

#### Sala della Piazza

11.30 - 11.40	<b>Introduction of the session</b> <ul style="list-style-type: none"> <li>• Paola Minghetti - AFI Vice-President - University of Milan</li> <li>• Maria Luisa Nolli - AFI - NCNbio</li> </ul>
<b>Moderators:</b>	<ul style="list-style-type: none"> <li>• Paola Minghetti - AFI Vice-President - University of Milan</li> <li>• Maria Luisa Nolli - AFI - NCNbio</li> </ul>
11.40 - 12.50	<b>Speakers:</b> <ul style="list-style-type: none"> <li>• Giorgio Bruno - AFI President</li> <li>• Sabrina Cazzaniga - AFI - AGCbiologics - ATMP</li> <li>• Anna Maria Granato - Cell Factory Romagna Institute for the Study of Tumors "Dino Amadori" - I.R.S.T.</li> <li>• Claudia Maldini - Miltenyi Biotech</li> <li>• Paola Stefanelli - AFI - MIAT</li> <li>• Speaker from AIFA (<i>to be confirmed</i>)</li> </ul>
12.50 - 13.00	<b>Discussion and end of session</b>
13.00 - 14.30	<b>Working lunch</b>

9.00 - 10.00	• Senator Elena Cattaneo
<b>Sala del Castello</b>	<b>KEYNOTE LECTURE</b> <b>There is no care without research</b>
10.00 - 18.45	<b>Technical and scientific sessions</b>
12.30 - 14.30	<b>Poster SESSION</b>

## SESSION VIII

### PREPARATION OF ONE-DOSE PACKAGES IN PHARMACIES: RISKS AND OPPORTUNITIES

#### Sala della Marina 1<sup>st</sup> floor

12.30 - 12.40	<b>Introduction to the topic with video</b>
	• Maurizio Battistini - AFI - EIPG
12.40 - 13.20	<b>Panel discussion: Swiss and Italian experiences</b>
<b>Moderators:</b>	<ul style="list-style-type: none"> <li>• Maurizio Battistini - AFI - EIPG</li> <li>• Paola Minghetti - AFI Vice-President - University of Milan</li> <li>• Giovan Maria Zanini - Canton Pharmacist</li> <li>• Arrigo Paciello - Servizio Farmaceutico Territoriale ATS Bergamo</li> <li>• Achille Gallina Toschi - Federfarma President Emilia-Romagna</li> <li>• FOFI (speaker to be defined)</li> <li>• SIFO (speaker to be defined)</li> </ul>
13.20 - 13.30	<b>Discussion and end of session</b>
	• Paola Minghetti - AFI Vice-President - University of Milan
13.00 - 14.30	<b>Working lunch</b>

## SESSION IX

**ENVIRONMENTAL RISK ASSESSMENT (ERA) OF MEDICINAL PRODUCTS.  
THE CONVENTIONAL APPROACH AND THE PROSPECTS RELATED  
TO THE NEW EUROPEAN DRUG DIRECTIVE****Sala del Castello**

- 14.00 - 14.05      **Introduction of the session**
- Piero Iamartino - AFI - EIPG
- Moderators:**
- Ivo Caldera - AFI
  - Piero Iamartino - AFI - EIPG
- 14.05 - 14.20      **Scientific approach to environmental risk assessment**
- Antonio Conto - AFI - Chemsafe
- 14.20 - 14.35      **Medicinal products and the environment: case study and future opportunities**
- Sara Zucchi - Angelini Pharma
- 14.35 - 14.50      **The different regulatory evaluations of the ERA: comparison between Agencies**
- Paolo Biffignandi - VI.REL Pharma
- 14.50 - 15.00      **Discussion and end of session**
- Piero Iamartino - AFI - EIPG
- 20.00              ***Gala Dinner of the Symposium at the Grand Hotel Rimini***

## SESSION X

### RESEARCH, AND DEVELOPMENT OF NEW TREATMENT APPROACHES TO DIABETES TREATMENT:

clinical, pharmacological, and social aspects. Technology platforms, portals, chronotherapy, and new approaches to diabetes treatment. New and conventional technologies for controlled drug release and personalized medical therapy in the treatment of endocrine disorders and blood-glucose control

#### Sala della Marina 1<sup>st</sup> floor

- 14.00 - 14.10      **Introduction of the session**
- Carla Caramella - AFI - University of Pavia
- Moderators:**
- Paolo Caliceti - University of Padua - Sitelf
  - Massimo Pedrani - AFI - Mogon Pharmaceuticals
- 14.10 - 14.40      **Diabetes market, trends, players and prospects**
- Isabella Cecchini - IQVIA Italia
- 14.40 - 14.50      **Digital platforms and portals for clinical trials: how to train data scientists and the big challenge of secondary data reuse**
- Massimo Beccaria - AFI - Advice Pharma Group
- 14.50 - 15.20      **Outcome predictive tools in medicine: the TOSCA web tool case**
- Andrea Rizzi - Sanofi
- 15.20 - 15.50      **New tools in the healthcare sector: digitalization of therapies for obesity and type-2 diabetes**
- Laura Lazzarotti - Theras Group - Lifetech
- 15.50 - 16.20      **Oral drug release systems for blood glucose control**
- Andrea Gazzaniga - AFI - University of Milan
- 16.20 - 16.30      **Discussion and end of session**
- 20.00              ***Gala Dinner of the Symposium at the Grand Hotel Rimini***

## SESSION XI

### CAR-T THERAPIES: FROM RECENT PAST TO NEAR FUTURE

#### Sala del Tempio

- 14.30 - 14.45      **Evolution of gene therapy: the most advanced ATMP sector**
- Maria Luisa Nolli – AFI – NCNbio
- Moderators:**
- Maria Luisa Nolli – AFI – NCNbio
  - Sara Vignati – AFTI
- Key note lecture**
- 14.45 - 15.30      **CAR-T breakthrough innovation in medicine: oncology and beyond**
- Francesca Del Bufalo – Bambino Gesù Children’s Hospital
- 15.30 - 16.00      **CAR-T therapy for the treatment of blood disorders**
- Annalisa Chiappella – Istituto Nazionale dei Tumori
- 16.00 - 16.40      **Coffee Break**
- 16.40 - 17.10      **CAR-T in early development**
- Marta Serafini – San Gerardo University Hospital
- 17.10 - 17.40      **Long-term outcome of hematopoietic stem-cell gene therapy**
- Maria Pia Cicalese – San Raffaele University Hospital
- 17.40 - 18.00      **CAR-T therapy management: legal and contractual aspects**
- Benedetta Cordovado – Johnson & Johnson Svizzera and Austria
- 18.00 - 18.20      **Panel discussion: challenges and opportunities of CAR-T**
- Moderators:**
- Paolo Barbanti – AFI
  - Monica Gunetti – AFI – Bambino Gesù Children’s Hospital
  - Stefano Baila – Eurofins Biolab
  - Annalisa Chiappella – National Cancer Institute
  - Maria Pia Cicalese – IRCCS San Raffaele Hospital
  - Benedetta Cordovado – Johnson & Johnson Switzerland and Austria
  - Francesca Del Bufalo – Bambino Gesù Children’s Hospital
  - Marta Serafini – IRCCS San Gerardo Foundation
- 18.20 - 18.30      **Discussion and end of session**
- 20.00                **Gala Dinner of the Symposium at the Grand Hotel Rimini**

## SESSION XII

### PHARMACOVIGILANCE AND QUALITY: WHEN A QUALITY COMPLAINT IMPACTS PATIENT HEALTH

Sala dell'Arco

- 14.30 - 14.40      **Introduction of the session**
- Andrea Oliva - AFI - Viatris
- Moderator:**
- Andrea Oliva - AFI - Viatris
- 14.40 - 15.10      **Quality defects in Pharmacovigilance**
- Elisabetta Beltrami, Daria Rasà - Alfasigma
- 15.10 - 15.45      **The role of AIFA in drug safety management**
- Laura Sottosanti - AIFA (to be confirmed)
- 15.45 - 16.25      **Panel discussion: how to ensure safety management of products impacted by quality complaints**
- Elisabetta Beltrami - Alfasigma
  - Giovanna Pescatore - Farindustria
  - Daria Rasà - Alfasigma
  - Laura Sottosanti - AIFA (to be confirmed)
  - Romina Tulumiero - Egualea
- 16.25 - 16.30      **Discussion and end of session**
- Andrea Oliva - AFI - Viatris
- 20.00              ***Gala Dinner of the Symposium at the Grand Hotel Rimini***



## SESSION XIII

SYNERGIES AND INNOVATION IN THE HEALTHCARE SECTOR:  
THE ROLE OF MEDICAL DEVICES

## Sala del Castello

- 15.00 - 15.05      **Welcome address and introduction to the session**
- Paola Minghetti - AFI Vice-President- University of Milan
- Moderators:**
- Marcella Marletta - Campus BioMedico University, Rome
  - Tiziana Pecora - AFI - Labomar
- 15.05 - 15.30      **New regulations and strategy for the Italian medical device sector: overview and considerations**
- Fernanda Gellona - Confindustria Dispostivi Medici
- 15.30 - 15.55      **Substance-based medical devices three years after the enforcement of EU Regulation 2017/745**
- Maria Grazia Leone - Ministry of Health
- 15.55 - 16.20      **The innovation challenge for the development of substance-based medical devices within the framework of the MDR**
- Doriana Pantano - AFI - Schwabe Pharma
- 16.20 - 17.00      **Coffee break**
- 17.00 - 17.20      **Evolution of the medical device regulation and update of the “Banca Dati Italiana” (Italian database)**
- Alessandra Basilisco - Ministry of Health
- 17.20 - 18.20      **Panel discussion with the Notified Bodies about certification processes and the harmonization of the approach in Italy and in Europe**
- Moderator:**
- Antonella Mamoli - AFI - IBSA
  - Daniele Bollati - IMQ
  - Sara Crocetti - Bureau Veritas
  - Paolo Dentis - Eurofins
  - Alessia Frabetti - Kiwa
  - Sara Gianellini - Italcert
  - Roberta Marcoaldi - Istituto Superiore di Sanità
  - Chiara Novi - TUV
  - Armando Romaniello - Certiquality
  - Tatiana Vignudelli - Ente Certificazione Macchine
- 18.20 - 18.30      **Discussion and end of session**
- 20.00              **Gala Dinner of the Symposium at the Grand Hotel Rimini**

## SESSION XIV

### ADVERTISING AND MEDICAL AND SCIENTIFIC INFORMATION IN THE DIGITAL ERA: RULES AND OPPORTUNITIES

#### Sala dell'Arco

- 16.30 - 16.35      **Introduction of the session**
- Alessandra Molin Zan - AFI - Zentiva Italia
- Moderators:**
- Lorenza Castelli - AFI - Astellas
  - Alessandra Molin Zan - AFI - Zentiva Italia
- 16.35 - 16.50      **Focus on medical and scientific information: "Discussion about AIFA Questions & Answers: from paper to digital"**
- Claudia Calò - AFI - Chiesi Farmaceutici
  - Laura Cotrino - AFI - Acarpi
- 16.50 - 17.05      **Focus on medical and scientific information for homeopathic doctors - critical issues and examples: "medical and scientific information for homeopathic medicines"**
- Alessandro Libero Lorini - AFI - Boiron
- 17.05 - 17.20      **Focus on advertising: "New guidelines: updates and new social scenarios"**
- Laura Bisi - AFI - CIT
  - Francesco Scapin - AFI - Fidia Farmaceutici
- 17.20 - 17.35      **Focus on advertising/: Devices/medicines "Medicines and devices: what is the option for promotion?"**
- Sveva Sanzone - AFI - Biogen
  - Veronica Casalini - AFI - Roche
- 17.35 - 17.50      **Focus on supplements: Rules to follow for advertising of food supplements**
- Renato Minasi - AFI - Dialfarm
- 17.50 - 18.20      **Panel Discussion**
- Moderators:**
- Lorenza Castelli - AFI - Astellas
  - Heide De Togni - AFI - Schwabe Pharma
  - Cinzia Berghella - AIFA (*to be confirmed*)
  - Cesare Costa - Assosalute - Angelini Pharma Italy
  - Milena Olivieri - Farindustria
  - Romina Tulumiero - Egualea
- 18.20 - 18.30      **Discussion and end of session**
- 20.00              **Gala Dinner of the Symposium at the Grand Hotel Rimini**

## SESSION XV

## INTERACTION OF MODIFIED RELEASE DRUG-DELIVERY SYSTEMS WITH PRIMARY PACKAGING MATERIALS: CRITICAL ISSUES AND NEW CHARACTERIZATION TECHNIQUES

### Sala della Marina 1st floor

- 16.30 - 16.35      **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
- 16.35 - 17.05      **Surface properties of primary glass containers: effects of steam sterilization**
- Giuseppina Sandri - University of Pavia
  - Alessandro Artioli - Fedegari Group
  - Luca Carnelli - Soffieria Bertolini
- 17.05 - 17.25      **Integrity testing of pre-filled glass syringes for ultra-low temperature storage**
- Odra Pinato - Stevanato Group
- 17.25 - 17.45      **mRNA encapsulated in lipid nanoparticles in pre-filled syringes for effective COVID-19 mass vaccination: evidence of stability**
- Francesca Selmin - AFI - University of Milan
- 17.45 - 18.05      **Leachables and extractables from primary plastic containers: scientific and regulatory aspects**
- Marco Ceccolini - AFI - Angelini Pharma Italia
- 18.05 - 18.20      **Panel discussion with the speakers**
- 18.20 - 18.45      **Yearly CRS Italy Chapter meeting**
- 20.00                ***Gala Dinner of the Symposium at the Grand Hotel Rimini***

## SESSION XVI

### PARENTERAL AND LYOPHILIZED DRUG MANUFACTURING: CHALLENGES AND SOLUTIONS ACCORDING TO THE ANNEX 1

#### Sala del Castello

- 09.00 - 09.15      **Introduction of the session**
- Lino Pontello - AFI
  - Francesca Selmin - AFI - University of Milan
- 09.15 - 09.45      **Communication from the GMP office - medicinal products**
- Luisa Stoppa - AIFA (*to be confirmed*)
- 09.45 - 10.15      **Innovative Horizons in Parenteral Development: A Patient-Centric Approach to Tomorrow's Therapies**
- Sandeep Nema - Saliogen Therapeutics
- 10.15 - 11.00      **Coffee break**
- 11.00 - 11.30      **Emerging technologies in parenteral drug manufacturing: continuous lyophilization**
- Roberto Pisano - Politechnic University of Turin
- 11.30 - 12.00      **Roadmap to bottle lyophilization: impact of process metrics and material attributes on product quality**
- Ruggero Terzi - AFI - NerPharMa
  - Michela Bordigoni - AFI - Grunenthal
- 12.00 - 12.30      **Lyophilization process and Annex 1**
- Filippo Trionfera - AFI - BSP Pharmaceuticals
  - Yuri Pupulin - BSP Pharmaceuticals
- 12.30 - 12.50      **Development of innovative methods and solutions for integrity testing of parenteral product containers**
- Andrea Simonetti - AFI - PDA
- 12.50 - 13.00      **Discussion and end of session**
- 13.00 - 14.30      **Working lunch**

## SESSION XVII

### AN OVERVIEW OF TECHNOLOGICAL INNOVATION BETWEEN THE PRESENT AND THE NEAR FUTURE

#### Sala del tempio

- 09.00 - 09.05     **Introduction of the session**
- Alberto Bartolini - AFI - CIT
- Moderator:**     • Alberto Bartolini - AFI - CIT
- Artificial Intelligence**
- 09.05 - 09.15     **Risks and opportunities**
- Alberto Bartolini - AFI - CIT
- 09.15 - 10.05     **Examples of innovative AI applications in companies**
- Paola Martini - AFI - Takeda Manufacturing Italia
- Process digitalization**
- 10.05 - 10.20     **Why digitalizing processes and what it means**
- Gian Paolo Baranzoni - AFI
- 10.20 - 10.35     **From customer demand to shipment**
- Giulia Terrazzano - CIT
- 10.35 - 10.50     **Quality**
- Laura Bisi - AFI - CIT
- 10.50 - 11.05     **New project management**
- Federico Casaglia - CIT
- 11.05 - 11.50     **Coffee break**
- Validation and Qualification 4.0 GAMP 5 2<sup>nd</sup> edition**
- 11.50 - 12.00     **Why and what need validation and certification**
- Gian Paolo Baranzoni - AFI
- 12.00 - 12.20     **10 chapters of the new GAMPs in summary**
- Sandro De Caris - AFI
- 12.20 - 12.50     **Comparison between the conventional validation system and the new approach in GAMP 5 2<sup>nd</sup> edition. IT and Compliance perspectives on GAMP5**
- Paolo Baranzoni, Sandro De Caris - AFI
- 12.50 - 13.00     **Discussion and end of session**
- 13.00 - 14.30     **Working lunch**

## SESSION XVIII

### THE ROLE OF APIS IN THE NEW EUROPEAN REGULATION

#### Sala dell'Arco

- 09.00 - 09.10      **Introduction of the session**
- Piero lamartino - AFI - EIPG
- Moderator:**
- Piero lamartino - AFI - EIPG
- 09.10 - 9.30      **The Impact of the EU pharmaceutical regulation in the API sector**
- Paolo Russolo - Aschimfarma
- 09.30 - 09.50      **Sustainability of API chemicals: a frontier for the near future**
- Marcello Fumagalli - CPA
- 09.50 - 10.10      **Critical Medicines Alliance and the role of APIs in preparedness to healthcare emergency**
- Maggie Saykali - EFCC/CEFIC
- 10.10 - 10.30      **The stance of AIFA**
- Giuseppina Ialongo - AIFA (*to be confirmed*)
- 10.30 - 11.00      **Discussion and end of session**
- 11.00 - 11.45      **Coffee break**



## SESSION XIX

### INNOVATION IN SPECIALTY PRODUCTS

#### Sala della Piazza

- 11.00 - 11.05      **Introduction of the session**
- Marilena Carazzone – AFI
- Moderators:**
- Manuela Monti – AFI – Romagna Institute for the Study of Tumors "Dino Amadori" - I.R.S.T.
  - Floriana Raso – AFI – Schwabe Pharma
- 11.05 - 11.25      **The future of radiopharmaceuticals**
- Maurizio Mariani – Bridge4Pharma
- 11.25 - 11.45      **Use of Artificial Intelligence in medical image and clinical decision support at GE HealthCare**
- Jan Wolber – GE HealthCare, UK
- 11.45 - 12.05      **Technology based on suspended plant cell cultures. Regulatory options in drug manufacturing**
- Giovanna Pressi – Aetherobiotech
- 12.05 - 12.25      **Mechanisms of action of plant-derived pharmaceutical products**
- Marco Biagi – University of Parma
- 12.25 - 12.45      **"Medicinal gases: a sustainable innovation model"**
- Marco Tonini – Assogastecnici
- 12.45 - 13.00      **Discussion and end of session**
- Isabella Marta – AIFA (*to be confirmed*)

THURSDAY 6<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.

## POSTERS

The **63<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 6<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 2024** (firm deadline) using the form that can be filled in at the following address:

<http://simposio.afiscientifica.it/eventi-e-formazione/poster-2024/>

**For further information, please contact Dr. Giovanni Boccardi**

AFI - Viale D. Ranzoni, 1 - 20149 Milan (Italy)  
Ph. +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 organisational purposes and grants access to the exhibition area, participation in the Workshops on Wednesday 5<sup>th</sup> June (morning), the Keynote Lectures (5<sup>th</sup> and 6<sup>th</sup> June), the Start-up Forum (5<sup>th</sup> June), the Women-in-Pharma Forum (6<sup>th</sup> June).

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

**However, access to the Scientific Sessions is subject to a fee** and requires the registration to the Symposium (fee for Public Bodies / Universities).

**[CLICK HERE for online 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 **6<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 **NEW DRUG DELIVERY STRATEGIES AND NEW VECTORS FOR FUTURE TREATMENT CHALLENGES**.

This is the 8th edition of the award, which was created to help advance the collaboration between universities and companies and to give a small yet tangible contribution to young students who are completing their studies.

As always, the two best dissertations selected by a panel of experts from universities and companies will receive a monetary prize and a certificate.

**The award ceremony will take place in the evening on Thursday 6th June at the Grand Hotel Rimini, during the Gala Dinner.**

## GENERAL INFORMATION

## SCIENTIFIC SECRETARIAT

## AFI

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

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Fax +39 02 48717573

[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 3 <sup>rd</sup> May 22% vat included	After 3 <sup>rd</sup> May 22% vat included
AFI, AFTI, CRS, SITELF Members	€ 1.037,00	€ 1.342,00
Non Members	€ 1.342,00	€ 1.464,00
Public Bodies, Universities, University Hospital, Community Hospitals, Ministries (excluding working lunches, WHITE&BLUE Beach Party and Gala Dinner)	€ 488,00	€ 549,00
Daily fee (for registration to one of the three Symposium days, excluding WHITE&BLUE Beach Party and Gala Dinner)	€ 732,00	€ 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)	€ 305,00	€ 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 5<sup>th</sup> June (not included in the daily fee and the fee for Public Bodies)
- Gala Dinner on 6<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 2024. No refunds will be given after that date.**

**Online registration must be completed by 17<sup>th</sup> May 2024**

**[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 17<sup>th</sup> May 2024 to:**

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

**TIMETABLE**

	<b>Wednesday 5<sup>th</sup> June 14:00 - 19:00</b>	<b>Thursday 6<sup>th</sup> June 09:00 - 13:30</b>	<b>Thursday 6<sup>th</sup> June 14:00 - 18:45</b>	<b>Friday 7<sup>th</sup> June 09:00 - 13:00</b>
<b>SALA DEL CASTELLO</b>	<b>14:00 - 15:00</b> <b>WELCOME AND OPENING OF THE SYMPOSIUM</b> <b>Keynote Lecture</b> The challenges for the Healthcare Industry: research, innovation and sustainability	<b>09:00 - 10:00</b> <b>Keynote Lecture</b> There is no care without research	<b>14:00 - 15:00</b> <b>SESSION IX</b> Environmental risk assessment (ERA) of medicinal products: the conventional approach and the prospects related to the new European human medicine directive	<b>09:00 - 13:00</b> <b>SESSION XVI</b> Parenteral and lyophilized product manufacturing: challenges and solutions according to Annex 1
	<b>15:00 - 19:00</b> <b>SESSION I</b> Sustainability project in the pharmaceutical sector	<b>10:00 - 13:00</b> <b>SESSION V</b> The future of clinical research: innovation and sustainability	<b>15:00 - 18:30</b> <b>SESSION XIII</b> Synergies and innovation in the healthcare sector: the role of medical devices	
<b>SALA DEL TEMPIO</b>	<b>15:00 - 19:00</b> <b>SESSION II</b> La supply chain... work in progress	<b>10:00 - 13:00</b> <b>SESSION VI</b> Special quality systems	<b>14:30 - 18:30</b> <b>SESSION XI</b> CAR-T therapies: from recent past to near future	<b>09:00 - 13:00</b> <b>SESSION XVII</b> An overview of technological innovation between the present and the near future
<b>SALA DELL'ARCO</b>	<b>17:00 - 19:00</b> <b>SESSION III</b> Packaging materials: manufacturing and applications	<b>10:00 - 13:00</b> <b>SESSION VII</b> The HTA Regulation is around the corner, what are the next steps? Europe and Italy among developers, stakeholders, and the Agency	<b>14:30 - 16:30</b> <b>SESSION XII</b> Pharmacovigilance and quality: when a quality complaint impacts patient health	<b>09:00 - 11:00</b> <b>SESSION XVIII</b> The role of APIs in the new European Regulation
			<b>16:30 - 18:30</b> <b>SESSION XIV</b> Advertising and medical and scientific information in the digital era: rules and opportunities	
<b>SALA DELLA PIAZZA</b>	<b>15:00 - 17:00</b> <b>SESSION IV</b> Synergies and innovation in the healthcare sector: the rise of AI technologies and digital therapies	<b>11:30 - 13:00</b> <b>LA PIAZZA DELLE DONNE DEL PHARMA</b> Women in the Pharma - Biotech manufacturing sector		<b>11:00 - 13:00</b> <b>SESSION XIX</b> Innovation in specialty products
	<b>17:30 - 19:00</b> <b>SESSION START UP</b> Life sciences Italian strategy for innovation revolution			
<b>SALA DELLA MARINA 1<sup>ST</sup> FLOOR</b>		<b>12:30 - 13:30</b> <b>SESSION VIII</b> Preparation of one-dose packages in pharmacies: risks and opportunities	<b>14:00 - 16:30</b> <b>SESSION X</b> Research and development of new treatment approaches to diabetes treatment	
			<b>16:30 - 18:45</b> <b>SESSION XV</b> Interaction of modified release drug-delivery systems with primary packaging materials: critical issues and new characterization techniques	
<b>LOBBY SALA DELL'ARCO</b>		<b>12:30 - 14:30</b> <b>POSTER SESSION</b>		



Associazione Farmaceutici Industria  
Società Scientifica

# 63

AFI SYMPOSIUM  
RIMINI 5<sup>TH</sup>·6<sup>TH</sup>·7<sup>TH</sup>  
JUNE 2024

**Scientific Secretariat**  
**AFI**

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