



Associazione Farmaceutici Industria
Società Scientifica

From knowledge
to digitalization
for competitiveness
of the health industry



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

PROGRAMME

SYMPOSIUM COMMITTEES

SCIENTIFIC COMMITTEE

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

ORGANIZING COMMITTEE

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

DISSERTATION COMMITTEE

Coordinator:

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

Members:

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

POSTER COMMITTEE

Coordinator:

- **Giovanni Boccardi** - AFI

Members:

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

ORGANIZING SECRETARIAT

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



MEETING POINTS

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

| N. STAND | AZIENDA ESPOSITRICE |
|-------------|---|
| 109 | AAF INTERNATIONAL |
| 133 | ABAR SPA |
| 26 | ABC FARMACEUTICI |
| 77 | ACOTEC MANGINI TURNKEY DIVISION |
| 2 | ADEODATA |
| 80-81 | ADIUTO - Bluenext |
| 45 | AKKODIS ITALY |
| 113 | ALCHEMY |
| 138 | ALFATESTLAB |
| 119-120 | ALIPHARMA |
| 5 | ALTEN Italia |
| 82 | ALTERGON ITALIA |
| 79 | AMARIS CONSULTING |
| 65 | AM INSTRUMENTS |
| 52 | AMITA HEALTH CARE |
| 104 | Analysis |
| 36-53 | ANTARES VISION GROUP |
| 29 | ANTON PAAR ITALIA |
| 87 | ARITHMOS |
| 73 | ASGENIA |
| 126 | AZELIS |
| 21 | B&D ITALIA |
| 127 | BRAM-COR |
| 66 | BURKERT ITALIA |
| 72 | C&P Engineering |
| 143 | CAI |
| 18 | CAMST - Life Science Solutions |
| 69 | CAPSULIT |
| 67 | CHEMSAFE |
| 24 | CIT Pharma Contract Packaging |
| 86 | CO.RA. |
| 8 | COMECER |
| 33 | CSV Life Science Group |
| 37-38 | CYTIVA |
| 146 | D.O.C. - DOCUMENTATION ORGANIZATION AND CONSULTANCY |
| 58 | DDA Quality Development For Industries |
| 36-53 | DE LAMA |
| 135 | DHL Supply Chain Italy |
| 84 | DI RENZO REGULATORY AFFAIRS |
| 142 | DMX Pharma |
| 141 | DYNAMIC FORWARDING INTERNATIONAL |
| 89 | ECOLAB |
| 54 | ELLAB |
| 19 | EMERSON |
| 27 | EN-COM |
| 98 | ENDRESS+HAUSER ITALIA |
| 55 | EUREKA InfoMed |
| 149-150-151 | Eurofins BioPharma Product Testing Italy |
| 149-150-151 | Eurofins Healthcare Assurance |
| 149-150-151 | Eurofins PSS Insourcing Solutions® |
| 149-150-151 | Eurofins Regulatory & Consulting Services Italy |
| 149-150-151 | Eurofins Medical Device Services |
| 15 | EUROMED PHARMA SERVICES |
| 107 | EURPACK |
| 116 | EUSOFT |
| 48 | EVIDENZE HEALTH |
| 103 | EXCiPACT / IPEC Europe |
| 25 | FARMADATI ITALIA |
| 36-53 | Farmo Res |
| 49 | FARMOL HEALTH CARE |
| 7 | Fine Foods & Pharmaceuticals |
| 60-61 | FLARER |
| 20 | Grafibox Sud |
| 145 | Gruppo SASI |
| 90-91 | HONEYWELL Life Sciences |
| 13 | HSC Holding |
| 44 | I.G.B. |
| 110 | IBD |

MEETING POINTS

| | |
|----------|--|
| 154-155 | IMA |
| 108 | INDENA |
| 153 | INNLFIVES |
| 80-81 | INPHARMATIC - Bluenext |
| 152 | IQVIA |
| 34 | ITALIANA SERVIZI |
| 115 | JRS Rettenmaier Italia |
| 148 | JSB Solutions |
| 129-140 | KÖRBER |
| 105 | KYMOS GROUP |
| 40 | LabAnalysis Process Pharma |
| 39 | LABOTICS ITALIA |
| 9-10 | LabWare |
| 130 | LAETUS |
| 64 | LifeBee Digitalizing Life Science |
| 100 | LIVES INTERNATIONAL |
| 17 | LP Pharma |
| 131 | LS Academy |
| 93-94 | MAASI Enterprises |
| 3 | MAKING LIFE |
| 22-23 | MARCHESINI GROUP |
| 12 | MASTERFILTER |
| 136 | MEDICAL AFFAIRS CONSULTING |
| 99 | Merck Life Science |
| 59 | NEOTRON TESTING LAB |
| 77 | NICOMAC |
| 137 | NORDTEST |
| 6 | NTT DATA |
| 106 | O.M.A.R. |
| 134 | OLD PHARMA International |
| 132 | OMRON |
| 124 | ORISE |
| 57 | P.B.L. |
| 63 | PEC – Pharma Education Center |
| 125-144 | PHA.SE. ENGINEERING & COMPLIANCE SERVICES |
| 71 | Pharma D&S |
| 62 | PHARMA PARTNERS a PALLADIO GROUP brand |
| 50 | Pharmadule Morimatsu AB |
| 92 | PRC TICONUM LAB |
| 88 | PRINEOS |
| 74-75 | PTM Consulting |
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| 30-31-32 | QSGROUP |
| 117 | QStep |
| 95-96 | QUALIMETRIX |
| 156 | QUASCENTA PTE. ITD. |
| 14 | RATTIINOX |
| 11 | RECIPHARM ITALIA |
| 106 | ROFARMA ITALIA |
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| 51 | S4BT |
| 145 | SafetyDrugs |
| 112 | SAUERMANN ITALIA |
| 22-23 | SEA VISION |
| 41 | SERVICE PHARMA CHEMICAL & FOOD |
| 101 | SIEMENS |
| 47 | SOITRA |
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| 35 | SOTAX |
| 68 | STERIGENICS |
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| 139 | SWAN Analitica |
| 78 | TEAM mastery |
| 28 | Tecniche Nuove - Notiziario Chimico Farmaceutico |
| 111 | TEMA SINERGIE |
| 16 | TESTO |
| 147 | TRUFFINI & REGGE' FARMACEUTICI |
| 85 | UNIVAR SOLUTIONS |
| 114 | UNIVERSAL PACK |
| 70 | VAISALA |
| 121 | VIEW SCIENCE |
| 36-53 | VIS VIVA |
| 83 | WAB-GROUP® |
| 123 | ZETA |
| 128 | ZETA FARMACEUTICI GROUP |

From knowledge to digitalization for competitiveness of the health industry

The 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 Raffaele 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 11TH 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 (<i>free admission subject to mandatory registration</i>) |
| Sala del Borgo | <ul style="list-style-type: none"> • AM Instruments: Beyond compliance: strategies and innovation to face Annex 1's challenges |
| Sala della Marina 2 | <ul style="list-style-type: none"> • Bonfiglioli Consulting in collaboration with expert.ai: Digital, data, intelligence: how to bring the pharmaceutical industry into the future |
| Sala della Marina 1 | <ul style="list-style-type: none"> • Eurofins BioPharma Product Testing Italy: Innovation and new technologies in microbiology: The frontier of "Rapid Methods" |
| Sala del Faro | <ul style="list-style-type: none"> • Eurofins Medical Device Services: Medical devices – Contaminants on trial: a matter of manufacture? |
| Sala del Parco 1 | <ul style="list-style-type: none"> • FTR ADVISOR: Are we in possession of "quality" clinical data relevant to the intended purpose of our medical device? Means to obtain them in the pre/post market |
| Sala del Parco 2 | <ul style="list-style-type: none"> • PTM CONSULTING: The necessary change of pace to integrate combination products in the pharmaceutical industry |
| 13.00 | Inauguration of the 64th AFI Symposium at the entrance of the exhibition area |
| 12.30 – 14.00 | <i>Welcome lunch</i> |
| 14.00 – 15.00 | <ul style="list-style-type: none"> • Giorgio Bruno – AFI President Welcome and Opening of the Symposium |
| Sala del Tempio | <ul style="list-style-type: none"> • Lucio Poma – Nomisma Chief Economist Keynote Speech (<i>free admission</i>) Shifts in the healthcare world |

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

TECHNICAL AND SCIENTIFIC SESSIONS

| | |
|----------------------------|--|
| 15.15 – 19.00 | <ul style="list-style-type: none"> • SESSION I – ENERGY AND SUSTAINABILITY New compliances and real-life cases in the sustainability of the pharmaceutical world: challenges and opportunities |
| Sala del Castello 1 | |
| 15.15 – 18.45 | <ul style="list-style-type: none"> • SESSION II – INNOVATION From 4.0 to 5.0: a guideline and some practical examples |
| Sala del Tempio | |
| 15.15 – 18.45 | <ul style="list-style-type: none"> • SESSION III – CLINICAL RESEARCH Digitalization, decentralization, Real World Evidence: how to make Italy and Europe competitive in the field of clinical research |
| Sala del Castello 2 | |
| 20.00 | WHITE&BLUE Beach Party at the Beach of Grand Hotel Rimini in collaboration with |

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THURSDAY 12TH JUNE

- | | |
|--|---|
| <p>09.00 – 11.00 Sala del Tempio</p> | <ul style="list-style-type: none"> • SESSION IV – HTA HTA Regulation from JCA to Full HTA in Italy |
| <p>11.30 – 13.00 Sala del Tempio</p> | <ul style="list-style-type: none"> • SESSION V – REGULATORY Package leaflet digitalization: Where we stand and future perspectives |
| <p>09.00 – 13.00 Sala del Castello 2</p> | <ul style="list-style-type: none"> • SESSION VI – QUALITY Evolution of the Pharmaceutical Quality System for the continuity of business and the prevention of drugs shortages |
| <p>09.00 – 13.00 Sala del Castello 1</p> | <ul style="list-style-type: none"> • SESSION VII – BIOTECH The new frontiers of Advanced Therapies: from production to delivery |
| <p>09.00 – 11.00 Sala dell'Arco</p> | <ul style="list-style-type: none"> • SESSION VIII – SPECIAL PRODUCTIONS Digital innovation in the research field, development and management of special productions: opportunities and challenges |
| <p>11.30 – 13.30 Sala dell'Arco</p> | <ul style="list-style-type: none"> • 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 |
| <p>12.30 – 14.30 Foyer Sala dell'Arco</p> | <ul style="list-style-type: none"> • 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. |
| <p>12.30 – 14.00</p> | <p><i>Working lunch</i></p> |
| <p>14.00 – 15.00 Sala del Tempio</p> | <ul style="list-style-type: none"> • Roberto Burioni – University Vita-Salute San Raffaele di Milano Keynote Lecture (free admission) Viruses and Pandemics |
| <p>15.15 – 18.45 Sala del Tempio</p> | <ul style="list-style-type: none"> • SESSION X – MEDICAL DEVICES Innovation and application of the new technologies for substance-based Medical Devices in the field of MDR |
| <p>15.15 – 18.45 Sala del Castello 1</p> | <ul style="list-style-type: none"> • SESSION XI – SUPPLY CHAIN Criticalities and opportunities within drugs distribution |
| <p>15.15 – 18.45 Sala del Castello 2</p> | <ul style="list-style-type: none"> • SESSION XII – PHARMACOVIGILANCE Educational materials: an efficient management in the digital era |
| <p>15.15 – 17.15 Sala dell'Arco</p> | <ul style="list-style-type: none"> • SESSION XIII – PHARMACEUTICAL SCIENCES (AFI/SITELF) Research and development of new therapeutical approach in gastroenterology: clinical, pharmacological and social aspects |
| <p>17.15 – 19.45 Sala dell'Arco</p> | <ul style="list-style-type: none"> • SESSION XIV – CRS/SITELF Functional and innovative pharmaceutical excipients |
| <p>20.00</p> | <p><i>Gala Dinner of the Symposium at the Grand Hotel Rimini in collaboration with</i></p> |

FRIDAY 13TH JUNE

09.00 – 13.00

Sala del Tempio

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

09.00 – 13.15

Sala del Castello 1

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

09.30 – 11.15

Sala del Castello 2

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

09.30 – 13.00

Sala dell'Arco

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

13:00 – 14:30

Working lunch

From knowledge to digitalization for competitiveness of the health industry

- | | |
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| 10.00 - 12.30 | • Workshop |
| 13.00 | • Inauguration of the 64th AFI Symposium at the entrance of the exhibition area |
| 12.30 - 14.00 | • <i>Working lunch</i> |

WORKSHOP PROGRAMME

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

[CLICK HERE](#)

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

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

- | | |
|---------------|---|
| 09.00 - 10.00 | • Registration of the Workshop participants (at the entrance of the meeting rooms) |
| 10.00 - 12.30 | • Sala del Borgo Workshop organized by AM Instruments <i>Beyond compliance: strategies and innovation to face Annex 1's challenges</i> |
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| 10.00 - 12.30 | • Sala del Faro Workshop organized by Eurofins Medical Device Services <i>Medical devices – Contaminants on trial: a matter of manufacture?</i> |
| 10.00 - 12.30 | • Sala del Parco 1 Workshop organized by FTR ADVISOR <i>Are we in possession of "quality" clinical data relevant to the intended purpose of our medical device? Means to obtain them in the pre/post market</i> |
| 10.00 - 12.30 | • Sala del Parco 2 Workshop organized by PTM CONSULTING <i>The necessary change of pace to integrate combination products in the pharmaceutical industry</i> |
| 12.30 - 14.00 | • <i>Working lunch</i> |

14.00 - 15.00
Sala del Tempio

- Giorgio Bruno – AFI President
Welcome and Opening of the Symposium
 - Lucio Poma – Nomisma Chief Economist
Keynote Speech (free admission)
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 **2024 ERA (Environmental Risk Assessment) revision and its implementation in the drug industry**
- Ivo Caldera – AFI
 - Piero Iamartino – AFI – EIPG
- 16.30 - 17.15 **Coffee break**
- 17.15 - 17.45 **Carbon net zero (purpose 1, 2 and 3), sustainability goals and case studies of Chiesi group**
- Elisa Bandini – Chiesi Farmaceutici
- 17.45 - 18.15 **GSK sustainability ambition. from innovation to impact: unlocking the full potential of renewables in pharma**
- Ilaria Lo Presti – Glaxosmithkline
- 18.15 - 18.45 **Reducing environmental impact in the production of pharmaceutical active principles – The experience of European project LIFE GREENAPI in Angelini Pharma**
- Anna Codazzi – Angelini Pharma
 - Tommaso Iacoangeli – Angelini Pharma
- 18.45 - 19.00 **Discussion and end of session**
- 20.00 **WHITE&BLUE Beach Party at the Beach of Grand Hotel Rimini in collaboration with**

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14.00 - 15.00
Sala del Tempio

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Keynote Speech (free admission)
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

- 15.15 - 15.20 **Welcome address and introduction to the session**
- Alberto Bartolini – AFI – CIT
- Moderator:** • Alberto Bartolini – AFI – CIT
- 15.20 - 16.00 **GUIDELINE PRESENTATION FOR THE USE OF NEW TECHNOLOGIES**
- Introduction**
- Alberto Bartolini – AFI – CIT
- 4.0 New Technologies**
- Paola Martini – AFI – Takeda Manufacturing Italia
- Cyber Security e Data Protection**
- Gian Paolo Baranzoni – AFI
- GAMP 5 second edition**
- Sandro de Caris – GAMP Italia
- 16.00 - 17.00 **EXAMPLES OF AI PRACTICAL IMPLEMENTATION**
- Digitization in support of knowledge - The human at the center**
- Lory Iafrate – Aenova Group
 - Maria Paravani – Seingim Life Science
- A Deep-Learning Approach to Predict Optical Density at 600 Nanometers**
- Franca Cattani – Dompé Farmaceutici
 - Giovanna Scaramuzzino – Orise
- AI and ML, new opportunities for performance improvement in pharmaceutical production**
- Claudio Ernesto Mario Manzati – 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 - 17.45 **Fostering innovation and digitalisation in pharmaceutical manufacturing - Quality Innovation Group (QIG)**
- Giampiero Lorenti – EMA
- 17.45 - 18.30 **Tavola rotonda sui temi presentati**
- Moderator:** • Alberto Bartolini – AFI – CIT
- Panelists:**
- Gian Paolo Baranzoni – AFI
 - Sandro de Caris – GAMP Italia
 - Marco Paolo Fulfaro – AIFA
 - Giampiero Lorenti – EMA
 - Paola Martini – AFI – Takeda Manufacturing Italia
 - Lino Pontello – AFI
 - Alessandro Regola – AFI Vice-president
- 18.30 - 18.45 **Discussion and end of session**
- 20.00 **WHITE&BLUE Beach Party at the Beach of Grand Hotel Rimini in collaboration with**

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14.00 - 15.00
Sala del Tempio

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Shifts in the healthcare world
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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
- 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

- Saverio D'Amico – Train
- Matteo Della Porta – IRCCS Clinical Institute Humanitas

17.45 - 18.30

Panel discussion with:

- Sara Cazzaniga – AFI – IQVIA
- Valeria Glorioso – Confindustria DM
- Caterina Golotta – Federchimica Assobiotech
- Roberto Triola – Farmaindustria

18.30 - 18.45

Discussion and end of session

20.00

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

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SESSION IV

HTA REGULATION FROM JCA TO FULL HTA IN ITALY

Sala del Tempio

- 09.00 - 09.10 **Welcome address and introduction to the session**
- Paola Minghetti – AFI Vice-president – University of Milan
- 09.10 - 09.20 **Institutional greetings: The voice of Institutions**
- Francesco Saverio Mennini – Health Ministry – University of Rome Tor Vergata
- Moderators:**
- Simona Montilla – AIFA
 - Anna Ponzianelli – AFI – Moderna
- 09.20- 09.40 **AIFA and HTA Regulation: from EU to AIFA evaluation**
- Pierluigi Russo – AIFA
- 09.40 - 09.50 **Q&A**
- 09.50 - 10.40 **Panel discussion**
- Moderator:**
- Anna Ponzianelli – AFI – Moderna
- Panelists:**
- Walter Marrocco – FIMMG, CSE
 - Simona Montilla – AIFA
 - Mauro Moruzzi – Presidenza del Consiglio dei Ministri – Dipartimento per la Trasformazione Digitale
 - Carlo Riccini – Farindustria
 - Paolo Sciattella – SIHTA – CEIS Università degli Studi di Roma Tor Vergata
- 10.40 – 11.00 **Discussion and end of session**
- 11.00 – 11.30 **Coffee break**

SESSION V

PACKAGE LEAFLET DIGITALIZATION: WHERE WE STAND AND FUTURE PROSPECTIVES

Sala del Tempio

11.30 - 11.40

Introduction of the session

- Alessandra Molin Zan – AFI – Zentiva Italia

Moderators:

- Alessandra Molin Zan – AFI – Zentiva Italia
- Maria Elena Trovati – AFI – Amgen

11.40 - 12.00

The ePI project: the harmonisation of electronic product information for EU medicinal products

- Margherita Parziale – AIFA

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

12.40-13.00

Panel discussion "The evolution of the package leaflet: opportunities and challenges of the digitization process - Confrontation of opinions"

Moderator:

- Maria Elena Trovati – AFI – Amgen

Panelists:

- Paolo Abrate – SIFO
- Salvatore Bauleo – FIMMG Bologna
- Luciano Diomedi – FOFI – Ordine Farmacisti di Macerata
- Margherita Parziale – AIFA

12.30 - 14.00

Working lunch

SESSION VI

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

Sala del Castello 2

09.00 - 09.10

Introduction of the session

- Alessandro Regola – AFI Vice-president

Moderators:

- Giovanni Boccardi – AFI
- Alessandro Regola – AFI Vice-president

09.10 - 09.40

Are GMP compliance and business continuity two sides of the same coin? How risk assessment can foster efficient synergy

- Gabriele Bellatorre – AFI
- Devis Lamberti – AFI – MITIM Recipharm

09.40 - 10.10

Risk Management and Guaranteeing the Continuity of Supplies

- Andrea Mezzelani – AFI – Zentiva Italia
- Tania Perfetti – AFI – Ingenus Pharmaceuticals

10.10 - 10.40

Production processes optimization: in continuous quality as key to success

- Claudia Bianchi Carnevale – AFI – Pfizer
- Francesca Speroni – AFI – PTM Consulting

10.40 - 11.20

Coffee Break

Moderators:

- Marco Adami – AFI
- Lino Pontello – AFI

11.20 - 11.50

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
- Marcella Bruno – AFI – Teva Italia
- Mariagrazia Marzorati – AFI – Thea Farma

11.50 - 12.30

AIFA Speech on "Shortages"

- Domenico Di Giorgio – AIFA

12.30 - 13.00

Discussion and end of session

12.30 - 14.00

Working lunch

SESSION VII

THE NEW FRONTIERS OF ADVANCED THERAPIES: FROM PRODUCTION TO DELIVERY

Sala del Castello 1

09.00 – 09.05

Welcoming

- Marica Nobile – Federchimica Assobiotech
- Maria Luisa Nolli – AFI – NCNbio
- Sara Vignati – AFI – AFTI

Moderator:

- Maria Luisa Nolli – AFI – NCNbio

09.05 – 09.50

Keynote lecture – Drugs overview for gene therapy: from development to commerce

- Alessandro Aiuti – IRCCS Ospedale San Raffaele

09.50 – 10.10

Use of in vivo lentiviral vectors

- Alessio Cantore – SR-Tiget

10.10 – 10.30

Manufacturing of the future

- Filippo Begarani – PBL
- Monica Gunetti – AFI – Bambino Gesù Children's Hospital

10.30 – 11.00

The new frontiers of Decentralized Production for Advanced Therapies products

- Marco Paolo Fulfaro – AIFA

11.00 – 11.30

Coffee Break

11.30 – 11.50

CAR model supply chain by Gilead / Kite

- Andrea Quadrio – AFI – Gilead / Kite

11.50 – 12.10

Case history: Nemo project experience with Zolgesma

- Beatrice Berti – Fondazione Policlinico Universitario Agostino Gemelli IRCCS

12.10 – 12.40

Panel discussion: "Decentralization of the CART production: new production strategy"

Moderators:

- Stefano Baila – AFI – Eurofins-Biolab
- Monica Gunetti – AFI – Bambino Gesù Children's Hospital

Panelists:

- Beatrice Berti – Fondazione Policlinico Universitario Agostino Gemelli IRCCS
- Valentina Fonsato – 2i3T – University of Turin
- Marco Paolo Fulfaro – AIFA
- Claudia Maldini – AFI – Miltenyi Biotec
- Andrea Quadrio – AFI – Gilead / Kite
- Anna Silvani – AFI – Federchimica Assobiotech
- Cristina Zanini – AFI – IWT Pharma

12.50 – 13.00

Discussion and end of session

12.30 – 14.00

Working lunch

SESSION VIII

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

Sala dell'Arco

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

HERBAL MEDICINES

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

RADIOPHARMACEUTICALS

- 09.40 – 10.00 **Digital technology and Artificial Intelligence in medical image analysis**
- Jan Wolber – GE HealthCare Pharmaceutical Diagnostics UK
- 10.00 – 10.20 **PET Radiopharmaceuticals preparation and management: current state and future implementations**
- Manuela Monti – 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 – Federchimica Assogastecnici – Sol Group

- 10.40 – 11.00 **Panel Discussion**

- Moderator:**
- Floriana Raso – AFI

- Panelists:**
- Alessandro Assisi – AIFA
 - Marco Biagi – Università degli Studi di Parma
 - Giorgio Cappellucci – SIFIT
 - Lorella Chiappinelli – AIFA
 - Andrea Fieschi – Federchimica Assogastecnici
 - Manuela Monti – AFI – IRCCS Istituto Romagnolo per lo studio dei tumori "Dino Amadori" IRST
 - Anna Tolomeo – AFI – Itelpharma

- 12.30 – 14.00 **Working lunch**

SESSION IX

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

Sala dell'Arco

- Moderators:**
- Simona Aloe – AFI – Daiichi Sankyo Italia
 - Laura Patrucco – AFI – PRINEOS
- 11.30 – 11.45 **Human Value Based Healthcare – HVBH and case studies**
- Maria Rosaria Natale – Your Business Partner
- 11.45 – 12.40 **Panel discussion: The value of a VBH model combined with the patient voice for an "ad personam" patient journey. The floor to the Stakeholders**
- Moderators:**
- Simona Aloe – AFI – Daiichi Sankyo Italia
 - Maria Rosaria Natale – Your Business Partner
 - Laura Patrucco – AFI – PRINEOS
- Panelists:**
- Tiziana Pia Latiano – AIOM
 - Marcella Marletta – Università Campus Bio-Medico, Roma – F.A.V.O.
 - Teresa Petrangolini – ALTEMS – Catholic University of the Sacred Heart
 - Luca Roberti – EPF
 - Fabrizio Russo – Azienda per il Governo della Sanità della Regione Calabria Azienda Zero
 - Paolo Sciattella - SIHTA - CEIS Università degli Studi di Roma Tor Vergata
 - Annalisa Scopinaro – UNIAMO
- 12.40 – 12.50 **Digital design thinking approach in support of HVBH – Digital innovation in HTA**
- Roberta Gilardi – G. Gravity – Associazione Scientifica Sanità Digitale ASSD
- 12.50 – 13.20 **Talk Show: The value of a VBH model combined with the patient voice for an "ad personam" patient journey. The floor to the Stakeholders**
- Moderators:**
- Simona Aloe – AFI – Daiichi Sankyo Italia
 - Laura Patrucco – AFI – PRINEOS
- Panelists:**
- Massimo Beccaria – AFI – Advice Pharma
 - Luisa De Stefano – AFI – Roche
 - Alessandra Ferrari – AFI – Fondazione IRCCS Policlinico San Matteo
 - Anna Ponzianelli – AFI – Moderna
 - Francesca Rollo – AFI – DOC GENERICI
- 13.20 – 13.30 **Discussion and end of session: Take Home Messages**
- 12.30 – 14.00 **Working lunch**

Foyer Sala dell'Arco

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

14.00 - 15.00
Sala del Tempio

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

SESSION X

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

Sala del Tempio

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

14.00 - 15.00
Sala del Tempio

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

SESSION XI

CRITICALITIES AND OPPORTUNITIES WITHIN DRUGS DISTRIBUTION

Sala del Castello 1

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

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

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

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

16.30 - 17.15 *Coffee break*

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

- 17.35 - 17.55 **Wholesale distributor's criticalities**
• Viviana Zanelli – Q FARMA

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

- 18.15 - 18.25 **A prototype of integrated cold chain management**
• 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

Moderator:

- Andrea Oliva – AFI – Viatrix

15.30 - 16.00

AIFA's point of view

- Giovanni Diana – AIFA

16.00 - 16.30

AFI Project: "Rethinking Safety Communication"

- Matteo Monti, Maria Signorelli – AFI – Roche

16.30 - 17.00

Coffee break

17.00 - 17.30

Trade associations' involvement: double interview

- Serena Dominici – SIFO
- Annalisa Scopinaro – UNIAMO

17.30 - 18.30

Panel discussion

Moderator:

- Andrea Oliva – AFI – Viatrix

Panelists:

- Giovanni Diana – AIFA
- Simonetta Palazzini – A.U.S.L. Romagna
- Vincenza Panzarella – AFI – Gilead Sciences
- Giovanna Pescatore – Farmindustria
- Milena Sirtori – Eupati
- Romina Tulimiero – Egualea

18.30 - 18.45

Discussion and end of session

- Andrea Oliva – AFI – Viatrix

20.00

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



14.00 - 15.00
Sala del Tempio

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

SESSION XIII

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

Sala dell'Arco

- 15.15 - 15.25 **Welcome address and introduction to the session**
• Carla Caramella – AFI – University of Pavia
- Moderators:**
- Paolo Caliceti – AFI – SITELF – University of Padua
 - Matteo Cerea – AFI – SITELF – University of Milan
 - Andrea Gazzaniga – AFI – University of Milan
- 15.25 - 15.45 **Gastrointestinal tract pathologies: drugs, trends, therapies, and perspectives**
• Massimo Pedrani – AFI – Mogon Pharmaceuticals
- 15.45 - 16.15 **Pancreatic enzyme replacement therapy in the treatment of pancreatic exocrine insufficiency. Clinical and regulatory pathway**
• Marco Anelli, Massimo Latino – 4S4P
- 16.15 - 16.35 **Eosinophilic esophagitis: a new medical need?**
• Salvatore Agostino Giammillari – AFI – DMX Pharma
- 16.35 - 17.05 **Oral drug delivery for the treatment of gastrointestinal pathologies**
• Anastasia Foppoli – AFI – University of Milan
- 17.05 - 17.15 **Discussion and end of session**
- 20.00 *Gala Dinner of the Symposium at the
Grand Hotel Rimini in collaboration with*  **tecniche nuove**

14.00 - 15.00
Sala del Tempio

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

SESSION XIV

FUNCTIONAL AND INNOVATIVE PHARMACEUTICAL EXCIPIENTS

Sala dell'Arco

17.15 - 17.20

Introduction of the session

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

Moderators:

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

17.20 - 17.40

Introduction

- Laura Rampi – Croda

High purity excipients for solubility and bioavailability enhancement

- William Small – Croda

17.40 - 18.00

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

- Héloïse Imbault – Gattefossé

18.00 - 18.20

Sustainable and conventional excipients: balancing innovation and performance

- Francesco Puoci – Università della Calabria

18.20 - 18.40

Excipienti PEGilati

- Paolo Caliceti – AFI – SITELF – University of Padua

18.40 - 19.00

Regulatory aspects of pharmaceutical excipients

- Maria Vitocolonna – AIFA

19.00 - 19.20

Panel discussion with every panelist

19.20 - 19.45

CRS Italy Chapter Annual Meeting

20.00

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



SESSION XV

2025 PRODUCTION: NEWS AND FUTURE DEVELOPMENTS

Sala del Tempio

- 09.00 - 09.05 **Introduction of the session**
- Lino Pontello – AFI
- Moderators:**
- Lino Pontello – AFI
 - Vittorio Tonus – AFI
- 09.05 - 09.25 **Computer supports for the integrated factory: experiences on drugs and APIs manufacturing**
- Emilia Imbriani – Federchimica 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**
- Luca Perani – AFI – Roche
 - Adriano Pietrosanto – Egualea
- 10.25 - 10.45 **Discussion and questions on the first part of the morning speeches**
- 10.45 - 11.30 **Coffee break**
- Moderators:**
- Luciano Gambini – AFI
 - Francesca Selmin – AFI – University of Milan
- 11.30 - 11.50 **The risk analysis for IMP production in manufacturing facilities**
- Sebastiano Carangelo – AFI – Evotec
 - Claudio Pagano – AFI – Evotec
- 11.50 - 12.20 **Elements of Quality by Design from the early stages of a complex injectable drug development**
- Marinella Capuzzi – AFI – Italfarmaco
 - Silvia Piersanti – PTM Consulting
- 12.20 - 12.50 **Experimental injectable products based on lipid nanoparticles: study and development**
- Giovanni Ghezzi – Thermo Fisher Scientific
 - Umberto Romeo – CordenPharma
- 12.50 - 13.00 **Discussion and end of session**
- 13.00 - 14.30 **Working lunch**

SESSION XVI

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

Sala del Castello 1

- 09.00 - 09.05 **Introduction of the session**
- Massimo Beccaria – AFI – Advice Pharma
 - Sara Cazzaniga – AFI – IQVIA
- Moderators:**
- Massimo Beccaria – AFI – Advice Pharma
 - Sara Cazzaniga – AFI – IQVIA
- 09.05 - 09.25 **Overview of the Italian digital system in healthcare: from AI to big-data**
- Enrico Caiani – Politecnico di Milano
- 09.25 - 09.45 **Criteria for the definition of Integrating digital health into the strategies of a global pharmaceutical company**
- Andrea Paolillo – Merck Group
- 09.45 - 10.05 **Innovation applied to drug distribution in clinical trials field: the Palladio Group case study**
- Gabriele Molari – AFI – Palladio Group
- 10.05 - 10.25 **Italian digital health: diffusion and future prospects, data from Politecnico di Milano's observatory**
- Chiara Sgarbossa – Politecnico di Milano
- 10.25 - 10.45 **Secondary use of data in scientific research and the European scenario: major privacy challenges**
- Laura Liguori – Studio Legale Portolano Cavallo
- 10.45 - 11.30 **Coffee break**
- Moderators:**
- Massimo Beccaria – AFI – Advice Pharma
 - Sara Cazzaniga – AFI – IQVIA
- 11.30 - 11.50 **MUSA Data: Rapid implementation of in silico Pipelines for pharmaceutical and healthcare innovation**
- Ernesto Damiani – University of Milan
- 11.50 - 12.10 **Use of digital medical devices: the RTA case study**
- Davide Gaudesi – Advice Pharma
- 12.10 - 12.20 **myPlenity APP, a digital ally for weight loss and lifestyle improvement**
- Laura Lazzarotti – Theras Group
- 12.20 - 12.40 **Strategy and implementation of a digital therapy from a pharmaceutical industry: Polifarma's Quark project**
- Andrea Bracci – Polifarma
- 12.40 - 13.00 **Innovation processes in a large company: Astrazeneca case study**
- Valeria Lovato – AFI – Astrazeneca
- 13.00 - 13.15 **Discussion and end of session**
- 13.00 - 14.30 **Working lunch**

SESSION XVII

MARKET AND CRITICALITIES OF API AND EXCIPIENTS' MANAGEMENT

Sala del Castello 2

- 09.30 - 09.35 **Introduction of the session**
- Piero Iamartino – AFI – EIPG
- Moderators:**
- Piero Iamartino – AFI – EIPG
 - Antonella Volpe – Federchimica Aschimfarma
- 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 – Federchimica 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**
- Iain Moore – IPEC Europe
- 10.55 - 11.15 **Critical issues in API management: summary of non-conformities and opportunities for continuous improvement**
- Giuseppina Ialongo – AIFA
- 11.15 - 11.45 *Coffee break*

SESSION XVIII

TRENDS AND SOCIAL PHENOMENA IN THE DRUGS' SUPPLY CHAIN

Sala dell'Arco

FIRST SECTION

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

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

09.30 - 09.40

Introduction of the session

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

09.40 - 09:55

Presentation

- Alessandro Libero Lorini – AFI – Boiron

09.55 - 11.00

Panel discussion

Moderator:

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

Panelists:

- Alfredo Lombardi – HR Executive Consultant
- Fedele Pini – AFI – Seingim Life Science
- Maria Lisa Platania – Incrementum Factory
- Rosa Sant'Angelo – SIP – APS Amigay
- Olimpia Alessandra Zuliani – AFI – HBA – Daiichi Sankyo Italia

11:00 - 11:30

Coffee break

SECOND SECTION

Women and startups in life science: a winning combination

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

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

11.30 - 11.40

Introduction of the session

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

11.40 - 11.55

Presentation

- Marica Nobile – Federchimica Assobiotec

11.55 - 12.50

Panel discussion

Moderators:

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

Panelists:

- Rossella Dorati – Università degli Studi di Pavia
- Eleonora Maretti – AFI – PerFormS
- Valentina Russo – Logogramma
- Simona Varani – XGEN Venture

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 **64th 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 12th June at the Grand Hotel Rimini, during the Gala Dinner.

The poster submission form and the abstract template must be received **no later than 15th 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: 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.l.

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 th May | | After 13 th 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 12th 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 31st May 2025

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

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

HOTEL BOOKING


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

[Download the hotel reservation form](#)

to be sent by 17th May 2025 to:

eventi@newaurameeting.it

TIMETABLE

| |  Wednesday 11th June 14.00 - 19.00 | Thursday 12th June 09.00 - 13.30 | Thursday 12th June 14.00 - 19.45 | Friday 13th 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 and future developments |
| | 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 | |
| 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 |
| SALA DELL'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 Trends and social phenomena in the drugs' supply chain |
| | | 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 | |
| FOYER SALA DELL'ARCO | | 12.30 – 14.30 POSTER SESSION | | |

Scientific Secretariat

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Associazione Farmaceutici Industria
Società Scientifica

