XI FORESIGHT TRAINING COURSE

# CHANGES IN REGULATORY SCIENCES IN THE EU

how to move from a reactive
to a multi-stakeholder proactive attitude

## PAVIA, ITALY

25 > 27 OCTOBER
2018

**ISTITUTI CLINICI SCIENTIFICI MAUGERI**
Via Salvatore Maugeri, 6

FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS

Master Biennale di II livello in
Discipline Regolatorie "G. Benzi"

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Change in Regulatory Sciences is a continuous challenging process! The challenge is to align scientific and patients' objectives with regulatory requirements along the whole development process of health products.

Moreover, all the stakeholders should be aware of the criteria by which the authorisation and access to products will be measured and decided to cover patients' specific needs. To ensure such an alignment, it is time to moving from a reactive regulation to a proactive involvement of all the involved parties, including users as well as producers.

This course is aimed at involving and networking people to properly understand the many novelties of the EU system and contributing to their implementation to anticipate good medicines and other products for human health and wellbeing on the market. The present Course will discuss the EU Pharmaceutical System novelties, with special focuses on three main topics. In addition, an initiative to set up a Regulatory Network will be presented.

## MAIN TOPICS

### Health data and health science

Health data represent a very crucial topic due to the increasing adoption of electronic technologies allowing FAIR data collection, interpretation, sharing and reuse in the developmental process of innovative health products ("health data science").

This large use of health data takes extraordinary advantage by the progress of the informatic technology as applied to health. In addition, 'health data science' should demonstrate high capacity to deal with the implementation of a new legal and regulatory approach to patients data protection and confidentiality following the General Data Protection Regulation (GDPR). A strong impact is expected from GDPR on data quality and reliability, consent and assent issues in all research activities sharing information, including clinical trials and studies.

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## MAIN TOPICS

### Medical devices

In April 2017, two new Regulations were adopted, (namely Regulation (EU) 2017/745 on medical devices, and Regulation (EU) 2017/746 on in vitro diagnostic medical devices) and entered into force on 25 May 2017. These replace the existing Directives and establish a modernised and more robust EU legislative framework to ensure better protection of public health and patient safety. The legislation now being in the form of a Regulation, rather than a Directive, means that the EU law is directly applicable at national level without requiring transposition through a specific national legislation. This should allow for greater legal certainty and prevent variation applied across EU Member States.

### Rare diseases and Orphan Medicinal Product Regulation time for revision?

The Orphan Medicinal Products Regulation has obtained great results in the last 18 years. However, many rare diseases are still without any treatment and the harmonisation of the real availability of therapies for patients has not been yet achieved. For these two reasons, a revision of Regulation (EC) 141/2000 is expected soon. It will be mainly aimed to foster preclinical and clinical research of new treatments for rare diseases and to harmonise best practices and procedures for orphan medicines evaluation. What is expected is to overlap the current barriers and difficulties encountered in the new products developmental process and to reduce the inequalities derived by the geographical dispersion of patients and specialised centres. Special ethical and methodological issues will be explored.

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## THURSDAY 25TH OCTOBER 2018

02,00 pm **Welcome address**

Adriana Ceci, Maurizia Dossena

Enrico Bosone, *SIAR representative*
Stefano Govoni, *SIF representative*
Mario Melazzini, *ICSM representative*
Francesco Svelto, *UNIPV representative*
Guido Rasi, *EMA representative*

03,00 pm **Opening Session**

**The role of the patients and healthcare professionals in the regulatory framework**

Chairs: Adriana Ceci, Alan G Fraser

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|---|---|---|
| 03,00 pm | EMA experience in supporting participation of patients and healthcare professionals in EU medicines regulation | **Ivana Silva**<br>*EMA* |
| 03,30 pm | How has the role of patients got stronger and what they have learnt so far | **François Houÿez**<br>*EURORDIS* |
| 04,00 pm | The evolving role of healthcare professionals in the regulatory field | **Giovanni Migliaccio**<br>*Consorzio per Valutazioni Biologiche e Farmacologiche* |
| 04,30 pm | The COST programme to create networks in the scientific setting | **Valentina Cardinale**<br>**Giulia Rotundo**<br>*Ministero dell'Istruzione, dell'Università e della Ricerca* |
| 05,00 pm | Presentation of COST proposal | **Viviana Giannuzzi**<br>*Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus; EMA-PDCO* |
| 05,30 pm | **Discussion** | |

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## FRIDAY, 26TH OCTOBER 2018

09,00 am **First Session**

**Medical Devices: the new era in Europe**

Chairs: Carla Caramella, Maurizia Dossena

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|---|---|---|
| 09,00 am | Novelties and implementation of the Regulation 745-2017 | **Alan G Fraser**<br>*European Society of Cardiology; Cardiff University* |
| 09,30 am | The new Regulations on medical devices and on in vitro diagnostics: a real revolution? | **Franco Gattafoni**<br>*ACCREDIA* |
| 10,00 am | The challenges of the new Regulation from the Notified Bodies point of view | **Luciana Gramiccioni**<br>*EUROFINS* |
| | Coffee break | |
| 11,00 am | The new provisions introduced by rule 21 | **Antonella Mamoli**<br>*IBSA Farmaceutici Italia* |
| 11,30 am | The manufacturing and control of medical devices in the perspective of the new regulation | **Fabio Geremia**<br>*CTP System, Akka Life Sciences* |
| 12,00 am | The new regulation and the management of software and applications | **Cettina Garufi**<br>*ACCREDIA* |
| 12,30 am | Conclusive remarks:<br>**Carla Caramella, Maurizia Dossena** | |

01,00 pm **Light lunch**

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## FRIDAY, 26TH OCTOBER 2018

02,00 pm **Second Session**

**Data Science supporting medicines and healthcare development**

Chairs: Fedele Bonifazi, Victoria Hedley

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|---|---|---|
| 02,00 pm | Big data & life sciences | **Graziano Pesole**<br>*Consiglio Nazionale delle Ricerche, University of Bari, ELIXIR* |
| 02,30 pm | Data integration systems to support scientific research and patient enrolment in clinical studies | **Riccardo Bellazzi**<br>*Istituti Clinici Scientifici Maugeri, University of Pavia* |
| 03,00 pm | When rare becomes FAIR: a discussion on how to manage sensitive, rare disease data to enable large scale analysis | **Marco Roos**<br>*Leiden University Medical Centre* |
| 03,30 pm | How to protect patients data in the light of the new Regulation? | **Deborah Mascalzoni**<br>*CRB Uppsala University* |
| 04,00 pm | Industry perspective and Novartis experience | **Roberto Orsenigo**<br>*Novartis Farma S.p.A.* |
| 04,30 pm | Conclusive remarks:<br>**Claudio Carta, Paola Baiardi** | |

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## SATURDAY, 27TH OCTOBER 2018

09,00 am

### Third Session

### Orphan products and perspectives on the horizon

Chairs: François Houÿez, Donato Bonifazi

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|---|---|---|
| 09,00 am | What member states have done so far at EU and national level | **Agenzia Italiana del Farmaco representative - TBC** |
| 09,30 am | Health outcomes of orphan medicines | **Joseph Torrent-Farnell**<br>*Catalan Health Service* |
| 10,00 am | The demonstration of significant benefit in the EU framework | **Laura Fregonese**<br>*EMA* |
| 10,30 am | Developing Advanced therapies for rare diseases in EU: opportunities and challenges in the experience of a Charity | **Michela Gabaldo**<br>*Fondazione Telethon* |
| 11,00 am | The complexity of developing innovative medicines for rare diseases | **Diego Ardigò**<br>*Chiesi Farmaceutici* |
| 11,30 am | Are patients satisfied from the implementation of EU policies on orphan medicines development and availability so far? | **Dimitrios Athanasiou**<br>*World Duchenne Organization; EMA-PDCO* |
| 12,00 am | Researchers, networks, new funds for rare diseases | **Daria Julkowska**<br>*E-Rare* |
| 12,30 am | Conclusive remarks: expectations from the Orphan Medicines Regulation revision<br>Viviana Giannuzzi, Enrico Bosone | |

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## SPEAKERS LIST

| | | |
|---|---|---|
| Ardigò | Diego | Chiesi Farmaceutici, R&D Rare Diseases Unit Head |
| Athanasiou | Dimitrios | World Duchenne Organization, Board Member; MDA Hellas, Member; European Medicines Agency, PDCO Member |
| Baiardi | Paola | Istituti Clinici Scientifici Maugeri, Scientific Coordinator; European Medicines Agency, PDCO Member |
| Bellazzi | Riccardo | Istituti Clinici Scientifici Maugeri, LIRSC Lab Director; Università degli Studi di Pavia, Department of Electrical, Computer and Biomedical Engineering Professor |
| Bonifazi | Donato | Consorzio per Valutazioni Biologiche e Farmacologiche, CEO; AICRO, President |
| Bonifazi | Fedele | Fondazione per la Ricerca Farmacologia Gianni Benzi Onlus, **Vice-**President and Secretary |
| Bosone | Enrico | Società Italiana Attività Regolatorie, President |
| Caramella | Carla | Università degli Studi di Pavia, Professor |
| Cardinale | Valentina | Ministero dell'Istruzione, dell'Università e della Ricerca, COST National Coordinator |
| Carta | Claudio | Istituto Superiore di Sanità, Researcher |
| Ceci | Adriana | Fondazione per la Ricerca Farmacologia Gianni Benzi Onlus, President |
| Dossena | Maurizia | Università degli Studi di Pavia, Professor |
| Fraser | Goldon Alan | European Society of Cardiology, Regulatory Affairs Committee Chairman; Cardiff University, Professor |
| Fregonese | Laura | European Medicines Agency, Scientific Officer |
| Gabaldo | Michela | Fondazione Telethon, Alliance Management & Regulatory Affairs Head |
| Garufi | Cettina | ACCREDIA, Medical Devices expert, Lead Auditor ISO 9001, ISO 13485, ISO 22716 |
| Gattafoni | Franco | ACCREDIA, Medical Devices and In Vitro Diagnostic Expert, Lead Assessor ISO 17020, ISO 17021, ISO 17025, ISO 17065, ISO 15189 |
| Geremia | Fabio | CTP System, Akka Life Sciences, Qualified Person Auditor and Senior Consultant, P&Q Northern Italy Responsible |

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|---|---|---|
| Giannuzzi | Viviana | Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus, Research Department Head;<br>European Medicines Agency, PDCO Member |
| Govoni | Stefano | Società Italiana di Farmacologia, Scientific Committee Member |
| Gramiccioni | Luciana | Organismo notificato EUROFINS, Scientific Director |
| Hedley | Victoria | Newcastle University John Walton Muscular Dystrophy Research Centre - MRC Centre for Neuromuscular Diseases, Rare Disease Policy Manager |
| Houyez | Francois | EURORDIS, Treatment Information and Access Director, Health Policy Advisor |
| Julkowska | Daria | E-Rare, Scientific Coordinator |
| Mamoli | Antonella | IBSA Farmaceutici Italia, Regulatory Affairs Manager |
| Mascalzoni | Deborah | Public Health and Caring Sciences department, Centre for Research Ethics & Bioethics (CRB) Uppsala University, Senior Researcher |
| Melazzini | Mario | Istituti Clinici Scientifici Maugeri, Scientific Director |
| Migliaccio | Giovanni | Consorzio per Valutazioni Biologiche e Farmacologiche, Scientific Director |
| Orsenigo | Roberto | Novartis Farma S.p.A., Medical Franchise Leader Immunology, Hepatology and Dermatology |
| Pesole | Graziano | Consiglio Nazionale delle Ricerche, Director of the Institute of Biomembranes and Bioenergetics;<br>University of Bari, professor;<br>ELIXIR, Head of Italian Node |
| Rasi | Guido | European Medicines Agency, Executive Director |
| Roos | Marco | Leiden University Medical Centre, Assistant Professor |
| Rotundo | Giulia | Ministero dell'Istruzione, dell'Università e della Ricerca, Committee of Senior Officials of COST Association Member |
| Silva | Ivana | European Medicines Agency, Public Engagement Department, Stakeholders and Communication Division |
| Svelto | Francesco | Università degli Studi di Pavia, Vice-Rector |
| Torrent-Farnell | Joseph | Catalan Health Service, Medicine Division Head |

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The **Gianni Benzi Pharmacological Research Foundation** is a non-profit scientific research organization founded in 2007 to uphold the ideas and continue the work of Professor Gianmartino Benzi.

Professor Benzi's forward-thinking idea was that the European pharmaceutical system can act as a key to both scientific development and economic growth, and that academia should be fully involved in it. As a result, he worked tirelessly on behalf of EMEA from 1989 to 2006.

He founded in Pavia the first Interdisciplinary and International Regulatory Science School in Europe.

Today, the Gianni Benzi Foundation is embracing his heritage by providing high-level training for Regulatory Sciences at a Europe-wide level, including the annual Foresight Training Courses, short-term international courses for highly-specialized professionals in the various fields of Regulatory Sciences. Each course is focused on the most recent innovation and advancement in the field and aims to put together different stakeholders and experts in the sector willing to share their experiences and knowledge.

## COURSE SCIENTIFIC COMMITTEE

**Paola Baiardi** | *Istituti Clinici Scientifici Maugeri*

**Enrico Bosone** | *Società Italiana Attività Regolatorie*

**Maurizia Dossena** | *Università di Pavia*

**Viviana Giannuzzi** | *Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus*

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ORGANISED BY

Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

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Master Biennale di II livello in Discipline Regolatorie "G. Benzi"

IN COLLABORATION WITH

Istituti Clinici Scientifici Maugeri

Società Italiana Attività Regolatorie

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