GIANNI BENZI
PHARMACOLOGICAL RESEARCH
FOUNDATION

XIth FORESIGHT TRAINING COURSE

Changes in Regulatory Sciences in the EU

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

25-27 October, 2018
Pavia (Italy)

organised by

Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus

FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS

Master in Discipline Regolatorie 'Gianni Benzi' Università di Pavia

Master Biennale di II livello in
Discipline Regolatorie "G. Benzi"
Università degli Studi di Pavia

In collaboration with

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DRAFT AGENDA

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.

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, 25 October 2018

02,00 pm
Welcome address
Stefano Govoni, SIF Representative

03,00 pm		
Opening Session		
The role of the patients and healthcare professionals in the regulatory framework		
How has the role of patients got stronger and what they have learnt so far	*François Houÿez* EURORDIS, Treatment Information and Access Director, Health Policy Advisor	03,00
The evolving role of healthcare professionals in the regulatory field	*Giovanni Migliaccio* Consorzio per Valutazioni Biologiche e Farmacologiche, Scientific Director	03,30
The COST programme to create networks in the scientific setting	*Valentina Cardinale* Ministero dell'Istruzione, dell'Università e della Ricerca, COST National Coordinator	04,00
Presentation of COST proposal	*Viviana Giannuzzi* Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus, Scientific research Coordinator; EMA, PDCO Member	04,30
Discussion		05,00

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Friday, 26th October 2018

09,00 am ***First Session*** ***Medical Devices: the new era in Europe***		
Novelties and implementation of the Regulation 745-2017. How the panorama has changed since its publication?	*Annamaria Donato* Ministero Salute, Ministero Salute Direzione generale dei dispositivi medici e del servizio farmaceutico- Ufficio 3, Director	09,00
The impact of the new Regulation on the activities of the notified body	*Luciana Gramiccioni* Eurofin, Scientific Director	09,30
The novelties introduced by rule 21	*Antonella Mamoli* IBSA Farmaceutici Italia srl, Regulatory Affairs Manager	10,00
New rules on the manufacture and control of medical devices	*Fabio Geremia* CTP System Srl, Qualified Person Auditor and Senior Consultant	10,30
The new Regulation and the management of software and applications	*Cettina Garufi* ACCREDIA, Inspector	11,00
Round table with companies		11,30

Light Lunch 12,00 pm

03,00 pm ***Second Session*** ***Data Science supporting medicines and healthcare development***		
Big data & life sciences	*G. Pesole* Consiglio Nazionale delle Ricerche and University of Bari ELIXIR Italia, Node Head	03,00
Data integration systems to support scientific research and patient enrolment in clinical studies	*Riccardo Bellazzi* Istituti Clinici Scientifici Maugeri, LIRSC Lab Director	03,30
When rare becomes FAIR: a discussion on how to manage sensitive, rare disease data to enable large scale analysis	*Marco Roos* Leiden University Medical Centre – Assistant Professor	04,00
The Ethics Committees role in protecting patients data	*Deborah Mascalzoni* Department of Public Health and Caring Sciences, Centre for Research Ethics & Bioethics (CRB) Uppsala University, Senior Researcher	04,30
Industry perspective and experience	*Anna Ponzianelli* Novartis, Institutional Affairs & Rome Office Head	05,00

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Saturday, 27th October 2018

09,00 am ***Third Session*** ***Orphan products and perspectives on the horizon***		
What regulatory agencies have done so far at EU and national level	*Domenica Taruscio* Istituto Superiore di Sanità, National Center for Rare Diseases Director	09,00
Health outcomes of orphan medicines	*Joseph Torrent-Farnell* Catalan Health Service, Medicine Division Head	09,30
The demonstration of significant benefit in the EU framework	*Laura Fregonese* EMA, Scientific Officer	10,00
Developing Advanced therapies for rare diseases in EU: opportunities and challenges in the experience of a Charity	*Michela Gabaldo* Fondazione Telethon, Alliance Management & Regulatory Affairs Head	10,30
New and innovative orphan medicines	*Diego Ardigò* Chiesi Farmaceutici, R&D Rare Diseases Unit Head	11,00
Patient expectations	*Dimitrios Athanasiou* World Duchenne Organization, Board Member MDA Hellas; EMA, Member of PDCO	11,30
Researchers, network, new funds for rare diseases	*Daria Julkowska* E-Rare, Scientific Coordinator	12,00
Conclusive remarks: expectations from the OMP Regulation revision	All speakers	12,30

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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

Viviana Giannuzzi - Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus
Maurizia Dossena - Università di Pavia
Paola Baiardi - Istituti Clinici Scientifici Maugeri
Enrico Bosone - Società Italiana Attività Regolatorie