

Preface

The idea to develop in Rome an European School for the Scientific and Regulatory Assessment of New Medicines was something that both of us shared during a conversation on the perspectives of the new Italian Agency for Medicines (AIFA). The idea became a reality in less than one year thanks to the intelligence of Prof. Alessandro Finazzi Agrò, Rector of Rome Tor Vergata University and the deep motivation of the Deans of the two Faculties involved, prof. Renato Lauro, Faculty of Medicine and prof. Nicola Vittorio, Faculty of Sciences.

Villa Mondragone (XVI century) belonging to Rome Tor Vergata University, was chosen as the seat of the School. Due to its historical value and facilities, it will create an ideal atmosphere of intellectual challenge, insight and this may lead to fruitful relations between teachers and post-graduate students.

The encouragement we received from Thomas Löngreen, Executive Director of the EMEA, who outlined the need at the European level of specific professionals with an outstanding training in drug assessment and the need for harmonization of the evaluation procedures among the different EU member States represented for us a valuable stimulus to go ahead with this initiative.

The effort we made in trying to achieve training courses of high profile is documented by the invited lecturers, most of them represent the best experts in Europe in a complex and rapidly evolving field.

The master courses are aimed at post-graduate students qualified in Medicine, Biology, Pharmacy and strictly related fields. A well structured programme was designed with two modules, the first dedicated to updating the scientific aspects of the main classes of drugs and to the requirements of the new pharmaceutical legislation for marketing authorisation and the second dedicated to clinical, therapeutic and regulatory aspects. Therefore, the attendees will be properly trained in the evaluation of pharmaceutical dossiers, both from the scientific and regulatory point of view. The master courses will be carried out with some flexibility due to their modular organization. The enthusiastic welcome by the pharmaceutical community and the participation of some of their experts in the didactic activity is considered by us a fundamental step for the success of the School.

Finally, the outstanding scientists who have accepted to stand in the Honorary Committee represent an authoritative guide for the organization of a series of invited lectures and “hot” topic events, which will contribute to render Villa Mondragone an international forum, open in a transparent way to all the stakeholders (Scientific Societies, Regulatory Authorities, Industries, patients and professional Associations, etc.) in order to find out new solutions in some still controversial topics.

The Directors of the School
Prof. Giuseppe Nisticò
Dr. Nello Martini





European School

for Scientific and Regulatory Assessment of New Medicines

PRESIDENT

Prof. Alessandro Finazzi Agrò
Rector of University of Rome Tor Vergata

DIRECTORS

Prof. Giuseppe Nisticò
*Full Professor of Pharmacology
University of Rome Tor Vergata
CHMP member, EMEA, London*

Dr. Nello Martini
*General Director of Agenzia Italiana del Farmaco
(AIFA)*

PRESIDENT OF THE SCIENTIFIC COMMITTEE

Prof. Renato Lauro
*Full Professor of Internal Medicine
University of Rome Tor Vergata*

HONORARY COMMITTEE

Prof. Patrizia Aducci
*Director of Biology Department
University of Rome Tor Vergata*

Prof. Enrico Bollero
General Director Polyclinic Tor Vergata

Prof. Daniel Brasseur
President CHMP, EMEA, London

Dr. Antonella Cinque
President of Agenzia Italiana del Farmaco (AIFA)

Dr. Sergio Dompè
President of Italian Pharmindustry, Rome

Prof. Enrico Garaci
President Istituto Superiore di Sanità, Rome

Prof. Silvio Garattini
Director of Mario Negri Institute, Milan

Prof. Salvador Moncada
*Director of the Wolfson Institute
University College, London*

Prof. Paolo Preziosi
*Director of Department of Pharmacology,
Catholic University, Rome*

Prof. Leonardo Santi
*President of CNBB,
Presidency of the Council of Minister*

COORDINATORS OF THE COURSES

Prof. Giuseppe Novelli
*Full Professor of Human Genetics
University of Rome Tor Vergata*

Prof. Mauro Piacentini
*Full Professor of Biology
University of Rome Tor Vergata*

Dr. Pasqualino Rossi
*Head of the European Assessment Department
Agenzia Italiana del Farmaco (AIFA)*

The University of Rome Tor Vergata will start a new master “II level” in “Scientific and Regulatory Assessment of New Medicines” in 2006-2007 academic year.

The master consists in a two-year advanced course with a well structured programme carried out with intensive sets of lectures concentrated in 2 periods (March-April and May-June). An additional 6-month stage period in a National Agency for Medicine is required.

MAIN OBJECTIVE

The main objective of the master is to train graduates in Medicine, Pharmacy, Biology and strictly related fields, in the scientific and regulatory assessment of new medicines in view of the requisites posed, according to the new pharmaceutical legislation in Europe, by the national and European regulatory authorities in order to get marketing authorisation.

At the end of the two years course the participants should acquire the following professional skills:

- preparation and evaluation (pharmaceutical chemistry, preclinical and clinical assessment reports) of pharmaceutical dossiers for registration and marketing authorisation by the national and European Agencies for Medicines;
- knowledge of the legal and economic national and international aspects related to drug registration policies;
- ability to run interactions with members of the Agencies and of the industrial companies.

ORGANIZATION OF THE COURSES

The two-year program is organized each year in two modules of lectures:

- **first module (March-April)** of lectures (6 hours a day) dealing with basic pharmacology, toxicology, biotechnology, pharmaceutical legislation, etc.
- **second module (May-June)** of lectures (6 hours a day) dealing with the clinical and therapeutic indications of the main classes of drugs, case reports and practical information on the preparation of pharmaceutical dossiers.

LANGUAGE

The official language of the lectures and exams is English.

ENROLLMENTS

The master is aimed at graduates in Medicine, Pharmacy, Biology and strictly related fields. A limited number (from a minimum of 20 to a maximum of 50) post-graduate students will be accepted. An essential prerequisite is the knowledge of written and spoken English. The selection of the students will be based on the curriculum vitae, working experience in the field, scientific publications and titles, interview by a School's commission, etc.

The enrollment fee is € 5.000,00 per year.

EMPLOYMENT OPPORTUNITIES

The trained graduate professionals will have employment opportunities in:

- National, European and International Agencies for Medicines
- Regional bodies and Hospitals dealing with public health, pharmacovigilance, clinical trials, etc.
- Pharmaceutical industries
- Public and Private agencies dealing with drug registration
- Independent professional activity

CREDITS AND HOURS OF DIDACTIC ACTIVITY

According to the Italian legislation the master will allow to gain 60 credits and 620 hours of lectures integrated by a series of invited lectures, meetings and other practical teaching.

ATTENDANCE

Attendance at the courses is compulsory and will be monitored. Overall attendance must cover at least 75% of the total teaching hours and a period of 6 month stage.

STAGES

During the two years course a training 6 month practical period in a National Agency for Medicines is required before the final examination.

ECONOMIC BENEFITS

The Board of Directors can approve financial aid for low-income candidates and for students with excellent curricula through:

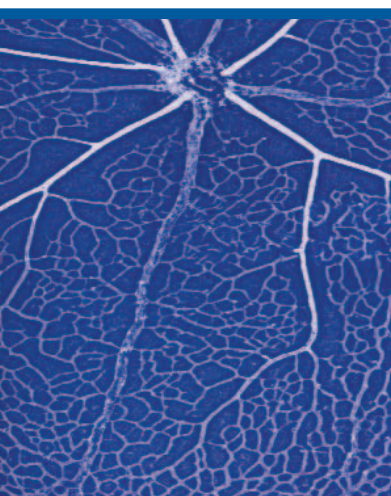
- scholarships
- total or partial fee exemption

Candidates with 66% proven disabilities are entitled to a fee exemption.

TESTING

Competence is tested at the end of each course through an oral and/or written exam given by an appointed Commission. At the end of the 2 year-course the final exam which confers the master's title will deal with the discussion of a case report or work project related to issues dealt during the 2 year-course.

In order to pass the exams the students must get at least 18/30 for each discipline. In order to obtain the master's title the final examination grade must be at least 66/110.



LOCATION OF DIDACTIC ACTIVITY

Villa Mondragone

Secretariat: Tel. +39 06 9401941

Fax +39 06 94019439

E-mail: info@pharmbiotechcenter.com

Web: www.pharmbiotechcenter.com

TEACHERS

The teaching staff includes professors of University of Rome Tor Vergata, other Universities or National Research Institutes, European Agency for Medicines (EMA), Italian Agency for Medicines (AIFA) other national drug Agencies and experts of international reputation of pharmaceutical companies.

INVITED LECTURES AND MEETINGS

A series of integrative lectures by invited top level scientists and experts and some meetings on “hot” topics in the pharmaceutical field will be periodically organized following suggestions of members of the Honorary Committee.



Organization
of the course
Topics 1st Year



FIRST QUADRIMESTER (12 MARCH - 14 APRIL)

Basic aspects

1. Quality Aspects (*M. Paci, E. Cogliandro, B. Botta*)
2. General Pharmacology, Pharmacodynamics (*P.L. Navarra, P. Luly*), Pharmacokinetics (*E. Perucca*), From discovery to development of new Medicines (*G. Gaviraghi*), New pharmaceutical preparations
3. Toxicology (*A.R. Meneguz, M.G. Leone, L. Braghioli*), Pharmacovigilance and Risk Management Plans, Pharmacoepidemiology (*P. Rossi*)
4. Clinical Pharmacology & Methodology (Phase I, II, III, IV) (*P. Castellani, E. Donato Di Paola*)
5. Biotechnology (*M. Piacentini, L. Santi*), Cell and Protein Engineering for industrial purposes (*A. Battistoni, G. Federici*)
6. Pharmaceutical Legislation (*F. Sauer, N. Behrndt, H. Cranz, G. Conti*) Pharmacoconomics (*N. Martini, A. Addis, M. Intorcica*)
7. Neuropharmacology (*R. Nisticò, E.A. Ratti*) Psychopharmacology (*M.L. Barbaccia, G. Gaviraghi*)
8. Antinflammatory drugs (*C. Patrono*), Free radicals (*G. Rotilio*), Cytokines, Immune system drugs (*V. Colizzi, J. Melino*)
9. Pharmacogenetics, Pharmacogenomics (*G. Novelli, L. Terrenato, C. Tomino, B. Flamion*)
10. Vaccines (*S. Salmaso, A. Tagliabue*)

SECOND QUADRIMESTER (7 MAY - 9 JUNE)

Clinical, Therapeutic and Regulatory aspects, Case reports

1. Quality Aspects (*J.L. Robert, R. Silvestri*)
2. Preparation of a dossier for centralized authorization (*P. Ricci, M. Pennini*)
3. Toxicology, Pharmacovigilance and Risk Management Plans (*B. Silva Lima, I. Persson, M. Venegoni*)
4. Clinical Pharmacology & Methodology (Phase I, II, III, IV), Preparation of an Assessment Report (*T. Salmonson, B. Flamion*)
5. Biotechnology (*R. Cortese, R. Crea*), Biosimilar Products (*P. Kurki, C. Pini, J.H. Trouvin*)
6. Referrals, Appeals, Suspensions, Withdrawals, Eligibility, Inspections (*T. Humphreys*), Guidelines (*B. Van Zwieten*)
7. Clinical Neuropharmacology (*N. Mercuri*), Psychopharmacology (*B. Van Zwieten, G. Muscettola*), Neurodegenerative diseases (*C. Sampaio, N. Vanacore, D. Bravi*)
8. Antinflammatory drugs (*M. Pirozynski*), Cytokines, Immune system drugs (*C. Pini, G. Rasi*)
9. Gene Therapy (*C. Galli*), Cell Therapies (*G. Migliaccio*) and Emerging Therapies and Technologies (*M. Papaluca*)
10. Vaccines (*M. Haase, D. Bresseur*)
11. Safety along the distribution chain. Counterfeit medicines (*O. Barra, D. Di Giorgio*)

FIRST QUADRIMESTER (3 MARCH - 5 APRIL)

Basic aspects

1. Cardiovascular Pharmacology (*F. Romeo, C. Cortese, G.L. Condorelli*), Respiratory Drugs (*P. Chiesi, P. Montuschi*)
2. Gastrointestinal Drugs (*F. Pallone, L. Biancone, D. Currò*)
3. Anticancer Drugs (*E. Bonmassar, A. Modesti*)
4. Paediatric drugs (*P. Rossi, A. Ceci, A. Addis*) and Geriatric Drugs (*M. Trabucchi*)
5. Orphan Drugs (*G. Benzi, D. Taruscio*)
6. Blood Products (*G. Vicari*)
7. Antimicrobial (*A. Cassone*), Antiviral (*G. Santoro, F. Perno*) and anti-HIV Drugs (*S. Vella, V. Colizzi*)
8. Endocrinological, Antidiabetic and Metabolism affecting drugs (*D. Lauro, P. Sbraccia*)
9. Dermatological Drugs (*A. Costanzo*)
10. Ocular Drugs (*C. Nucci*)

SECOND QUADRIMESTER (5 MAY - 7 JUNE)

Clinical, Therapeutic and Regulatory aspects, Case reports

1. Cardiovascular Pharmacology (*E. Abadie, G. Calvo Rojas*), Respiratory Drugs (*D. Lyons, C. Saltini*)
2. Gastrointestinal Drugs (*L. Biancone*)
3. Anticancer Drugs (*T. Salmonson, P. Demolis, F. Rotblat*), Hemato-oncological Agents (*S. Amadori, D. Alberti*)
4. Paediatric drugs (*D. Brasseur, I. Hudson*)
5. Orphan Drugs (*V. Bertelè*)
6. Blood Products (*B. Ljungberg, C. Peschle*)
7. Antimicrobial (*I. Hudson*), Antiviral and anti-HIV Drugs (*E. Abadie*)
8. Endocrinological (*B. Flamion*), Antidiabetic and Metabolism affecting drugs (*E. Abadie, F. Lekkerkerker*)
9. Dermatological Drugs (*T. Salmonson, S. Chimenti*)
10. Ocular Drugs (*L. Cerulli*)

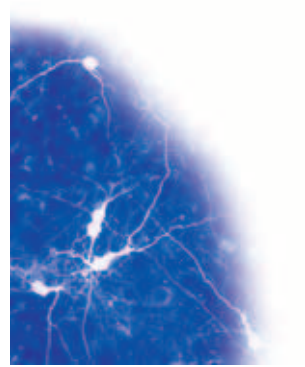
During the first two years a series of lectures will be given by the following scientists and experts:

*Lectures
by invitation*

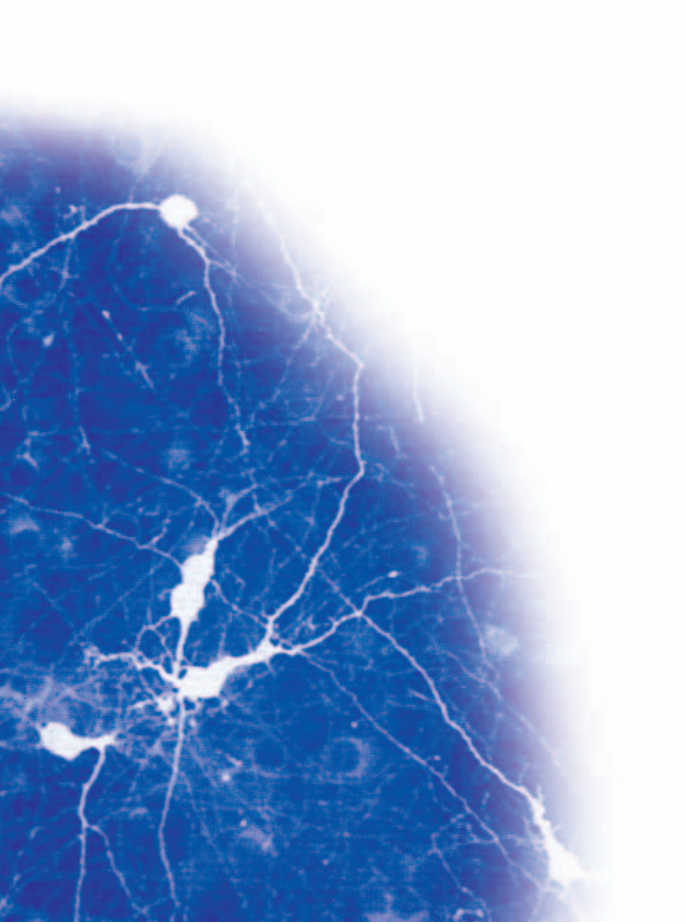
Lucio Annunziato, *University of Naples*
Giacinto Bagetta, *University of Calabria, Cosenza*
John Joseph Borg, *Member of CHMP, EMEA, Malta*
Janos Borvendég, *Member of CHMP, EMEA, Ungary*
Philippe Busquin, *Former Commissioner for Research, EU*
Piero Canonico, *University of Novara*
Graham Collingridge, *University of Bristol*
Vincenzo Cuomo, *University of Rome “La Sapienza”*
Gianbattista De Sarro, *University of Catanzaro, Italy*
Sergio Dompè, *President of Farmindustria, Rome*
Nikolaos Drakoulis, *Member of CHMP, EMEA, Greece*
Julia Dunne, *Alternate Member of CHMP, EMEA, UK*
Silvio Garattini, *Director of Institute Mario Negri, Milan*
Jacqueline Genoux-Hames, *Member of CHMP, EMEA, Luxemburg*
Arthur Isseyegh, *Member of CHMP, EMEA, Cyprus*
Erkki Liikanen, *Former Commissioner for Industry, EU – Governor of Bank of Finland*
Metoda Lipnik-Stangelj, *Member of CHMP, EMEA, Slovenia*
Romaldas Maciulaitis, *Member of CHMP, EMEA, Lithuania*
Vincenzo Mollace, *University of Calabria, Catanzaro*
Salvador Moncada, *University College, London*
Alan Morrison, *Senior Director AMGEN, Cambridge, UK*
Sandra Petraglia, *AIFA, Rome*
Cristina Pintus, *AIFA, Rome*
Heribert Pittner, *Member of CHMP, EMEA, Austria*
Juris Pokrotnieks, *Member of CHMP, EMEA, Lettonia*
Giuseppe Rosano, *San Raffaele Institute, Rome*
Franco Rossi, *University of Naples*
Dagmar Roth-Behrendt, *Vice President of European Parliament*
Vincenzo Salvatore, *Head of Legal Sector, EMEA, London*
Vittorio Silano, *Health Ministry, Rome*
Eva Skovlund, *Member of CHMP, EMEA, Norway*
Milan Šmíd, *Member of CHMP, EMEA, Czech Republic*
Steffen Thirstrup, *Member of CHMP, EMEA, Denmark*
Antonios Trakatellis, *Professor of Biochemistry, University of Thessaloniki, Greece*
Patricia Vella Bonanno, *Director of Medicines Agency, Malta*
Salvatore Venuta, *Full Professor of Clinical Oncology, University of Catanzaro, Italy*

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*E*uropean
School



*for Scientific
and Regulatory
Assessment of New
Medicines*



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PROF. ALESSANDRO FINAZZI AGRO'

CURRENT POSITION

Full Professor of Biochemistry, University of Rome Tor Vergata (since 1984)
Rector of University of Rome Tor Vergata
President of the School

EDUCATION AND ACADEMIC CAREER

1965 Qualified in Medicine

1970 Ph.D. in Biochemistry

Associate Professor of Biochemistry, University of Rome

Full Professor of Biochemistry, Faculty of Pharmacy, University of Cagliari

Full Professor of Molecular Biology, Faculty of Medicine, University of L'Aquila

Full Professor of Biochemistry, Faculty of Pharmacy, University of Rome

1984 till now Full Professor of Biochemistry, University of Rome Tor Vergata

Dean of the Faculty of Medicine, University of Rome Tor Vergata

1996 till now Rector of University of Rome Tor Vergata

PUBLICATIONS

Author of approx 350 scientific papers published in international journals and 3 volumes of Biochemistry

SCIENTIFIC INTERESTS

Structure and function of enzymes and their biotechnological application, spectroscopic technologies, oxido-reductive mechanisms, free radical species and their pathophysiological role.

SCIENTIFIC SOCIETIES

Member of the Italian Society for Biochemistry

Member of the UK Biochemical Society and of the American Society of Photobiology

Member of the Publication Committee of European Federation of Biochemistry

Editor of "Cell Death and Differentiation" and member of the editorial board of European Journal of Biochemistry

Referee of many international journals of Biochemistry



PROF. GIUSEPPE NISTICO'

CURRENT POSITION

Full Professor of Pharmacology, University of Rome Tor Vergata
Director of the School

EDUCATION

1965 Degree in Medicine (110/110 with honours)
1968 Specialized in Neuropsychiatry (70/70 with honours)
1972 Libera Docenza (Ph.D.) in Pharmacology

PROFESSIONAL BACKGROUND

1963-1973 Assistant Professor in Pharmacology, University of Naples
1973-1980 Associate Professor of Pharmacology, University of Messina
1976-1983 Director of the Institute of Pharmacology, Faculty of Medicine, University of Messina
1980 Full Professor of Pharmacology, University of Messina
Director of the Institute of Pharmacology, Faculty of Medicine, Catanzaro
Prorector of Reggio Calabria University
Dean of the Faculty of Pharmacy
1991 till now Full Professor of Pharmacology, University of Rome Tor Vergata
1994-1995 Vice Minister of Health
1995-1998 President of Calabria Region
1999-2004 Member of the European Parliament

MEMBERSHIP IN THE EMEA SCIENTIFIC COMMITTEES

Member of the Committee for Human Medicinal Products (CHMP) since 2004

OTHER MEMBERSHIPS

Member of several National and International Societies of Pharmacology and Neurosciences

PUBLICATIONS

Author of approx 250 publications in international journals of Pharmacology and Neuroscience
Author or Editor of approx 20 volumes published by Academic Press, Raven press and other international Publishing Companies
Invited speaker to many international Congresses and organizer of several international Meetings

SCIENTIFIC INTERESTS

Role of neurotransmitters in sleep/arousal mechanisms, in cardiovascular control and in the regulation of hypothalamic-pituitary hormones
Role of nitric oxide in the control of central functions and in the pathophysiology of neurodegeneration
Electrophysiology and pharmacological control of epilepsy

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DOTT. NELLO MARTINI

CURRENT POSITION

General Director of the Agenzia Italiana del Farmaco (AIFA)
Director of the School

EDUCATION

- 1972 Qualified in Pharmacy, University of Padua
- 1976 Specialization in Clinical Pharmacology, University of Milan
Long stage of research at the Mario Negri Institute Milan and abroad
(Ohio, Cincinnati University and Montpellier Paul Lamarque Center)
- 1973 Director of the Pharmacy Department at Verona Polyclinic Hospital
Currently he is the President of the AIFA Scientific Committee for drug
evaluation in Italy (CTS) and of the Price and Reimbursement Committee (CPR)
In addition he represents Italy in the EMEA management board

PUBLICATIONS

Invited speaker at many National and International Meetings
Author of more than 150 scientific papers and many volume

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PROF. RENATO LAURO

CURRENT POSITION

Dean of Faculty and Full Professor of Internal Medicine, University of Rome “Tor Vergata”
Medical School

President of the School Scientific Committee

EDUCATION

University of Palermo Medical School (with Honors “summa cum laude”)

1965 Italian Board of Medicine

ACADEMIC APPOINTMENTS

1972 Assistant Professor of Internal Medicine, University of Torino Medical School

1976 Assistant Professor of Internal Medicine, University of Rome-La Sapienza
Medical School

1980 Full Professor of Endocrinology and Medicine, Catholic University of Rome
Medical School

1983 Full Professor of Endocrinology and Medicine, University of Rome-Tor
Vergata Medical School

1984 Director of the Residency Program in Endocrinology and Metabolism
University of Rome-Tor Vergata Medical School

1991 *till now* Full Professor of Internal Medicine, University of Rome-Tor Vergata Medical
School

1996 *till now* Dean of Faculty, University of Rome-Tor Vergata Medical School

PUBLICATIONS

Author of approx 350 publications, many of them in international peer-review journals

Invited speaker at many International Congresses

SCIENTIFIC INTERESTS

Adrenal and gonadal steroids, hypertension, diabetes, expression of insulin receptors and their
structure and function

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PROF. PATRIZIA ADUCCI

ACADEMIC ACTIVITY

- 1975 Degree in Biological Sciences- University of Rome “La Sapienza”
- 1981-1987 Research associate, University of Rome “La Sapienza” - Faculty of Science
- 1982-1983 Teaching fellow “Biochemistry of nutrition” and “Physiology of nutrition” in the Advanced School of Nutrition Science- University of Rome “La Sapienza”
- 1987-1994 Associate professor of Plant Physiology, University of Rome “Tor Vergata”
- 1991-1992 Teaching contract in “Crop Physiology”, University of Basilicata, Potenza, Faculty of Agriculture
- 1994-present Full professor of Plant Physiology, University of Rome “Tor Vergata”
- 1995-2004 Director of the Advanced School of Biotechnology, University of Rome “Tor Vergata”
- President of the Italian Society of Plant Physiology
- 1997-2005 Director of Consorzio Interuniversitario “Biologia Molecolare delle Piante”
- 2001-2004 President of the course of Biotechnology (I level degree), University of Rome “Tor Vergata”
- 2004-present Head of Department of Biology, University of Rome “Tor Vergata”

SCIENTIFIC ACTIVITY

The activity is contained in 190 publications on the following areas:

Plant phytotoxins: study of fusicoccin signal transduction. Isolation, purification, biochemical structure and gene cloning of fusicoccin receptors from maize tissues. Identification of components of transduction chain.

Plant transport: Plasmalemma H⁺-ATPase and its regulation by 14.3.3 proteins.

14-3-3 proteins: Role and regulation in plants

Plant proteinases: isolation, purification, localization and biochemical and kinetic characterization of proteinases from different plants.

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PROF. ENRICO BOLLERO

PROFESSIONAL EXPERIENCE

Degree in Medicine 1966 (summa cum laude)
Specialization in *Oncology* 1969, *Public Health* 1971, *Clinical Pathology* 1974, *Occupational Medicine* 1976, *Legal Medicine* 1979

2000 till now General Director of Policlinico Tor Vergata, Rome
1991-2000 Secretary General of the National Union ANAAO ASSOMED
1997-2000 Vice President of National Federation of Physicians and odontostomatologists FNOMCEO

Scientific participation

Since 1979 Member of the Executive Board of SAPOI Society (Società anatomopatologi ospedalieri)
Member of AIC (Associazione italiana citologia).
Foreign Member of ASCP (American Society Clinical Pathologists)
Member of Pan American Cancer Cytology Society

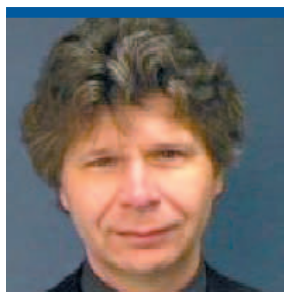
QUALIFIED UNIVERSITY TEACHER

University of Medicine “La Sapienza”, Rome
University of Medicine, Milan
University of Medicine “Tor Vergata”, Rome
National School for Public Administration, Rome

PUBLICATIONS

Over 50 Papers published by national and international scientific journals

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PROF. DANIEL BRASSEUR

CLINICAL AND MANAGEMENT ACTIVITIES

- Consultant in Nutrition & Pharmacology, University Children's Hospital Queen Fabiola, Brussels (since 2004)
- Head of Infantile Department & Paediatric Unit for Nutrition and Metabolic Diseases (1988-2004)
- Associate Head of Infantile Department, Hospital Saint Pierre, Brussels (1984-1985)
- Head of Paediatric Emergency Ward (1982-1983),
- Civil servant (Cooperation) in Congo & Rwanda, for Vaccination & Malnutrition programmes in collaboration with Unicef & WHO (1979-1981)
- Fellowship in Paediatrics, University Hospital Saint Pierre, Brussels (1976-1979)

RESEARCH, TEACHING AND CLINICAL INVESTIGATIONS ACTIVITIES

Teaching Activities

- Associate Professor of Paediatrics for Pharmacology, Nutrition & Vaccinology, Free University of Brussels (ULB) since 1990
- Associate Professor at the School of Public Health and Epidemiology, Mother and Infant Health Care, since 1994
- Lecturer for Master in Pharmacology & Applied Medicine for the Pharmaceutical Industry, since 1997
- Organizer & lecturer, European Diploma Pharmaceutical Medicines (Eudipharm), since 2002

EUROPEAN REGULATORY AND SCIENTIFIC ACTIVITIES

European Medicines Agency (EMA-London)

- Chair of CHMP (since 2001, re-elected in 2004)
- Member of CPMP (1997-2000)
- Chair of Paediatric Expert Group/Working Party (since 1999)
- Chair of the EMA/CHMP Task Force for the Implementation of the revised Pharmaceutical Legislation (since 2005)
- Chair of the EMA/CHMP Think tank Force on Innovative Medicines (since 2005)
- Member of Vaccine Expert Group/Working Party (since 2000)
- Member of EMA/CHMP Patients Group (since 2001)

European Food Safety Agency (EFSA-Parma)

Member of Scientific Panel for Dietetic Products, Nutrition & Allergies (since 2002)

PHARMACEUTICAL INDUSTRY EXPERIENCE

Director Medical & Regulatory Affairs Departments: KabiPharmacia Benelux (1986-1987)

PUBLICATIONS

37 articles in peer review journals, 29 chapters in books, 42 other publications, more than 250 posters & oral communications

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DR. ANTONELLA CINQUE

CURRENT POSITION

President of the Italian Medicines Agency (AIFA) since 2004

EDUCATION

High School Diploma (60/60)

Honours Degree in Law, from the University of Rome “La Sapienza” in 1984 (110/110)

PROFESSIONAL BACKGROUND

- since 20/11/2002* Member of the Board of Directors of the ‘Istituto Superiore di Sanità’
- from 24/07/2003 to 22/08/2006* Head of the Departments of Prevention and Communication in the Italian Ministry of Health:
Member of the National Oncology Commission
Coordinator of the Ministry’s communication framework
President of the Technical Committee for the supervision of actions to be taken in the informational-educational campaign against HIV/AIDS
Member of the Editorial Committee of the ‘Bulletin on medicine dependencies and alcoholism’
Head of the Task Force “Life Styles and Communication” for the Italian Ministry of Health, in view of the Italian Presidency of the European Union during the second semester 2003
President of the Committee of experts in communication and television scheduling for the Ministry of Health
- from 24/09/2002 to 24/07/2003* General Director of the Head Office for the Study of documentation regarding health issues and of Communication to the public:
Member of the Commission for “Dental Prosthesis Coverage for the elderly”, following a ruling of the Ministry of Health
Participated in the project for schools regarding life styles “Mission for Health”
Member of the Commission “Women and Health”
- from 11/10/2001 to 24/09/2002* Head of the Ministry of Health’s Technical Secretariat:
Member of the Committee for strategies regarding health issues.
Participated in the works concerning the PSN 2002-2004
- from 01/01/1987 to 30/06/2001* Executive in Farindustria (National Association of Pharmaceutical Industries) from 1996:
from 2000 to 30/06/2001 Coordinator of the Information and Public Relations Department
1998-2000 Responsible for External Relations
1996-1998 Responsible for Relations with the Regional Institutions
1994-1996 Marketing Manager
1989-1994 Responsible for Hospital Relations
Lecturer of Business Communication and Marketing at the Bocconi University of Milan
- 1987-1989* Legal Advisor for Farindustria
1984-1986 Practising Attorney in civil and company law

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DR. SERGIO DOMPE'

CURRENT POSITION

President of Farindustria and President of Dompé Biotech

EDUCATION

- 1996 Laurea Honoris Causa in Pharmaceutical Biotechnologies, University of Bologna
- 2005 Laurea Honoris Causa in Medical Biotechnologies, University of L'Aquila

Previous scientific and economic studies

- 1983-1985 Dompé Farmaceutici, General Manager
- 1985 Dompé Farmaceutici, Managing Director
- 1988 He founded Dompé Biotech, leader biotech company, in Milan
- 1993 He founded Dompé s.p.a. (manufacturing site and research centre) at L'Aquila

Over 850 people are currently employed in the eight different company sites including, besides Dompé farmaceutici, Dompé Biotec and Dompé Pharma, also the Branch International, whose headquarters is located in Losanna, Biogen-Dompé, ISTA ed ATA.

INSTITUTIONAL POSITIONS

- 1986-1994 Vice President of Farindustria (the Italian Association of Pharmaceutical Enterprises, Confindustria member)
- 1996 to July 1999 Chairman of the Biotech Group of the Association Federchimica (Italian Federation of the Chemical Industry, Confindustria member) Board Member
- from 1998 from 1999 Member of the Steering Committee of the Federation
- 1998 to 2004 President of Assobiotec (Italian Association for the Development of Biotechnology, within Federchimica)
- from July 2005 Member of the Board of Directors and of the Steering Committee of the Association
- from 1998 Member of EuropaBio (The European Association for Bioindustries) Steering Committee
- 2000 to 2002 Vice President and President of "Emerging Enterprises sub-board"
- June 2005 Appointed President of Farindustria and Member of Confindustria (Confederation of Italian Industry) Board for years 2005-2007
- January 2006 Appointed Chairman of CNR Committee of Evaluation by the Minister of Education, University and Research

*Scientific Board
Curricula Vitae*



PROF. ENRICO GARACI

CURRENT POSITION

President of the Italian National Institute of Health (Istituto Superiore di Sanità) since 2001.
Full professor of Microbiology University of Rome Tor Vergata since 1975.

EDUCATION

Qualified in Medicine, University of Rome (with honours).
He carried out his academic career at Rome University in Microbiology until he was appointed full Professor of Microbiology at University of Rome Tor Vergata

POSITION

Rector of University of Rome Tor Vergata (1982-1993).
President of the Italian Council for Research (CNR) from 1993 to 1997.
President of the Italian Microbiology Society (1997).
He is member of more than 20 scientific Committees at national and international level.

PUBLICATIONS

More than 200 scientific papers in international journals and coeditor of 5 volumes published by international companies.

SCIENTIFIC INTERESTS

Interactions between micro-organisms and host.
Acquired immune defence mechanisms against tumours, micro-organisms and viruses.

PRIZES

He was awarded many prestigious national and international prizes.

*Scientific Board
Curricula Vitae*



PROF. SILVIO GARATTINI

CURRENT POSITION

Director of the Istituto “Mario Negri” for Pharmacological Research (since 1963). Actually the Mario Negri Institute consists of four different seats (Milano, Bergamo, Ranica and Santa Maria Imbaro) with a staff of approx 850 units

EDUCATION

Diploma in Chemistry

Qualified in Medicine, University of Milan

University career of the Institute of Pharmacology, University of Milan until 1962

PUBLICATIONS

Author of several hundreds of scientific papers in national and international journals and of several volumes published by international companies

SCIENTIFIC INTERESTS

Cancer research, Chemiotherapy, Immunology, Neuropsychopharmacology, Cardiovascular and Renal pharmacology

POSITIONS

Founder of the European Organization for Research on Treatment of Cancer

Member during last 20 years of the Committee for Biology and Medicine of the Italian

Council for Research, Committee for Research of the Italian Government (Health Ministry)

President of the Steering Advisory Group on Current Controlled Trials

Italian Member of the CHMP, EMEA, London until 2004

Vice-President and member of the management board of the Italian Health Institute

Member of several international Societies of Biology, Medicine, Oncology, Chemiotherapy

President of the European Society of Biochemical Pharmacology

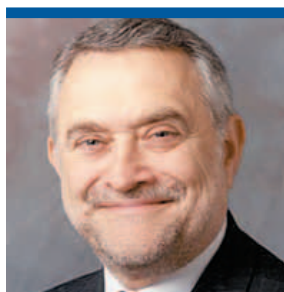
Fellow of the New York Academy of Sciences, American Association for the Advancement of Science

Honorary Fellow of the Royal College of Physicians

PRIZES

He was awarded many prestigious national and international prizes including Honorary Legion of French Republic, several qualifications *ad honorem*

*Scientific Board
Curricula Vitae*



PROF. SALVADOR MONCADA

CURRENT POSITION

Director of the Wolfson Institute, University College, London

EDUCATION

- 1970 Qualified in Medicine, University of Salvador
- 1971 Fellowship at the Royal College of Surgeons (London) under the supervision of Sir John Vane, Nobel laureate
- 1975 Research fellow and then (1984) Director of Research at the Wellcome Laboratories in Beckenham
- 1995 Director of the Wolfson Institute, London
- Candidate for the Nobel prize for his fundamental discoveries in Biology

RESEARCH INTERESTS

His research is of major impact in the international literature. He is one of the most quoted scientist in the world in the last decade.

He contributed with Sir John Vane to the discovery (1970) of the mechanism of action of aspirin (prostaglandin synthesis inhibition at the cyclo-oxygenase level). He played a primary role in the discovery of thromboxane and prostacyclin (1975).

In 1985 he discovered that EDRF (endothelial derived relaxing factor) was nitric oxide, synthesized from l-arginine through a nitric oxide synthase enzymatic activity (NOS).

*Scientific Board
Curricula Vitae*



PROF. PAOLO PREZIOSI

CURRENT POSITION

Full Professor of Pharmacology
Director of the Department of Pharmacology, Catholic University, Rome

EDUCATION

1952 Qualified in Medicine (110/110 with honours)
1958 Libero Docente (Ph.D.) in Pharmacology
1962-1964 Professor of Pharmacology and Chairman, University of Sassari
1965-1979 Chairman of Pharmacology, University of Naples
1979 till now Chairman of Pharmacology, Catholic University, Rome

PUBLICATIONS

Author of approx 500 publications most of them in international journals of Pharmacology and Toxicology

SCIENTIFIC INTERESTS

Pharmacology of hypothalamic-pituitary axis and adrenal glands
Pharmacodynamics and toxicology of various classes of xenobiotics including their effects on endocrine, pulmonary and cardiovascular systems

SCIENTIFIC SOCIETIES MEMBERSHIPS

Member of numerous Scientific Societies of Pharmacology, Toxicology in Europe, North America
President of Italian Society of Toxicology (1983-1986), Italian Society of Pharmacology (1989-1992), WHO/officer for IUTOX (1993-1995) and IUPHAR (1994-1999)

POSITIONS

1997-2001 Member of the Scientific Committee of Medicines (Ministry of Health) and of the European Community Scientific Committee on Medicinal Products

PRIZES

He was awarded several national and international prizes

*Scientific Board
Curricula Vitae*



PROF. GIUSEPPE NOVELLI

CURRENT POSITION

Full Professor of Human Genetics Tor Vergata University of Rome, School of Medicine
And Adjunct Professor, Division of Cardiology, University of Arkansas, Little Rock, (USA)

EDUCATION

1981 BS Biology, Urbino University
1985 PhD Medical Genetics, University of Rome La Sapienza

PROFESSIONAL BACKGROUND

1981-1983 Assistant Researcher Urbino University
1983-1992 Assistant Professor Urbino University
1983-1984 Visiting Researcher Unite' de Recherches de Biologie Prenatale
INSERM U 73, Paris (France)
1990-1990 Groupe de Gènétique Molèculaire INSERM U.91 Creteil (France).
1992-1995 Associate Professor Catholic University of Rome
1996 Visiting Professor University of Southern California (Los Angeles),
Department of Biochemistry and Molecular Biology;
1995-1999 Associate Professor Tor Vergata University of Rome
2001 Director of Medical Genetics Laboratory at The Tor Vergata Hospital
2002 Professor of Medical Genetics Faculty of Science University of Urbino

MEMBERSHIP IN SCIENTIFIC SOCIETIES

Member of the Editorial Board of: Neuromuscular Disorders (1999-2003); Clinical Genetics (pending); Acta Myologica (pending); Expert Opinion on Pharmacotherapy (pending); BMC Medical Genetics

Membership: American Society of Human Genetics (USA); European Society of Human Genetics (ESHG); American Association for the Advancement of Science (USA); Human Genome Organization (HUGO); Italian Society of Human Genetics (SIGU); World Muscle Society (WMS); American Society of Physiology; American Society of Gene Therapy

PUBLICATIONS

Author of 280 scientific publications appeared on International and Peer reviewed Journals.
Author and co-author of 4 books on Medical Genetics
Inventor and co-inventor of 3 Patents regarding antibodies and molecular protocols.

SCIENTIFIC INTERESTS

Genomic analysis of significant public health problems,
Genomic analyses of humankind,
Gene/environment interactions,
Functional analysis of SNPs (single nucleotide polymorphisms),
Molecular Genetics of rare diseases

*Scientific Board
Curricula Vitae*



PROF. MAURO PIACENTINI

CURRENT POSITION

Full Professor of Cellular and Developmental Biology, Faculty of Sciences, University of Rome “Tor Vergata”

EDUCATION

- 1977-1983* Research Associate, Institute of Histology and Embryology, University of Rome “La Sapienza”
- 1984-1987* Researcher Department of Biology, University of Rome “Tor Vergata”
- 1988* Assistant Professor, Department of Biology, University of Rome “Tor Vergata”
- 1991* Professor of Developmental Biology, Faculty of Sciences, University of Rome “Tor Vergata”

RESEARCH POSITIONS

- 1978* Institute of Pathology, Karolinska Institutionen, Huddinge Hospital, Sweden
- 1984* Laboratory of Cellular, Development and Oncology, NIDR, NIH, MD, USA
- 1986* Laboratory of Cellular, Development and Oncology, NIDR, NIH, MD, USA
- 1988* Laboratory of Cellular, Development and Oncology, NIDR, NIH, MD, USA
- 1988* Visiting scientist at the Department of Biochemistry, University Medical School of Debrecen, Debrecen, Hungary
- Since 1998* Director of the Department of Basic Sciences of the National Institute of Infectious Diseases “Lazzaro Spallanzani” Rome, Italy
- Since 2004* President of the Biotechnology undergraduate School of the Faculty of Sciences, University of Rome “Tor Vergata”, Italy

*Scientific Board
Curricula Vitae*

PUBLICATIONS

Cell Death and Differentiation (since 1993, Founder and Director of the Editorial Office in Rome)

Serves as reviewer for more than 20 International Journals

CONGRESS ORGANIZATION

He organized during the past 10 years many international Meetings and Conferences mainly on apoptosis and cell differentiation and death



DR. PASQUALINO ROSSI

CURRENT POSITION

Head, European Assessment Unit – AIFA (Italian Medicines Agency)
Italian Alternate CHMP Member - EMEA

EDUCATION

Medical Doctor
Specialisation in Obstetrics and Gynaecology
Reproduction Physiopathology

PROFESSIONAL BACKGROUND

Regulatory
Head of Pharmacovigilance Unit (AIFA) from September 2002 to September 2005

OTHER TITLES

Coordinator of AIFA Working Parties for Centralised Procedures

PUBLICATIONS

Author of approx 10 publications appeared in International Journals

SCIENTIFIC INTERESTS

Pharmacology
Clinical Methodology
Pharmacovigilance

*Scientific Board
Curricula Vitae*

*List of
teaching staff*

*E*uropean
School



*for Scientific
and Regulatory
Assessment of New
Medicines*

List of teaching staff

- Eric Abadie**
Director Therapeutic Evaluation, AFSSAPS, Paris, France
Vice-chairman CHMP, EMEA, London
- Antonio Addis**
Director, Information Service, AIFA, Roma
- Daniele Alberti**
Medical Director Oncology, Novartis, Milan
- Sergio Amadori**
Full Professor of Haematology, Faculty of Medicine, University of Rome Tor Vergata
- Maria Luisa Barbaccia**
Full Professor of Pharmacology, Faculty of Medicine, University of Rome Tor Vergata
- Ornella Barra**
Executive Director, Alliance UniChem, London
- Andrea Battistoni**
Associate Professor of Biochemistry, Faculty of Sciences, University of Rome Tor Vergata
- Nils Behrndt, LL. M.**
European Commission, Member of Cabinet of Vice-President Verheugen
- Gianmartino Benzi**
Full Professor of Pharmacology, Institute of Pharmacology, University of Pavia
- Vittorio Bertelè**
Director of Clinical Pharmacology, Mario Negri Institute, Milan
- Livia Biancone**
Associate Professor of Gastroenterology, Faculty of Medicine, University of Rome Tor Vergata
- Enzo Bonmassar**
Full Professor of Pharmacology, Faculty of Medicine, University of Rome Tor Vergata
- Bruno Botta**
Full Professor of Organic Chemistry, University of Rome La Sapienza
- Laura Braghiroli**
Preclinical Assessor, AIFA, Rome
Italian Member of SWP, EMEA, London
- Daniel Brasseur**
President of CHMP, EMEA, London
- Daniele Bravi**
Group Director Europe & Canada, International Clinical Research, H. Lundbeck A/S
- Gonzalo Calvo Rojas**
Senior Clinical Pharmacologist, Hospital Clinic, Barcellona
Member of CHMP, EMEA, London
- Antonio Cassone**
Director of Infectious Diseases Department, Istituto Superiore di Sanità, Rome
- Paola Castellani**
Vice President Research & Development, Astrazeneca, Milan
- Adriana Ceci**
Full Professor of Paediatrics, University of Bari
- Luciano Cerulli**
Full Professor of Ophthalmology, Faculty of Medicine, University of Rome Tor Vergata
- Paolo Chiesi**
Vice President Research & Development, Chiesi Farmaceutici, Parma
- Sergio Chimenti**
Full Professor of Dermatology, Faculty of Medicine, University of Rome Tor Vergata
- Eugenia Cogliandro**
Italian Member of the QWP, EMEA, London
Chemical Assessor, AIFA, Rome
- Vittorio Colizzi**
Full Professor of General Pathology, Faculty of Sciences, University of Rome Tor Vergata
- Gianluigi Condorelli**
Associate Professor, University of Rome La Sapienza
- Gabriella Conti**
Head of European Regulatory Affairs Unit, AIFA, Rome
- Claudio Cortese**
Full Professor of Clinical Biochemistry, Faculty of Medicine, University of Rome Tor Vergata
- Riccardo Cortese**
Full Professor of Molecular Biology, IRBM, Rome
- Antonio Costanzo**
Assistant Professor of Dermatology, Faculty of Medicine, University of Rome Tor Vergata
- Hubertus Cranz**
Director General of AESGP, Bruxelles, Belgium

List of teaching staff

- Roberto Crea**
Researcher, San Francisco
Executive Chief Creagri Ltd
- Diego Currò**
Associate Professor, Institute of Pharmacology,
Catholic University, Rome
- Pierre Demolis**
Assessor of Anticancer Products, French
Medicines Agency
Member of the Scientific Advisory Working Party,
EMA, London
- Domenico Di Giorgio**
Senior Chemist Officer - General Direction,
AIFA, Rome
- Eugenio Donato Di Paola**
Assistant Professor of Pharmacology, University
of Catanzaro
- Giorgio Federici**
Full Professor of Clinical Biochemistry, Faculty of
Medicine, University of Rome Tor Vergata
- Bruno Flamion**
Professor, University of Namur, Belgium
Scientific Advice Working Party, EMA, London
- Cristina Galli**
Department of Cell Biology and Neurosciences,
Istituto Superiore di Sanità, Rome
- Giovanni Gaviraghi**
Scientific Director CEO,
Siena Biotech S.p.a., Siena
- Manfred Haase**
Paul-Ehrlich-Institut, Langen, Germany,
Member of CHMP, EMA, London
- Ian Hudson**
Director, Licensing Division, Medicines and
Healthcare products Regulatory Agency, UK, and
member of CHMP, EMA, London
- Anthony Humphreys**
Head of Sector of Regulatory affairs and
organisational support, EMA, London
- Michele Intorcchia**
Outcomes Research and Pharmacoeconomics
Associate Director, Bristol Meyer Squibb
- Pekka Kurki**
Head of Biotechnology, National Agency for
Medicines, Finland
Member of CHMP, EMA, London
- Davide Lauro**
Associate Professor of Endocrinology, Faculty of
Medicine, University of Rome Tor Vergata
- Frits Lekkerkerker**
Chairman Medicines Evaluation Board, The
Netherlands
Alternate Member of CHMP, EMA, London
- Maria Grazia Leone**
Preclinical Assessor, AIFA, Rome
- Paolo Luly**
Full Professor of General Physiology, Faculty of
Sciences, University of Rome Tor Vergata
- Bengt Ljungberg**
Clinical Assessor at the Swedish MPA, Sweden
Alternate Member of CHMP, EMA, London
- David Lyons**
Director of Irish Medicines Agency, Member of
CHMP, EMA, London
- Nello Martini**
General Director of AIFA, Rome
Member of Management Board, EMA, London
- Gennaro Melino**
Full Professor of Molecular Biology, Faculty of
Medicine, University of Rome Tor Vergata
- Anna Rita Meneguz**
Director of Biochemical Pharmacology, Istituto
Superiore di Sanità, Rome
- Nicola Biagio Mercuri**
Full Professor of Neurology, Faculty of Medicine,
University of Rome Tor Vergata
- Giovanni Migliaccio**
Director of Gene and Cell Therapy, Istituto
Superiore di Sanità, Rome
- Andrea Modesti**
Full Professor of General Pathology, Faculty of
Medicine, University of Rome La Sapienza
- Paolo Montuschi**
Associate Professor, Institute of Pharmacology,
Catholic University, Rome
- Giovanni Muscettola**
Full Professor of Psychiatry, Faculty of Medicine,
University Federico II, Naples
- Pierluigi Navarra**
Full Professor of Pharmacology, Institute of
Pharmacology, Catholic University, Rome

List of teaching staff

Robert Nisticò
Associate Professor of Pharmacology, Faculty of Pharmacy, Calabria University, Cosenza

Giuseppe Novelli
Full Professor of Human Genetics, Faculty of Medicine, University of Rome Tor Vergata

Carlo Nucci
Assistant Professor of Ophthalmology, Faculty of Medicine, University of Rome Tor Vergata

Maurizio Paci
Full Professor of Biochemistry, Faculty of Sciences, University of Rome Tor Vergata

Franco Pallone
Full Professor of Gastroenterology, Faculty of Medicine, University of Rome Tor Vergata

Marisa Papaluca Amati
Deputy Head of Clinical Safety and Efficacy Sector, EMEA, London

Carlo Patrono
Full Professor of Pharmacology, Catholic University, Rome

Maurizio Pennini
Drug Regulatory and Public Affairs Director, Lundbeck Italia SpA, Milano

Carlo Federico Perno
Full Professor of Virology, Faculty of Medicine, University of Rome Tor Vergata

Ingemar Persson
*Professor of Pharmaco-epidemiology, Karolinska Institute, Stockholm, Sweden
Member of CHMP, EMEA, London*

Emilio Perucca
Full Professor of Clinical Pharmacology, Dept. of Internal Medicine, University of Pavia

Cesare Peschle
Responsible for Haematology and Molecular Medicine Department, Istituto Superiore di Sanità, Rome

Mauro Piacentini
Full Professor of Developmental Biology, Faculty of Sciences, University of Rome Tor Vergata

Carlo Pini
Director of Immunology Department, Istituto Superiore di Sanità, Rome

Michal Pirozynski
Former President of the Office for Medicinal Products, Medical Devices and Biocides, Poland, Member of CHMP, EMEA, London

Guido Rasi
Head of Section of Molecular Medicine, Institute of Neurobiology and Molecular Medicine - CNR, Rome

Emiliangelo Ratti
Director of the excellence Center for Drug Discovery in Psychiatry, GlaxoSmithKline

Paola Ricci
Senior Executive Vice-President Pharmaceutical Affairs, Serono International S.A.

Jean-Louis Robert
*Head of Department, Department of Medicines Control Laboratory, Luxembourg
Member of CHMP, EMEA, London*

Francesco Romeo
Full Professor of Cardiology, Faculty of Medicine, University of Rome Tor Vergata

Paolo Rossi
Full Professor of Paediatrics, Faculty of Medicine, University of Rome Tor Vergata

Pasqualino Rossi
*Head, European Assessment Department – AIFA
Alternate Member of CHMP, EMEA, London*

Frances Rotblat
*Expert Assessor Post Licensing Department MHRA
Member of CHMP, EMEA, London*

Giuseppe Rotilio
Full Professor of Biochemistry, Faculty of Sciences, University of Rome Tor Vergata

Stefania Salmaso
Director of National Epidemiology Center, Istituto Superiore di Sanità, Rome

Tomas Salmonson
*Director of Medical Products Agency, Uppsala
Member of CHMP, EMEA, London*

Cesare Saltini
Full Professor of Respiratory Diseases, Faculty of Medicine, University of Rome Tor Vergata

Cristina Sampaio
*Professor of Clinical Pharmacology and Therapeutics, Lisbon School Medicine, Portugal
Member of CHMP, EMEA, London*

List of teaching staff

Luca Santi

*Associate Professor of Plant Biotechnology,
Faculty of Sciences, University of Rome Tor Vergata*

Gabriella Santoro

*Full Professor of Virology, Faculty of Sciences,
University of Rome Tor Vergata*

Fernand Sauer

*Honorary General Director, European
Commission, Bruxelles*

Paolo Sbraccia

*Associate Professor of Internal Medicine, Faculty
of Medicine, University of Rome Tor Vergata*

Beatriz Silva Lima

*Professor, Department of Pharmacology, Faculty
of Pharmacy, University of Lisboa, Portugal*

Romano Silvestri

*Associate Professor of Pharmaceutical Chemistry,
University La Sapienza, Rome*

Aldo Tagliabue

Scientific Director, CHIRON S.p.A, Siena

Domenica Taruscio

*Responsible for Orphan Diseases, Istituto
Superiore di Sanità, Rome*

Luciano Terrenato

*Full Professor of Human Genetics, Faculty of
Sciences, University of Rome Tor Vergata*

Carlo Tomino

Director of Clinical Assessment, AIFA, Rome

Marco Trabucchi

*Full Professor of Neuropsychopharmacology,
Faculty of Medicine, University of Rome Tor
Vergata*

Jean-Hugues Trouvin

*Director of the Directorate for evaluation of
medicinal products and biologicals, AFSSAPS,
Paris*

Alternate Member of CHMP, EMEA, London

Nicola Vanacore

*National Centre of Epidemiology, Istituto
Superiore di Sanità, Rome*

Barbara Van Zwieten

*Staff member, Medicines Evaluation Board,
The Netherlands
Member of CHMP, EMEA, London*

Stefano Vella

*Director of Pharmacology Department, Istituto
Superiore di Sanità, Rome*

Mauro Venegoni

Head of Pharmacovigilance Unit, AIFA, Rome

Giuseppe Vicari

*Former President of Istituto Superiore di Sanità,
Rome*

Table of contents

page

Preface 1

Scientific Board and Honorary Committee..... 2

Main Objective and Organisation of the School 3

Topics First Year of the Master 6

Topics Second Year of the Master..... 7

List of Lectures by Invitation..... 8

Scientific Board Curricula Vitae..... 9

List of the Teaching Staff..... 27

