EXPERIENCE

Mag. 2015 – to date: Senior Consultant at SIC – Italian Society of Cardiology

May 2012 – to date: President at SIFEIT

Italian Society for Studies in Economics and Ethics on Drug and Therapeutic Interventions (Società Italiana per Studi di Economia ed Etica sul Farmaco e sugli Interventi Terapeutici).

October 2011 – to date: Senior Pharma and Management consultant

Scientific, managerial and strategic **consultancy for Pharma Companies** (Clinical Research, Medical Affairs, Regulatory, Market Access, Start up foreign companies, Compliance and Governance, Crisis Management) as well as **Scientific Societies** (Research and Scientific projects, Clinical Studies, Management and Organizational aspects, Networking - Institutional Bodies, other Scientific Societies, Phrama Companies - , Fund Raising).

October 2009 – September 2011: The Medicines Company (Italy)

Senior Medical Director Global Medical Science and Affairs, with responsibilities in the following areas:

- Clinical Research and Development
- Medical Affairs
- Regulatory affairs
- Medical Marketing
- Scientific Training
- Company compliance
- Pharmacovigilance
- Health Economic/Market access

Furthermore general managing responsibilities as for the local company and member of the EU Management Team.

In the course of two years in The Medicines Company Italy**,**
many important goals were achieved, including **successful price negotiation and reimbursability** for an hospital drug**, inclusion in most Regions Prontuarios, 2 large** (about 8.000 patients in total) **clinical trials started, Pharmacovigilance Unit set up,** pharmacoeconomic evaluations**, company compliance and EU support in these areas.**

April 2009 – September 2009: Speciality European Pharma

Medical Director with responsibilities in the following areas:

- Clinical Research and Development
- Medical Affairs
- Regulatory affairs
- Medical Marketing
- Scientific Training
- Pharmacovigilance (scientific/medical aspects)
- Health Economic/Market access

In the few months in SEP a **successful price negotiation and reimbursability** for an hospital drug**,** was achieved as w**ell as inclusion in most Regions Prontuarios, a Pharmacovigilance Unit and a medical/marketing project in OAB set up.**

May 2008 – March 2009

* **Freelance consultant at Pharma Companies**
* Member of the Governing Council of **SITAC** (Italian society for Alcoholism and its Complications)
* Co-founder and Member of the Governing Council of **ALGOSS** (Italian Society for treatment of Pain)
* Consultant of **AILAS** (Italian Psychiatric Society for fighting Stigma) as for scientific, educational, networking (research, training, e-learning, info to consumers, media) projects and relationships with Public Institution, other scientific Societies and Pharma Companies

* Requested by the **Italian Heart Foundation** for being Executive Director for scientific, educational, networking (research) projects and relationships with Public Institutions, other Scientific Societies and Pharma Companies (in progress).

September 1994 – May 2008: ORGANON ITALIA

Medical Director and Member of the Company Board with responsibilities in the following areas:

- Clinical Research and Development
- Medical Affairs
- Medical Marketing
- Scientific Training
- Pharmacovigilance (scientific/medical aspects)
- Health Economic/Market access

For almost one Year responsibility for Regulatory Affairs Department.

In the course of 14 years in Organon Italia, the research and clinical activity was centred on **pharmacological and clinical research (phase II, III, III B and post commercilisation trials)** in strict cooperation with Organon Headquarters at Oss.

In this respect **many projects have been planned and some multicenter (large scale) trials have been set up, started and finalized,** entrusting, in some cases, monitoring and data management/statistical analysis to Contract Research Organisations.

Since 1997 a **GCM (Global Clinical Monitoring organization) subsidiary was set up in Italy** , directly reporting to Head Quarters; scientific/medical support is constantly given to GCM as for pre-registrative clinical research.

I have been responsible for the **scientific support and training for prelaunch, launch (and postlaunch) of Organon Italia (CNS and gynecological) products as well as medical marketing.**

Main therapeutic Organon areas are: gynecology (contraception, hormone replacement therapy and profertility), osteoporosis,CNS (depression and schizofrenia), and also hospital products, antitumoral and muscle-relaxant agents (acquisition of Organon Teknika by Organon Italia).

Excellent introduction with top opinion leaders in these areas has been acheived **as well as in the main units of the Ministry of Health, other Public Institutions, Scientific Societies and other Pharma Companies.**

Market access has been a large part of my activity, including pharmacoeconomic issues and evaluations/studies, **price negotiations with Health Authorities, obtainement of registration and/or reimbursability of most important products;** also responsible for **business development aspects, licensing in/out opportunities** as weel as pre-launch and marketing and sales activities in niche areas (subdermal contraception and HIT- heparin induced throbocytopenia).

Active participation in various **international teams** (e.g. gynecology, pharmacoeconomy, ect.) and also in some **working groups of Farmindustria** (Italian Association of Pharma Companies).

Organisation and/or active participation as chairman or speaker in numerous courses and/or meetings of Farmindustria, University of Rome, etc., focused on clinical research.

Responsible for scientific training and all ethical, medical, scientific, deontological (also Farmindustria Code) and legal aspects of promotional activities, including congersses, (local) meetings, scholarships, scientific consultancies, relation with scientific societies, pharmacovigilance, products' defence and crisis management, etc., as well as for related procedures (compliance manager).

Since 2006, also Regions Issues dealing with promotion (scientific information, congresses, etc.) have been part of my activity.

May 1989/August 1994: JANSSEN FARMACEUTICI

Director of Research and Development and Member of the Company Board with responsibilities in the following areas:

- Clinical Research and Development of Drugs
- Medical Marketing
- Scientific Training

- Regulatory Affairs
- Pharmacovigilance

January 1989/May 1989: JANSSEN FARMACEUTICI

R & D Manager with responsibilities for phase II, III and IV, marketing support and regulatory aspects for cardiovascular, oncological and neuropsychiatric compounds.

1982-1988: JANSSEN FARMACEUTICI

Assistant to and subsequently Medical Adviser with responsibilities of Clinical Research and Marketing support for cardiovasculars, neurologicals, antimycotics and gastrointestinals.

In the course of the twelve years in Janssen, my activity was centered on **clinical research for the development of new compounds (phase II and III)** as an active member of teams working on international projects chaired by Mother Company and the Research Foundation of Janssen Pharma at Beerse.

Particular contribution has been given as for identification of patients and clinical data in cardiovascular, gastroenterological and infectious diseases field, with involvement of the most prestigious centers and **finalization of the studies towards the international registration file.**

For the Italian Company, I have been responsible for the **scientific support and training for prelaunch and launch of several products, development of new indications and/or new pharmaceutical formulations,** mainly for neurologicals, gastrointestinals, cardiovasculars and antimycotics.

In this context, many congresses and meetings were organized, with Janssen sponsorship in the main national and international events.

Excellent introduction with top opinion leaders, was achieved in the following areas: gastroenterology, cardiology, neurology, psychiatry, dermatology and oncology, **as well as in the main units of the Ministry of Health.**

Finally, I obtained the **registration of new chemical entities and new formulations and/or line extension of ethical products as well as registration of veterinary and OTC products.**

Moreover I created a **Pharmacovigilance Department,** in accordance to local (Ministry of Health) and external (Mother Company) requirements.

EDUCATION

1971: G.C.E.

1978: University La Sapienza, Rome (Italy), Degree in Medicine and Surgery cum Laude

1979: University of Rome, qualification for medical profession

1979: Enrolment to Rome Medical Association

1983: University of Rome, Specialization in Liver Diseases

Excellent knowledge of written and spoken English.

Author of many scientific publications and communications to national and international congresses.

1990/1992:Contract Professor at the University of Naples (Italy), School of Specialisation in Pharmacology and Clinical Pharmacology.

2003/2004: Contract Professor at the University of Pavia, School of Specialisation in Regulatory Disciplines.

Member of Directive Council of Italian Society of Applied Pharmacological Science;

Member of Directive Council of Fare Rete Onlus;

Former active member of SIdR (Italian Society of Reproduction), ESHRE (European Society of Human Reproduction)

Member of:

SITAC (Italian Society for Treating Alcohol Consumption);

AILAS (Italian Society for avoiding Stigma);

SIFEIT (Italian Society for the study of drug Economics and Ethics and Therapeutic Intervention);

SIMeF (Italian Society of Pharmaceutical Medicine);

Ricerca e Salute NPO, Scientific Committee;

Italian Journal of Health Technology Assessment and Delivery, Advisory Board

Teaching Professor at

UCSC (Catholic), Sapienza, Tor Vergata Universities, Rome