CURRICULUM VITAE

Name: **Stefano Milleri**
Phone numbers: **++393346270464**
Nationality: **Italian**

OVERVIEW:

More than 25 year experience of clinical Research & Development, Clinical Study Unit management and Experimental Medicine procedures

Providing medical and scientific leadership to a Clinical Research Study Centre involved in studies in both healthy subject and patients

Principal Investigator or Sub-Investigator in more than 100 clinical trials with healthy volunteers and patients in different therapeutic areas (*e.g.* Oncology, Cystic Fibrosis, Neurology, Anti-infective, Respiratory, Obstetrics/Gynaecology)

Accountable for conducting safety assessments in the protocol definition phase based on preclinical toxicology findings as well as evaluating results during and after the clinical phase.

Co-author of dossiers submitted to European Regulatory Agencies and to the FDA.

Areas of interest/expertise include Clinical Pharmacology, Clinical Development, Regulatory Development, safety assessments.

CAREER HISTORY

2016 - Current : Scientific Medical Director, Centro Ricerche Cliniche di Verona srl University Hospital "GB Rossi", Verona, Italy

2006 - 2016 : Scientific Director, Centro Ricerche Cliniche di Verona srl University Hospital "GB Rossi", Verona, Italy

Responsibility for:

- Ensuring high level of scientific quality in clinical studies
- Ensuring regulatory compliance and ethical feasibility of study protocols
- Developing the relationship with Sponsors through interactive discussions regarding study design, protocol development, operational management and budget negotiations

- Training and developing medical staff (physicians as well as Research Nurses) for the supervision and conduction of clinical studies within the Unit
- Ensuring full compliance with all applicable Medical, Ethics and Regulatory requirements of all CRC operations
- Ensuring that all Unit operations are covered by Standard Operation Procedures according to GCP requirements and local Quality Assurance procedures
- Overseeing development of a volunteer panel to meet Unit needs
- Managing the relationship with the Hospital Units of the Teaching Hospital in order to develop the specialist clinical scientific capabilities of the Centre and to enable clinical Phase I and II studies in patients
- Managing the Unit budget including oversight of day-by-day costs

From 2002 to 2005
Director of Clinical Pharmacology & Discovery Medicine (CPDM) Unit, GlaxoSmithKline, Verona, Italy.

Responsibility for:

- Providing Medical and Scientific leadership to the research activities of the unit and the development of specialist technologies and human disease models to meet the needs of the Discovery Medicine function
- Meeting project team needs during definition of concepts and study protocols
- Contributing to the design of all CPDM clinical studies from an operational perspective *via* participation in CPDM Protocol Review Processes
- Ensuring full compliance of all Unit operations with all appropriate local Medical, Ethical and Regulatory requirements as well as global GSK Clinical Unit policies
- Managing the relationship with Verona, Padua and Milan Universities in order to develop the specialist clinical scientific capabilities of the Unit to carry out added value clinical studies
- Developing new standards of practices for the application of novel technologies and human disease models
- Managing administrative issues in the Unit by locally based administrative staff or through central Global Business Unit Manager
- Contributing to the Psychiatric Leadership Team.

From 1992 to 2002
Physician responsible for Clinical Pharmacology Unit in Glaxo and in GlaxoWellcome, Verona, Italy.

From 1985 to 1992
Attending physician at the Respiratory Physiopathology Unit within Internal Medicine Department at Catholic University Hospital in Rome.

Education

2008 PhD in Neuroscience, Padua University, Faculty of Medicine

1993 Specialization in Geriatrics, 50/50, Catholic University in Rome, Faculty of Medicine

1989 Specialization in Lung Diseases, 50/50 cum laude, Catholic University in Rome, Faculty of Medicine

1985 Degree in Medicine, 110/110 cum laude, Catholic University in Rome, Faculty of Medicine.

Relevant Training Courses

2003 "Psychiatry: a comprehensive update and Board preparation"; one-week training course organised by Harvard Medical School & Massachusetts General Hospital

1994 "A one-week workshop in advanced pharmacokinetics"; Prof. Malcolm Rowlands, Manchester University

1993 "A one-week workshop in basic pharmacokinetics"; Prof. Malcolm Rowlands, Manchester University

1987 "Clinical Electrocardiography" and "Emergency situations in internal medicine" organized "Medical Register" of Rome

Basic Life Support – Defibrillation (BLS-D) course and Retraining from 2001 to present.

Other:

- Lecturer at "Indirizzo di Eccellenza in Biomedicina" organized by Istituto di Studi Superiori, Genoa University, 2015
- Visiting professor at specialization course of Clinical Pharmacology, Florence University from 2012 to present
- Visiting professor, Master in "Ricerca e Sviluppo Pre-clinico e Clinico dei Farmaci" organized by University of Milan Bicocca; from 2009 to present.
- Lecturer at Master in "Sperimentazione Clinica dei Farmaci in Medicina Internistica at Ematologia ed Oncologia", organised by Department of Pharmacology, Pisa University; from 2004 to present
- Lecturer, Master in "Regulatory compliance", organised by Department of Pharmacology, Catania University, 2004-2005 and 2005-2006 academic years

Full Papers:

Co-author of more than 20 full papers published in peer reviewed journals and 40 conference abstracts/proceedings

Affiliations:

- Ordine dei Medici di Verona n. 7682 from 2006
- Italian Society of Pharmacology from 2007

I authorise the use of my personal data according to the D.L. 196/2003.

References available upon request.