CURRICULUM VITAE

PROFESSIONAL EXPERIENCE

2003 – Present
Independent consultant

Serono International S.A - Geneva Head quarter

1998 - 2003
Head of Worldwide R& D Quality Systems (GMP - GLP - CGP)

Main Duties:

- To coordinate R&D discovery, research and manufacturing sites for compliance to GLP/GCP/GMP/GXP
- To direct the Worldwide Quality System for the clinical trials
- To direct the Quality System for pharmaco-vigilance and to coordinate a common quality system between R&D and manufacturing on annual product quality reports

LCG GROUP – external division owned by the Ares-Serono Group

1993 - 1998
LCG Group (RBM-SIMED-BOURNE HALL and SLI) Coordinator for Quality and Regulatory Affairs

Main Achievements in this period:

- Third and fourth **US-FDA GLP** audit resulting in no FDA 483
- **GLP** certification by the Italian Ministry of Health for safety testing of biotechnological product cell lines
- **GMP** certification for bioassays of biotechnological medicinal products and bulks
- **UK DoH GLP** certification of the coordinated company in the UK
- Implementation of a **GCP** quality system in a coordinated clinic in the UK and in a coordinated data management company in France followed by successful audits by Sponsor's inspectors
- Renewal of the **GLP** certification by Japanese **MAFF**
- Implementation of **GCP/GLP** quality system in the two centralized laboratories for clinical pathology analyses
- Implementation of a **GMP** quality system for storage and dispatch of investigational medicinal products to clinical centers.

RBM – A. MARXER Research Institute (affiliates of the Ares-Serono Group)

1992-1993
RBM Regulatory Affairs and Quality Coordination Director
Member of RBM Board for new projects

Main Achievements in this period:

- The Quality Coordination and Regulatory Affairs Unit included Ecotoxicology, Pharmaceutical Chemistry and Centralized Pharmacy Units. This modification was aimed to create a coordinating unit for all EEC notifications of new chemicals (mainly pharmaceutical intermediates and fine chemicals).

1989-1992
Responsible for Regulatory Affairs Quality Coordination
Responsible for RBM GLP Archives

Main Achievements in this period:

- Second US FDA and Italian MoW joint audit resulting in no FDA 483
- **GLP** certification by Japanese MAFF
- **GLP** certification by Italian Ministry of Health

1988-1989
Responsible for a two year post graduated course on experimental toxicology granted by the EEC

- The course was attended by 15 university graduates

1987-1988
Associate to General Director - Responsible for Quality Coordination

Main Achievements in this period:

- First US FDA and Italian MoW joint inspection resulting in no FDA 483
- Grade A certification for **GLP** compliance from Japanese MoHW

1985-1986
Associate to the Toxicology Department Director

- Responsible for **FDA-GLP** implementation
- Consulting in pharmaceutical companies and CROs in the US to tailor **GLP** organization to FDA requirements.

Zambon Pharmaceuticals, Bresso, Milan, Italy

1984
Associate to the R&D Director

- Responsible for GLP implementation and updating
- Prepares the Company Good Laboratory Practice for Italian Regulatory Authorities

1978-1983
Associate to the Director, Toxicology Department

- Responsible for the co-ordination of safety studies on adrenergic agonist and non-steroidal anti-inflammatory drugs
- Responsible for irritancy studies and “in vitro” studies on hemolytic properties of drugs
- Responsible for GLP training of animal Technicians
- Maintains responsibilities as the Toxicology Laboratory Head

1974-1978
Head of the general Toxicology Laboratory

- Responsible for conduct of short-term toxicity studies and for teratogenesis studies
- Participants in protocol preparation, scientific analysis of experimental data, final reporting
- Responsible for Hematology and Urine analysis labs.
- Supervisor of Blood Chemistry lab’s technicians

1972-1973
Supervisor, Toxicology R&D Department

- Responsible for the supervision of animal and laboratory technicians
- Responsible for the training of technicians

1970-1971
Senior Laboratory and Animal Technician, Pharmacology and Toxicology R&D Department

1964-1969
Laboratory Technician, Pharmacology and Toxicology, R&D Department

LECTURER

- Courses for Italian GLP Inspectors
  Istituto Superiore di Sanita, Rome, (1996-1999)

- Post-graduate course on « Experimental Toxicology : the quality organisation of CRO's
  Universita di Milano, Facolta di Farmacia, Milan, Italy

- Post-graduate course on "Medicine and technology of laboratory animals: regulatory requirements for animal experimentation"
  Universita di Milano, Facolta di Veterinaria, Milan, Italy

- Course on "Rules for notification on new chemical substances
  Universita di Torino, Facolta di Chimica, Turin, Italy

- Course for post-graduate training
  Istituto M. Negri, Milan, Italy

EDUCATION

1990
- Cambridge first certificate - English for science

1989
- Cambridge first certificate

1967
- Liceo classico "G. Parini", Milano (Italia)

Fluent verbal French

TRAINING & SEMINARS

2001

- GMP for IMP
  BARQA, Cambridge, UK

1992

- Management Development Programme, upgrade course
  Serono International S.A., Geneva, Switzerland

1991

- Management Development Programme, intermediate course
  Serono International S.A., Geneva, Switzerland

- "Sesta riunione scientifica nazionale del coordinamento italiano per l'applicazione delle colture di tessuto in Tossicologia"
  Padova, Italy.

1990

- Management Development Programme, fundamental of Management
  Serono International S.A., Geneva, Switzerland

- International meeting on GLP
  QAG, UK

1989

- Safety tests for the notification of new chemicals EEC Directive 79/831
  RBM Meetings 5, Milan, Italy

1988

- Rules regulating the access to clinical experimentation of new drugs seminar
  Istituto Superiore della Sanita, Rome, Italy

1987

- Five years experience on application of EEC Directive 79/83/ Regulating new chemical substances seminar
  Istituto Superiore della Sanita, Rome, Italy

- GLP requirements in Japan
  Masani Kitano (Chem. Insp. Institute, Tokyo), Milan, Italy

- Responsibility of Management and QAU under GLP
  P. Lepore (FDA- Head of Regulatory Compliance)

- Toxicity testing - Hepatic alteration
  RBM meeting 3, Ivrea, Italy

1986

- Course on validation of Computer Systems for Pharmaceutical Research and Development
  Centre for Professional Advancement, Amsterdam, Netherlands

- Receptors in Pharmacology
  RBM Meetings 1, Ivrea, Italy

- Topics in Reproductive Toxicology
  RBM Meetings 2, Ivrea

1985

- Course on GLP
  Centre for Professional Advancement, Amsterdam, Netherlands

- Training courses on FDA/GLP Implementation
  Serono Lab. Inc, Randolph, MA., USA
  WIL, Research Lab., Ashland, Ohio, USA
  Hazleton Research Lab. Madison, Ws., USA

1984

- 2nd International Workshop on experimental Nephrotoxicity
  University of Surrey, Guilford, UK

1981

- Course on experimental audiometry in rodents
  University of Milan, Italy

- IFCC International Congress on Clinical Chemistry
  University of Vienna, Austria

1980

- The rat electrocardiogram in acute and chronic toxicity studies
  Satellite workshop - *2nd International Toxicology Congress, University of Hanover, Germany*

- Drug-related ocular toxicity workshop
  Federal Health Office, Berlin, Germany

1979

- Symposium on:
  Chronic toxicity studies: objectives, conduct, evaluation
  Target-organ toxicity study
  Safety test for medical services
  Federal Health Office, Berlin, Germany

- Course on experimental electrocardiography in dogs
  University of Parma, Italy

1978

- Course on experimental teratology
  Expert Committee on Teratogenesis, Milan, Italy

1972-1973

- Course on Biochemistry
  University of Milan, Italy

1967

- Training course on rodent and dog necropsy
  University of Milan, Italy

CONGRESSES

2008

- GIQAR National Meeting
  Italy Italian Group of Quality Assurance in Research, Genoa, Italy

2000

- Clinical Development Conference 2000
  Business Intelligence, Barcelone,Spain

1998

- International FERQAS Congress on Quality Systems in Research
  Tour, France

1997

- RAPS European Conference
  Cannes, France

1996

- GIQAR/FERQAS National Meeting
  Italian Group of Quality Assurance in Research, Florence, Italy

1992

- 8th BARQA International meeting on GLP
  London, UK

- European Congress on laboratory animal science
  Stockholm, Sweden

1991

- 3eme Colloque de la Societe de Pharmaco-Toxicologie cellulaire - SPTC
  Paris, France

- GIQAR National Meeting
  Italian Group of Quality Assurance in Research, Nemi-Rome, Italy

1990

- "Animals and alternatives in Toxicology, present status and future prospects" FRAME conference
  London, UK

1989

- VIII Congress of Italian Society of Toxicology
  Bologna, Italy

1988

"The 6th amendment: the light of experience". EEC/ E.S.T. 2nd International Conference
Seville, Spain

- 6th International Congress on GLP organised by UK QAU Group
  Stratford upon Avon, UK

1987

- Products from biotechnology of pharmaceutical interest
  SISF, Societa Italiana Scienze Farmacologiche, Milan Italy

1986

- 5th QAG International Meeting on GLP
  UK Quality Assurance Group, Frankfurt, Germany

- International Symposium: "The Contribution of acute toxicity studies in new drug evaluation"
  IFPMA, Geneva, Switzerland

PUBLICATIONS

1993

- " A European interlaboratory evaluation study of an in Vitro ocular irritation model (Skin 2TM Model ZK 1100) using 15 chemicals and 3 shampoos"
  In: Collaborative study on the evaluation of alternative methods to the eye irritation test. CEC

1992

- "Studio interlaboratorio di valutazione di un metodo di irritazione in vitro"
  Oral communication presented at the 1st National Meeting of Celltox -
  Italian Association of in vitro toxicology - Rome, (A.T.L.A.)

- "CEC Collaborative Study on the Evaluation of Alternative Methods to the Eye Irritation Test"
  In: Around the World - A.T.L.A. Frame 20 (3), 480

1991

- "CEC- Validation Study on Alternative to the Draize Eye Irritation Test: Pilot Interlaboratory comparison of the in-vitro cytotoxicity tests"
  In: Collaborative study on the evaluation of alternative methods to the eye irritation test. CEC-Doc XI/632/91, Part II; Part II; Appendix 2, 143, 143-211

- Preliminary inter-laboratory validation exercise on various « in vitro » cytoxicity tests to be used for regulatory purposes for irritation labelling.
  Oral communication presented at "Sesta Riunione scientifica nazionale del Coordinamento italiano per l'applicazione delle colture di tessuto in Tossicologia",
  Padova, Italy

- "Controllo statistico computerizzato dei dati in accordo con la normativa UNI 4842.
  Oral communication presented at Il convegno Nazionale GIQAR,
  Nemi, Rome, Italy.

- Less or More Quality Assurance Regulation.
  Oral communication presented at the 2nd International Conference on Research Policies and Quality Assurances
  Ares-Serono Symposia - Rome - Accountability in Research 2,175 (1992)

1990

- Validation of cell substrates used for human biological: an overview of international regulatory documents
  In*: In vitro Toxicology 4, 720*

- In vivo skin irritation in rabbits
  In: Collaborative study on relationship between "in vivo" primary irritation and "in vitro" experimental models CEC/V/E/Lux/157/88
  i

1989

- Inspections by International Regulatory Authorities: a 3 years experience
  Oral communication presented at the meeting "Le Buone Pratiche nella Ricerca Bimoedica"
  Istituto Superiore della Sanita, Rome Italy

- Safety evaluation of Continuous Cell Lines as Substrate for Biologicals for Medicinal Use.
  Abstracts of Simposio AFI 1989; Fourth European Conference on Industrial Biotechnology i

- Safety evaluation of Continuous Cell Lines producing Monoclonal Antibodies intended for use in the Purification of Biological for Human use
  Abstracts of Simposio AFI 1989: Fourth European Conference on Industrial Biotechnology

- Comparative Evaluation of Relevant International Regulatory Requirements on Production and Quality Control of Biological.
  Abstracts of Simposio AFI 1989: Fourth European Conference on Industrial Biotechnology

- Italian legislation on the care and use of animals for experimental purposes.
  Lecture presented at the annual meeting of the European Discussion Group - Society of Toxicology Pathologists

1988

- Inspections by International Regulatory Authorities: a 3 years experience
  Oral communication presented at the 1st meeting of GIQAR (Italian Group of Quality Assurance)

- A comparative "in vitro - in vivo" study on twelve compounds with different skin irritation potentials
  A.T.L.A (Alternatives to laboratory animals) FRAME 16(1), 71

- Atti della 1a Giornata sulla Professionalita degli Operatori nella animal care
  SSFA/GISAL, Milan, Italy.
  .

1987

- Italian and International Guidelines and Rules on Animal Experimental.
  Oral communication presented at the 1st GISAL meeting "La professionalita degli operatori nella animal care"

1984

- Experimental design for evaluating the interference of drugs with reproduction in the rat.
  Oral Communication presented at the 1st GISAL meeting.

- Effetto inibitorio della 5-HT somministrata s.c. alle 15.00 del giorno del proestro sul picco preovulatorio di LH e sull'ovulazione nel ratto.
  Oral communication presented at the 1st National Congress of Gynecology and Endocrinology,

1982

- Selective suppression of spontaneous ovulation by 5-HT on the day of proestrus in the rat.
  Poster presented at the 21st Congress of the Italian Society of Pharmacology, Naples, Italy

1980

- Protective effects of oral Acetyl-N-Cysteine on hepatic acute toxicity of Acetaminophen in the mouse
  Poster presented at the 2nd International Congress of Toxicology, Brussels.

1977

- Effects of partial hepato-ectomy and renal impairment on Thiamphenicol metabolism.
  Pharmacological Research Communication, 9, 609, 1975 Oral Communication presented at the 18th Congress of European Society of Toxicology (June 1975)

PROFESSIONAL AFFILIATIONS AND MEMBERSHIPS

- Italian Society of Applied Pharmacology Sciences (SSFA)
  Since affiliation (1983) actively involved in GLP and GCP "Group" Meetings

- Italian Association for laboratory animal sciences (AISAL)
  Former Councillor in the Scientific Committee - Lecturer at the AISAL training courses

- British Association of Research Quality Assurance - BARQA

- American Society of Quality Assurance

- Cell Tox - Italian Society of in vitro toxicology

- Invited participant in "Ad hoc" Expert Committee Meetings on alternative methods to eye and skin irritation tests
  EEC, DG XI-V, Brussels, Belgium