CURRICULUM VITAE

[redacted]

Place of birth: [redacted]
Date of birth: [redacted]
Family: [redacted]
Current address: [redacted]
Nationality: [redacted]

Past and Current Fields of Expertise

- *Experimental Toxicology*:

Analytical toxicology, forensic toxicology, drug metabolism, pharmacokinetics, local tolerance, in vitro and in vivo toxicology, mechanistic toxicology.

- *Hazard and Risk Assessment:*

Raw materials and intermediates in chemical manufacturing, industrial waste, food contaminants, food additives, food packaging materials, environmental pollutants, pesticides, genetically modified crops and early and late development of medicines.

- *Regulatory Toxicology:*

Classification and labelling of dangerous substances and preparations, new and existing products notification, market restrictions, occupation exposure limits, food contact materials registration, pesticide registration, medicines registration.

- *Preclinical Development:*

Toxicology, safety pharmacology, pharmacokinetics, metabolism and regulatory submission of antiviral drugs (HIV, RSV, HCV, HBV) and drugs against TBC.

Education/certifications

European Registered Toxicologist (ERT), Belgian Register of Toxicology of EUROTOX (June 2011, renewed in September 2016)
Ph.D., University of Ghent, School of Pharmacy, 1976.
Certification in haematology (cytology and haemostasis), University of Ghent, 1976.
Certification in clinical chemistry, University of Ghent, 1974.
Certification in industrial pharmacy, University of Ghent, 1973.
Certification in toxicological analysis applied in clinical and forensic toxicology, University of Ghent, 1972.
Certification in toxicological analysis of phytopharmaceutical products, University of Ghent, 1972.
M.S. in Pharmacy, University of Ghent, 1972.

Continuous education throughout career by attending training courses and workshops in toxicology and risk assessment (e.g. Advanced Courses in Toxicology by Huntingdon Life Sciences, American Society of Toxicology educational programmes, lecturing at universities, residencies and project assignments in government services and chemical and pharmaceutical industry)

Current and Past Professional Memberships

Belgian Society of Pharmaceutical Sciences.

International Pharmacy Federation.
International Association of Forensic Toxicologists
Flemish Chemical Society
European Society of Toxicology
Belgian Society of Toxicology and Ecotoxicology
Belgian Environmental Mutagenesis Society
American Society of Toxicology
British Society of Toxicology
Belgian-Netherlands Society of In Vitro Methodology (INVITROM)
Member of the managing board of FORMAC pharmaceuticals
Member of the Steering Committee of Greenfacts
Member of the Scientific Advisory Committee of the Belgian Fund for Occupational Diseases
Member of the Medical Commission on Chemical Agents of the Belgian Fund for Occupational Diseases
Member of the Medical Commission on Continued Medical Surveillance of the Belgian Fund for Occupational Diseases

Current and Previous Positions

Consultant in Preclinical Development and Toxicology (May2010-current)
Providing toxicology and preclinical development support to chemical, agrichemical and pharmaceutical industry and other consulting organisations.

Vice President Preclinical Development, Tibotec (Infectious Diseases Therapeutic Area of Johnson&Johnson), Mechelen, Belgium (March 2005- June 2010)
Organisation of a fully functional preclinical development department in Tibotec and lead of global preclinical development activities of all early and late development projects of HIV, respiratory syncytial virus (RSV), hepatitis C virus (HCV) and tuberculosis drugs. Member of governance bodies responsible for the progress and of all infectious diseases development projects such as the Development Management Committee (DMC), the Research and Early Development Management Committee (REDMC), the Early Development Team and the Early Development Leadership Team (EDLT). Member of the govermance bodies responsible for the coordination of preclinical development activities within the J&J Global Preclinical Development (GPCD) organisation such as the GPCD Global Leadership Team, the European Core team and the European Leadership team.
Major achievements are the successful registration in the US, EU, Japan and many other countries of two HIV drugs (TMC114 and TMC125), progression of two late development projects to NDA phase of an HIV drug (TMC278) and a first-in-class HCV drug (VX-950), passage of the HCV drug TMC435 into late development and a successful deal with TB alliance for the progression of the development of a fist-in-class tuberculosis drug (TMC207). Pre-first-in-human development of two hepatitis C polymerase inhibitor drugs one non nucleoside and one nucleoside. Early development up to proof of concept of a new high genetic barrier HIV drug (TMC310). A significant contribution was made to the concept of the development of parenteral HIV drugs for prophylactic and maintenance indications (TMC278).

Sr Director Toxicology of Tibotec-J&J, Mechelen, Belgium (January 2004-March 2005)
Toxicology support for late lead optimisation and drug evaluation projects for candidate drugs against HIV, RSV, HCV and TB. Operations support for the pre-clinical development

organisation of Tibotec including the production of regulatory submission documents of medicines in full development phase (TMC114, TMC125, TMC278).

Promoted to Monsanto Science Fellow (2002)

Toxicology Director, Europe/Africa, Monsanto Technical Centre, Louvain-La-Neuve and Brussels, Belgium (1994-2004).
Regulatory toxicology and risk assessment support for the Chemical Group (before the spin off of the chemical business as Solutia) and Agricultural Group businesses and their operations in the Europe/Africa region. These activities include the gathering (i.e. literature search, Monsanto studies, and commissioning of toxicology studies in contract laboratories), selection and interpretation of health effects data within the European regulatory context and Monsanto internal liability procedures such as SDSs, poisoning assistance and environmental, safety and health risk assessments for products under development, registration and notification in the EU. Important projects were the risk assessment of existing chemical substances for the OECD and for the EU (rubber chemicals and water treatment chemicals), oestrogenicity and exposure assessment research for polymer modifier defence for OSPAR member countries, positioning of cancer classification issues of herbicides and rubber chemicals for the EU and registration defence of Monsanto's pesticides in EU member states and other countries of the Europe/Africa region. Contributions were made to GMO public acceptance by giving presentations and seminars on health safety assessment of GM plants to academia, scientific associations and consumer organisations.

Assistant professor in toxicology, Public Health School, St Louis University, St Louis, MO, USA (1993-1994).
The courses given were inflammatory effects of chemicals on skin and eyes and forensic toxicology.

Manager, product toxicology, corporate toxicology, Monsanto WHQ, St Louis (1993-1994).
Co-ordination of corporate product toxicology research and hazard assessment for the Chemical Group of Monsanto. Product toxicology work was comprised of data gathering on the toxicology of all Monsanto products, identification of data gaps and commissioning and management of toxicology studies, hazard and risk assessment. Important contributions were made to the redesign of the product stewardship organisation of the Chemical Group of Monsanto and the review of the environmental, safety and health assessment process for substances under development. Active toxicology defense of chloroacetanilide herbicides in the EU.

Toxicology manager, corporate toxicology, Monsanto WHQ, St Louis (1992-1993).
This function was occupied during the first part of my assignment at Monsanto WHQ in the USA. Co-ordination of special projects such as the investigation of a possible relationship between arthralgias and exposure to a maleic anhydride catalyst, active toxicology defence of alachlor and acetochlor in Europe and the design of human metabolism studies for non medicine chemicals in the USA.

Toxicology manager, Europe, Monsanto Europe/Africa, Brussels, Belgium (1989-1992).
Regulatory toxicology support for the Chemical and the Agricultural Groups of Monsanto Europe/Africa. The most important activities were toxicology defence of Monsanto products in the EU, SDS composition, labelling and classification of chemicals, internal liability

procedures for new products under development, risk assessment and emergency response. An important contribution was made to the EU dangerous substances classification and labelling process through the CEFIC representation at the meetings of the EU working group on classification and labelling.

Head of the department of toxicology, Institute of Hygiene and Epidemiology, Brussels, Belgium (1984-1989).
I founded this department and developed it into a national centre for toxicology advice to the Belgian government and to the EU. The main activities of this department were regulatory toxicology and experimental toxicology. For regulatory toxicology, advice was given on dossiers for the registration of pesticides and pesticide formulations and premarketing notification for all new chemicals put on the EU market via Belgium. The department was actively involved in all EU regulatory development work in the area of dangerous substances and preparations. The experimental work consisted primarily of acute toxicity, in-vitro and in-vivo mutagenicity, skin and eye irritation and in-vitro toxicology. The experimental research was directed toward the validation and development of new testing methods mostly under contract with the EU.
As head of the department I was member of the Dangerous Substances Committee, member of the Registration Committee for Pesticide Formulations and invited expert at the Supreme Health Council, expert to the cabinet of the minister of health for all policy issues regarding dangerous substances and member of the Scientic Advisory Committee for Toxicology and Ecotoxicology of the EU.

Head of the toxicology information centre, Institute of Hygiene and Epidemiology, Brussels (1980-1984).
This department was the growing core for the toxicology department described above. The most important activities were the development of a database for toxicological information on chemicals in collaboration with the EU and the UNEP (IRPTC), the elaboration of data sheets for the EU labelling programmme and the development of computerised expert programmes such as the automatic health hazards labelling system (used by EU as a basis for the development of its own expert programme).

National inspector for the accreditation of clinical biology laboratories, Institute of Hygiene and Epidemiology, Brussels, Belgium (1979-1980).
This function consisted of the further elaboration of the Belgian accreditation system for clinical laboratories and to perform inspections to judge clinical biology laboratories on their quality and compliance with accreditation requirements.

Head of the department of mass spectrometry and drug metabolism, Continental Pharma, Brussels, Belgium (1976-1979).
The identification by GC-MS of intermediate products in chemical synthesis in the discovery of new drugs and the study of the pharmacokinetics and metabolism of new drugs. Studies were performed on rats, mice, rabbits and Rhesus monkeys. As head of the department I was member of the Scientific Council of the company to give advice on the registration strategy of newly developed drugs in the UK, France, Germany, The Netherlands, Italy, Spain and Japan.

Assistant professor in toxicology, school of pharmacy, University of Ghent, Belgium (1972-1976).

Beside the PhD work assistance to the lecturing programmes of forensic, clinical and analytical toxicology to students of the last year M.Sc. pharmacy, industry pharmacy, hospital pharmacy, clinical biology and criminology. I was also responsible for the toxicological analyses to be performed for the emergency unit of the University hospital and for the medical examiner of the district of Ghent.

Military service (1972-1974)
Reserve officer and lecturer at the national school of the health service of the army in the medical aspects of nuclear, chemical and biological warfare. Promoted later to captain and captain commander of the reserve force.

Resident in the analytical laboratory for intoxication emergencies at night, department of toxicology, University of Ghent, Belgium (1971-1972).
This last year pharmacy student residency work consisted of the analysis of drugs and chemicals in blood, urine and gastric content of intoxicated patients admitted in the university hospital of the state university at Ghent.

Experience with International and National Organisations
(1) EU Commission and Council
Delegate of Belgian authorities:

- Technical progress of the Directives on the classification of paints and varnishes (1980-1982)
- Technical progress of the Directive on the classification of solvents (1980-1983)
- Development of the official EU toxicology testing guidelines (Annex V of the EU Directive on dangerous substances) (1980-1989)
- Development of the Directive on the classification of dangerous preparations (1982-1988)
- Development of the labelling guide (Annex VI of the EU Directive on dangerous substances) (1981-1983)
- Chairman of the Council of the EU meetings on the classification and labelling of dangerous substances and preparations (1987)
- All EU meetings on the classification and labelling of dangerous substances (1984-1989)
- EU working group for the development of alternative test methods for skin irritation (1987-1988)
- EU steering committee for the reactivation of toxicological research in Europe (1987)
- Member of the Scientific Advisory Committee on Toxicology and Ecotoxicology of the EU (1988-1989)

Delegate of the European Chemical Industry (CEFIC):

- All EU meetings on the classification and labelling of chemicals (1990-1992)
- All EU meetings on the informatics of EUCLID, EU database on hazards of existing chemicals (1995)

Delegate of the World Association of the Rubber Chemicals Industry (WTR):

- All the EU meetings on classification and labelling of dangerous substances (1994-1997)

(2) OECD Chemicals Group
Delegate of the Belgian authorities:

- Management Committee and Chemicals Group of OECD, including the high level meeting on notification of new chemicals in 1982 as advisor to the Minister of Health (1981-1984)
- OECD working group for the adaptation of test methods in acute toxicology (1986)
- Member of OECD mission to Finland to audit the Finnish authorities on their chemical safety policies (1986)
- OECD meeting on existing chemicals (1987)

Delegate of CEFIC:

- OECD clearing house on harmonisation of classification systems (1992)

Delegate of the American Industrial Health Council AIHC (USA):

- OECD working group on the international harmonisation of carcinogenicity risk assessment (1993-1994)

(3) International Programme on Chemical Safety (IPCS)

Delegate of the Belgian authorities:

- Environmental Health Criteria (EHC) documents task force on tetrachloroethylene, dichloromethane, and epichlorohydrine (1983)
- EHC working programme (1984, 1987)
- EHC documents task force on ethylene oxide and propylene oxide (1985)
- IPCS steering group for the development of the International Chemical Safety Card (ICSC) system (1986)
- IPCS working group for the ICSC project (host and rapporteur) (1988)

Delegate of European chemical industry (ECETOC):

- EHC document task force on PCB's (1990)

(4) United Nations Environmental Programme (UNEP-IRPTC)

Participation on behalf of the Belgian authorities:

- IRPTC dangerous chemicals database (1985-1986)

(5) International Agency for Research on Cancer (IARC)

- ECETOC representative at the IARC monograph meeting on mechanisms of carcinogenicity (1991)
- AIHC representative at the IARC monograph meeting on carbon black and nitroaromatics (1995)

(6) European Centre of the Chemical Industry for Toxicology and Ecotoxicology (ECETOC)

Participation on behalf of the Belgian authorities:

- Member of the ECETOC task force on skin irritation (1988-1989)

Participation on behalf of Monsanto:

- Chairman of the ECETOC task force on pharmacokinetics and metabolism (1991-1992)
- ECETOC task force on reproductive toxicology (1996-1999)
- ECETOC task force on endocrine modulation (1997-1999)

(7) European Council for the Chemical Industry (CEFIC)

Participation as a representative of Monsanto:

- CEFIC toxicology working group of the plasticizers sector group, ECPI (1989-1997)
- CEFIC working group on the product information aspects (PIA) (1995-1997)

- CEFIC working group on the international harmonisation of classification systems (1995-1997)
- Chairman of the CEFIC subgroup on the international harmonisation of classification on the basis of acute toxicity (1995-1997)
- CEFIC working group on the international harmonisation of classification on the basis of chronic toxicity, reproductive toxicity and carcinogenicity (1995-1997)
- CESIO task force to OSPAR member states on phthalate ester endocrine modulation (1996)

(8) European Crop Protection Association (ECPA)
Participation as a representative of Monsanto:

- ECPA toxicology expert group (1998-2004)
- Chairman of the ECPA toxicology subgroup on safety assessment of GM foods and feeds (1999-2001)
- Chairman of the ECPA toxicology subgroup on the risk assessment of mixtures (2002-2004)

(9) *Fonds voor Beroepsziekten (FBZ)*
Participation as a representative of the Belgian Pharmaceutical Industry:

- Member of the Scientific Counsel (2007- current)
- Member of the Expert Group on Chemical Agents (2007-current)
- Member of the Expert Group on Continued Medical Surveillance (2011-current)

(10) *Belgian Society of toxicology and Ecotoxicology (BelTox)*
Co-founder of the society in 1989

- President from 2005 to 2014
- Secretary from 2014 - current

Lecturing in Toxicology and related Sciences
University of Antwerp (UIA), University of Brussels (VUB, ULB), University of Louvain, Woluwe-Brussels (UCL), University of Leuven (KUL), St Louis University (US), Beltox introduction and advanced courses in toxicology.

Book
Co-author of a book on drug development:
Global New Drug Development, An Introduction
Rosier JA, Martens MA and Thomas JR.
ULLA Postgraduate Pharmacy Series, Wiley Blakwell, 2014

Scientific publications
Listed in annex to this CV

Patents
Patent holder of US patent for the invention of a new medicine no 4,639,468 of 01/27/1987: Derivatives of glycinamide, their preparation and their use.

Language skills
Dutch (mother's tongue), French (good) and English (good) and German (moderate).

Hobby's
Drawing (graphite, ink, carbon), painting (water colours, airbrush), tennis, biking, sailing, tinkering.