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Professional Experience

Key experience	During my 29-year career in pharmaceuticals, I have had the opportunity to work on a wide variety of projects in very different settings. Apart from my work in "big pharma", I have made substantial contributions to the development and approval of biologicals (Egrifta®, Jetrea®) and to the commercial launch of the first Advanced Therapy Medicinal Product, ChondroCelect®. As an independent consultant, I have provided feasibility assessments and/or scientific support for over 60 development projects involving novel small molecules, biologicals, as well as repurposed generics. During this work, I have had face to face interactions with several Regulatory Agencies including FDA, EMA, MHRA, BfArM, AFFSAPS and AEMPS. My recent experience includes systematic reviews and meta-analyses, as well as clinical trial data exploration for publication purposes or business decision support.
Key competencies	• The ability to quickly spot key project strengths and weaknesses. • The ability to identify and communicate the business impact of diverse aspects of a project (early and clinical development, safety matters, health economic and marketing plans). • Develop and present clear and convincing communications to convey project messages.
Feb 2018 - now	**Director, Xintera BV (Gent, Belgium).** Strategic consulting services in drug development.
Jun 2012 – Feb 2018	**Director, Xintera Ltd (Cambridge, UK).**
Sep 2009 – Sep 2010	**Chief Medical Officer, TiGenix NV (Leuven, Belgium)** • Responsible for Clinical Development & Medical Affairs in a company launching the first EMEA-approved Advanced Therapy Medicinal Product, ChondroCelect. • Scientific advice meetings with FDA and EMA.
Mar 2007 – Mar 2009	**Chief Medical Officer, elbion NV (Leuven, Belgium)** • Lead the medical and regulatory aspects of drug development in a small pharma company with a specialty pharma component focused on addiction, and a homegrown discovery and development portfolio geared towards CNS disorders, inflammation & immunosuppression.

- As member of the Senior Management Team (CEO, CFO, CSO, CMO), contribute to the shaping of corporate strategic decisions, including licensing and M&A activities.
- Major achievement: obtained full concurrence from BfArM re: an innovative development pathway for a depot preparation in the treatment of alcohol dependence.

Apr 2007 – Dec 2013 **Managing Director, Xintera Consulting bvba – Strategic Clinical & Regulatory Decision Support**

Aug 2005 – Feb 2007 **Theratechnologies inc. (Montreal, QC)**
Executive Director, Clinical Research

- Major responsibilities
  - Reporting to the President and CEO, lead the Clinical Research Division (Phase 1 → 3) of a Canadian biotechnology company specialized in peptide development, including the aggressive Phase III development of the company's lead compound in HIV-associated lipodystrophy.
  - Interact with FDA on clinical development matters; endpoint determination, statistical analysis issues, Patient-Reported Outcomes, Phase 3 Special Protocol Assessment.
  - Act as the Company's scientific representative vis-à-vis financial analysts and investors.
  - Provide medical/clinical input into review and selection of licensing candidates.
- Major achievements
  - Successfully and timely delivered the tesamorelin (TH9507) Phase 3 pivotal study, including a *New England Journal of Medicine* publication.
  - Attracted and maintained highly talented professionals in the clinical research department, expanding critical in-house functions while continuing to outsource non-core activities.
  - In close collaboration with Regulatory Affairs, successfully interacted with FDA on various development issues, including a successfully negotiated Special Protocol Assessment.

Dec 2004 – Aug 2005 **Pfizer Canada Inc (Kirkland, QC)**
Director, Scientific Affairs and Medical Operations

- Provide medical and scientific leadership for the marketed cardiovascular product portfolio.
- Provide cross-functional support to the Medical Division thru the Medical Operations department.

2004 **Pfizer Canada Inc (Kirkland, QC)**

Director, Medical Operations

- Areas of responsibility include:
  - Resource Management & Planning (including Finance, Strategic Planning & Metrics)
  - Business Technology
  - Pharmacy Operations
  - Contracts & Outsourcing
  - Regional Medical Research Operations
- Major Achievements:
  - Business Assessment of the Canadian biotechnology opportunity for Pfizer Inc.
  - Systems & processes standardization of newly merged early phase and late phase research groups.
  - Creation of the Medical Contracts Office to minimize company exposure and ensure optimal efficiency and consistency vis-à-vis external stakeholders.

2000 – 2003 **Pfizer Canada Inc (Kirkland, QC)**

Director, Clinical Research Operations

- Responsible for planning & operations of Pfizer Canada's phase IIIB/IV clinical program, including Project Management, Data Management & Biometrics.
- Responsible for management and planning of the Medical Division's Finances (~$50m) and its Systems.
- Additional ad-hoc assignments:
  - Medical lead in the merger task force (Pharmacia merger, 2003).
  - Acting Director, Medical Information (2nd half 2002).
  - Country representative on several international Pfizer task forces on clinical trial process redesign, outsourcing and systems.
- Major Achievements:
  - Standardization and improvement of clinical research processes, including financial forecasting capabilities, leading to on-target budget performance (within 1%) for the direct R&D budget line (~$30m).
  - Overhaul of the monthly clinical reporting process to focus on forward-looking project & financial risk assessment rather than on past performance.
  - Pilot and rollout of Remote Data Capture technology, which, in combination with other process redesigns, lead to significantly faster availability of clinical data post study completion while achieving significant savings.

1999 – 2000 **Pfizer Canada Inc (Kirkland, QC)**

Associate Medical Director

- Responsible for Pfizer Canada's phase IIIB/IV clinical program for anti-infective and anti-inflammatory drugs, and Viagra.

1996 – 1998 **Pfizer Inc. (New York, NY)**

Associate Medical Director, Trovan Global Development Team

- Medical member of the Global Development Team (ex-US), in charge of medical support to the Global Team, Area Teams and country offices, for the global launch of this hospital/community use quinolone which was subsequently withdrawn because of liver toxicity concerns.
- Responsible for international research and development of Trovan Phase IIIB global pre-launch program, including training of subsidiary personnel on scientific content and key marketing messages.
- International opinion leader development.
- Publication review.
- Constant interaction with Regulatory and Legal on promotional and regulatory issues.
- Major Achievement:
    - Implementation of an ambitious Phase 3B clinical program hospital infection across 16 ex-US countries, with minimal internal resources.

1995 – 1996 **Pfizer Inc. (New York, NY)**

Associate Medical Director, Medical Operations Europe

- Medical support for European countries, including country protocol review, Operating Plan review, SOP writing.
- Major Achievement:
    - Design and implementation of a Europe-wide database for the planning and exchange of clinical study information.

1992 – 1995 **Pfizer Belgium (Jette, Belgium)**

Medical Adviser

- Responsible for local R&D and marketing support of Pfizer Belgium's anti-infective products (fluconazole, azithromycin, doxycycline)
- Oversight of the Belgian components of the international tenidap R&D program

1991 – 1992 **Institute for Tropical Medicine Antwerp, Belgium**

Resident, Tropical Medicine/AIDS Ward

- Responsible for medical care of hospitalized patients with acute tropical disease and AIDS
- Major Achievement:
  - In collaboration with Dr. J. Van den Ende as a content expert, wrote a Windows-based medical decision-making program for the Institute's Tropical Medicine students. This program ended up being used as the final examination in clinical decision making.

1987 – 1990 **Médecins sans Frontières (Brussels, Belgium)**

Tropical Doctor

Various assignments, including:

- Mali (1989-1990) – Magasins-Santé Project, a Drug Cost Recovery Program with educational aspects in the Timbuctu province
- Sudan (1988-89) – nutritional surveys, refugee camp administration, exploratory mission in Raga, western Bahr El Ghazal, meningitis vaccination campaign
- Head Office (1988) – participated in the redaction of the first edition of the MSF-B field document "The Operational District", an attempt to evaluate the overall cost of medical care in a developing country
- Ethiopia (1987) – curative medicine in a rural war zone hospital

Education

1987	Diploma in Tropical Medicine, Institute for Tropical Medicine, Antwerp, Belgium. Magna cum laude.
1986	Doctor in Medicine, Ghent State University, Ghent Belgium. Cum laude.
1979	High School, H.-Maagdcollege, Dendermonde, Belgium. Magna cum laude.

Presentations

Nov 7, 2011	How will innovator technologies fare in an increasingly restrictive global reimbursement environment? Lessons from comparison of cell and gene therapies to conventional biopharmaceuticals. Issue Panel Presentation at the 14th Annual European ISPOR Congress, Madrid.
Oct 12, 2011	Communicating Risk to Clinical Trial Subjects and Investigators. Presentation at the 5th Annual DIA Clinical Forum, Basle.
Oct 14, 2003	Televised debate "Human Guinea Pigs" – a TV Ontario (TVO) talk show aired on Oct 15, 2003.

Nov 21, 2003	"Bonnes Pratiques Cliniques" (McGill Ethics Lecture, Montréal, Québec).
May 28, 2003	"Conflicts of Interest in Clinical Research" (McGill BioEthics Conference, Montréal, Québec)).
Oct 22-23, 2004	"Institutional Conflict of Interest – The Sponsor's Perspective" (Invitational Meeting on Conflict of Interest, Canadian Institutes for Health Research, Aylmer, Québec).

Publications

1. Jackson, T. L., Haller, J., Blot, K. H., Duchateau, L. & Lescrauwaet, B. Ocriplasmin for Treatment of Vitreomacular Traction and Macular Hole A Systematic Literature Review and Individual Participant Data Meta-Analysis of Randomized, Controlled, Double-Masked Trials. *Surv Ophthalmol* (2021) doi:10.1016/j.survophthal.2021.08.003.
2. Khanani AM, Constantine RN, Blot KH, Lescrauwaet B, Szurman P. Effectiveness of ocriplasmin in real-world settings: A systematic literature review, meta-analysis, and comparison with randomized trials. Acta Ophthalmol. Dec 26 2020; doi:10.1111/aos.14686
3. Lescrauwaet B, Blot K, Jackson TL. Patient-reported outcomes of ocriplasmin for the treatment of vitreomacular traction: a systematic review and synthesis of the literature. Patient Relat Outcome Meas. 2019 Mar 27;10:101-116. doi: 10.2147/PROM.S153718. PMID: 30988647; PMCID: PMC6443223.
4. Blot K, Duchateau L, Lescrauwaet B, Liyanage N, Ray D, Mirakhur B, Vinik AI. A Patient-Reported Outcomes Analysis Of Lanreotide In The Treatment Of NETs Patients With Carcinoid Syndrome: Evidence From The ELECT Trial. Patient Relat Outcome Meas. 2019 Oct 29;10:335-343. doi: 10.2147/PROM.S219982. PMID: 31754316; PMCID: PMC6825468.
5. Michel MC, Radziszewski P, Falconer C, Marschall-Kehrel D, Blot K. Unexpected frequent hepatotoxicity of a prescription drug, flupirtine, marketed for about 30 years. Br J Clin Pharmacol. 2012 May;73(5):821-5. doi: 10.1111/j.1365-2125.2011.04138.x. PMID: 22044433; PMCID: PMC3403210.
6. Blot K, Michel MC. Authors' response to Hermann et al. Minimum quality criteria are needed in the assessment and communication of unexpected drug safety findings of marketed products from RCTs. Br J Clin Pharmacol. 2012 Jul;74(1):209-10. doi: 10.1111/j.1365-2125.2012.04180.x. PMID: 22242895; PMCID: PMC3394149.
7. Falutz J, Allas S, Blot K, Potvin D, Kotler D, Somero M, Berger D, Brown S, Richmond G, Fessel J, Turner R, Grinspoon S. Metabolic effects of a growth hormone-releasing factor in patients with HIV. N Engl J Med. 2007 Dec 6;357(23):2359-70. doi: 10.1056/NEJMoa072375. PMID: 18057338.
8. Colebunders R, Blot K, Mertens V, Dockx P. Psoriasis regression in terminal AIDS. Lancet. 1992 May 2;339(8801):1110. doi: 10.1016/0140-6736(92)90701-4. PMID: 1349120.
9. Colebunders R, Sow S, Coulibaly M, Blot K. Efficacy of octreotide in the management of chronic diarrhoea in AIDS. AIDS. 1992 May;6(5):512. PMID: 1616659.
10. Sternon J, Leclerq P, Knepper C, Blot K. Azithromycin compared with clarithromycin in the treatment of adult patients with acute purulent tracheobronchitis: a cost of illness study. J Int Med Res. 1995 Nov- Dec;23(6):413-22. doi: 10.1177/030006059502300602. PMID: 8746608.
11. Blot S, Vandewoude K, Blot K, Colardyn F. Prevalence and risk factors for colonisation with gram-negative bacteria in an intensive care unit. Acta Clin Belg. 2000 Sep-Oct;55(5):249-56. doi: 10.1080/17843286.2000.11754307. PMID: 11109639.
12. Colebunders R, Vael C, Blot K, Van Meerbeeck J, Van den Ende J, Ieven M. Bordetella pertussis as a cause of chronic respiratory infection in an AIDS patient. Eur J Clin

Microbiol Infect Dis. 1994 Apr;13(4):313-5. doi: 10.1007/BF01974608. PMID: 8070437.
13. Colebunders R, Sow S, Blot K, Vandenbruaene M, Heerackers Y, Kestens L, Van Ham G, Cornelissen W, Blot K. HIV diagnosis delay in Antwerp, Belgium. J Epidemiol Community Health. 1994 Apr;48(2):212. doi: 10.1136/jech.48.2.212. PMID: 7910627; PMCID: PMC1059937.
14. Van den Ende J, Blot K, Kestens L, Van Gompel A, Van den Enden E. Kabisa: an interactive computer-assisted training program for tropical diseases. Med Educ. 1997 May;31(3):202-9. doi: 10.1111/j.1365-2923.1997.tb02568.x. PMID: 9231140.
15. Colebunders R, De Serrano P, Van Gompel A, Wynants H, Blot K, Van den Enden E, Van den Ende J. Imported relapsing fever in European tourists. Scand J Infect Dis. 1993;25(4):533-6. doi: 10.3109/00365549309008539. PMID: 8248757..

Languages

- Dutch – mother tongue
- English, French – written and spoken fluently
- Spanish – retrievable