Curriculum Vitae

Gillian Frances Elizabeth MORGAN

Career Summary

More than 25 years of diagnostic industry experience. Created GCP compliant clinical departments, regulatory departments and implemented ISO compliant quality systems for small companies (5- 40 employees). Directed clinical and regulatory departments in multinational companies. Completed global registration trials and product registrations for a diverse portfolio of diagnostic products, including the highly regulated complex molecular diagnostics. Strategic planning, project management and business development experiences ensure a perspective on most aspects of product development, commercialization and product partnering.

Professional Career

September 2012 –

Director; Sestria Ltd.
Consulting services for the *in vitro* diagnostic industry, including development of regulatory and clinical registration strategies, implementation of ISO 13485 quality systems, risk management, product registration in the EU and North America and quality systems supplier audits.

October 2012 – December 2014

Chief Operating Officer and Regulatory/Quality consultant. Fahy Gurteen Labs Ltd., Cambridge UK

A family owned start-up company researching novel oncology diagnostics for commercialization in the EU. Implemented their quality system and established their lead product registration pathway. Business model shifted in January 2015 to providing contract research services.

October 2011 – September 2012

Chief Operating Officer, Crescent Diagnostics, Dublin, Ireland

A small (5 employees) VC backed diagnostics company developing a novel osteoporosis test based upon Raman Spectroscopy technology. Responsibilities included regulatory interactions with FDA and IMB, implementation of quality systems, product development, clinical development and IP.

March 2009 – October 2011

Chief Development Officer, Myconostica Ltd, Manchester, U.K.

Gillian Morgan
gillianmorgan@hotmail.com Telephone (mobile) +44 7794 265 473

A molecular diagnostics company specialising in fungal diagnostics. Company launched 3 products in the EU and was acquired by Lab 21 in 2011.

- Managed the regulatory, quality and clinical group (staff of 2)
- Oversight of manufacturing operations, quality control and R&D.
- Shareholder and investor management role up to the successful completion of the sale of Myconostica to Lab 21.
- Transfer of Myconostica regulatory knowledge to Lab 21. Assisted with their US clinical/regulatory development plans.

January 2008 – March 2009

European Scientific Director, Monogram Biosciences.

One of an executive team of 4 people established in Europe and sponsored by Pfizer to launch the Monogram Trofile assay in Europe and other ex-US countries as a companion diagnostic to the Pfizer Celsentri antiretroviral drug. Monogram Biosciences was acquired by LabCorp of America in 2009.

January 2007 – Dec 2007: Siemens Medical Solutions Diagnostics, Tarrytown NY
July 2004 – December 2006 Bayer Healthcare, Diagnostics Division, Tarrytown NY (acquired by Siemens September 2006)

Head of Global Clinical Trials and Biostatistics: reporting to Sr. VP of Research & Development.

- Responsibility for the Bayer/Siemens clinical programmes in the fields of molecular diagnostics, immunoassays, chemistry, urinalysis and blood gas.
- Global registration trials including Class II and III *in vitro* diagnostics in the US and IVDD Annex II and III in Europe.
- Completed trials and registrations for 20-35 products per year.

March 2003 – July 2004 Bayer Healthcare, Nucleic Acid Diagnostics, Berkeley CA

Director, Regulatory and Clinical Affairs: reporting to the Senior VP of Quality, Regulatory, Medical Affairs, Health and Safety, Government Affairs and Reimbursement

- Head of the regulatory and clinical group for Bayer Nucleic Acid Diagnostics
- Represented regulatory affairs on multi-disciplinary project teams.
- Functional interface for regulatory affairs managers in all other Rest of World regions
- Member of the NAD Business segment strategic management team and product portfolio management team

- Successful registration of Class III (US) and IVDD Annex II (EU) molecular diagnostic infectious disease assays and systems.

September 2000 – March 2003 Visible Genetics UK Ltd, High Wycombe U.K. (acquired by Bayer in 2002)

Senior Director, Regulatory Affairs and Clinical Research: reporting to the President of VG Europe

- Registration of Annex II List A products and post market compliance.

March 1998 - September 2000 Visible Genetics, Toronto, Ontario, CANADA

Senior Director, Regulatory Affairs and Clinical Research reporting to the CEO

- First product approval for the company from the US FDA.
- Coordinated the clinical and regulatory strategy and project managed research & development, manufacturing and customer training / product support to complete the FDA submission in 21 months.
- Created the clinical research and regulatory affairs departments for the company.
- Implemented quality system in compliance with ISO 13485 in the European organisation, required for European registration of the Annex II List A *In Vitro* diagnostic devices.

September 1995- March 1998 Guilford Pharmaceutical, Baltimore MD, USA

Associate Director, Clinical Research and Business development and Project Team Leader reporting to the Medical Director and Vice President of Clinical Research, and the Vice President of Business Development, who both reported to the President and CEO.

- Project leader for an ^{123}I based radiopharmaceutical agent for imaging dopamine transporters. Lead regulatory authority communications and coordinated outsourcing of manufacture. Progressed to post Phase II.
- Wrote the business development plan for product partnering. 2 large multi-national pharmaceutical companies submitted offers.

1992-1995 Amersham International plc, Amersham, Bucks UK

Worldwide Neurology Business Manager reporting to the Medical Marketing Director, Imaging.

1989-1992 IRE- Medgenix- Nordion S.A., Fleurus, Belgium

Director, Research and Development reporting to the Chief Scientific Officer

1987-1988 Royal Liverpool Hospital, Liverpool, UK.

Senior Radiopharmaceutical Scientist, Dpt of Nuclear Medicine.

1985-1987 Leicester Royal Infirmary, Leicester, Leics, UK

Radiopharmaceutical Scientist, Dpt of Nuclear Medicine

LANGUAGES : EnglishFrench.

QUALIFICATIONS

Ph.D Loughborough University of Technology, Loughborough, Leics. UK Thesis title: Chemical and Radiopharmaceutical studies of Technetium containing Complexes.
B.Sc London University (First Class Honours) in Chemistry and Graduate Certificate of Education

Gillian Morgan
gillianmorgan@hotmail.com Telephone (mobile) +44 7794 265 473