Bryan Allman

A clinical biochemist with senior management experience in the medical device and diagnostics industries—both major international companies and start-ups. A recognised expert in medical device regulations who represented Europe in the Global Harmonization Task Force, led several trade association working groups, and chaired the Medical Technology Steering Group of TOPRA. An experienced and flexible leader who delights in new challenges and who has specific expertise with companion diagnostics, mobile device apps, and drug-device combination products.

PERSONAL DETAILS

Nationality:BritishLanguages:English, conversational German, basic FrenchPhone:+44 7917 404214E-Mail:bryanallman@me.com

ACADEMIC QUALIFICATIONS

BSc (Hons) Medical Biochemistry University of Surrey

MSc, Clinical Biochemistry University of Surrey PhD (Thesis: Fluoroimmunoassay of Steroid Hormones) St Mary's Hospital Medical School, University of London

Awarded Edgar Lawley scholarship to fund research in Florence, Italy.

CAREER SUMMARY

• Senior functional management experience with Abbott Laboratories and Boston Scientific; responsible for UK commercial operations at Boston Scientific (sales growth to £100mio).

• Broad international experience with long-term assignments in Belgium, France, Germany, Italy, and the US, plus multiple short-term assignments in Japan.

• High-level, strategic, functional expertise in Regulatory Affairs, Quality Assurance and Clinical Trials; broad industry experience including technology / product development, programme management, customer service, marketing, and commercial operations.

• Extensive experience in planning the strategic response to complex regulatory changes arising from changing regulations or new product types and in developing the organisational capability to address those challenges.

• Experience with a broad range of medical device types including IVD systems, drug-device combinations, companion diagnostics, and software.

• Implemented Quality Management Systems (ISO 9000 / 13485) in multiple organisations.

• Heavily involved in the development of European regulations, GHTF / European guidance documents for IVDs and medical devices.

• Expert witness in relation to compliance to European regulatory requirements in a major Australian class action case involving surgical mesh implants; my evidence focused on technical documentation, clinical studies and risk management.

• Course Director, and External Examiner, at Cranfield University (MSc Regulatory Affairs) and lecturer on other courses at Cranfield and Imperial College (London).

EMPLOYMENT HISTORY

Independent Consultant

Aug. 2016– Present: Primarily Regulatory projects: acting as an Expert Witness in the Federal High Court of Australia in a case involving mesh implants, and an interim role as European head of Regulatory Affairs for BD based in Switzerland.

GSK Vaccines, Rixensart, Belgium and London, UK

Sep. 2011 – July 2016: Director, Global Regulatory, Diagnostics Responsible for the regulatory aspects of the companion diagnostics programme at GSK Vaccines and supported other GSK medical device projects (e.g. mobile device apps).

Cranfield University, UK

Sep. 2012 – Present: External Examiner for the MSc in Medical Technology Regulatory Affairs Nov. 2007 – Jan. 2009: Course Director (part-time) for the MSc in Medical Technology Regulatory Affairs.

Independent Consultant

Jan. 2007 – Sep 2011: Regulatory, Quality Assurance, and strategic Clinical projects with medical device / IVD companies—including qPCR based companion diagnostics.

KIKA Medical, Nancy France and Boston USA

Sep. 2005 - Dec. 2006: Vice-President QA, Regulatory Affairs & Operations

Sorin Biomedica, Saluggia, Italy

Jan. 2005 - Jun. 2005: Vice President Regulatory, Cardiac Surgery

Boston Scientific Corporation, European Headquarters, Paris, France

Feb. 2004 – Dec. 2004: Vice President QA and Regulatory Affairs

Jun. 1998 – Jan. 2004: Vice President QA, Clinical & Regulatory Affairs Europe

Abbott Laboratories, Diagnostics Division European Area, Wiesbaden, Germany

Sep. 1995 - Jun. 1998: Director European Area Quality & Regulatory Affairs Oct. 1993 - Aug. 1995: Manager Quality & External Affairs Sep. 1992 - Sep. 1993: Manager, Scientific & Technical Affairs, Europe Feb. 1992 - Aug. 1992: Manager, European Regulatory Futures

Abbott Laboratories, Diagnostics Division, Chicago, USA

Feb. 1991 - Feb. 1992: Manager, European Regulatory Affairs

Abbott Laboratories, Diagnostics Division European Area, Wiesbaden, Germany Jun. 1989 - Feb. 1991: Manager, Scientific & Regulatory Affairs, Europe

Serono Diagnostics, Woking, UK

Dec. 1987 - Jun. 1989: Manager, Clinical Trials *Jan. 1986 - Nov. 1987:* Technical Centre Manager (technical support to Marketing) *Aug. 1984 - Dec. 1985:* Project Leader Research and Development (product development)

Amersham International, Amersham, UK

Apr. 1983 - Aug. 1984: Development Scientist (technology and product development)

St Mary's Hospital, London, UK / Oldchurch Hospital, Romford, UK

Jan. 1982 - *Apr.* 1983: Senior Biochemist; part 2 MRCPath training *Jul.* 1978 - *Dec.* 1981: Basic Grade Biochemist (post-probationary); part 2 MRCPath training *Sep.* 1976 - *Jun.* 1978: Basic Grade Biochemist (probationary); part 1 MRCPath training