Bryan Allman

A clinical biochemist with senior management experience in the medical device and *IVD* medical device 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. Specific expertise with implantable devices, drug-device combination devices, companion diagnostics, and mobile device apps.

PERSONAL DETAILS

Nationality: British

Languages: English, conversational German, basic French

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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, implantables, drug-device combinations, companion diagnostics, and software including mobile device apps.
- Implemented Quality Management Systems (ISO 9000 / 13485) in multiple organisations and countries.
- Heavily involved (though trade associations) in the development of the European medical device directives and the associated guidance.
- Represented European industry in the Global Harmonisation Task Force (GHTF) at both the Work Group and Steering Committee Levels. The GHTF worked to harmonise global regulatory requirements for medical devices.
- 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 with medical device / IVD companies and

expert witness work.

GSK Vaccines, Rixensart, Belgium and London, UK

Sep. 2011 - July 2016: Director, Global Regulatory, Diagnostics

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