

David Harrison



Extensive domestic and international leadership in medical device and diagnostics Regulatory Affairs and Quality Systems, leveraging experience in Strategic Planning, Project Management, Sales, Service, and HES (Health, Environment and Safety).

Strong Asian business experience, supported by exceptional communication skills, science, business and technical qualifications.

Qualifications

*B. Applied Science
Dip. Bus. (Marketing)
Grad Cert in QA*

As a medical device and invitro diagnostics Consultant for selected clients, David provides advice on effective regulatory and quality strategies to support the life cycle of products and services for Australia and export activities to International markets.

Business Profile

David has broad expertise in regulatory affairs in Asia and Japan. Additionally he has leadership in introducing and expanding the effectiveness of quality systems, including effective delivery of change. This provides clients with regulatory solutions and the processes to ensure robust business practices. His combination of project and line management coupled with effective communications facilitates delivery of outcomes.

He has worked at all levels of business; in small Australian-based companies through to multinationals. He has extensive experience of regulatory and quality leadership in mergers and acquisitions.

Professional Experience

David has more than 25 years experience in the medical device and *in vitro* diagnostics industry.

Until 2009 he was Asia Pacific and Japan Director of Regulatory Affairs and Quality Systems for Siemens Healthcare Diagnostics, working extensively in China, and across key Asian markets. From 2006 – 2009 most of his time has been spent in merger and acquisition activities across this region, addressing complex regulatory and quality issues. This role has required strong interaction and negotiation with government agencies across Asia.

Prior to this, David resided in Japan, working for Bayer Medical Ltd supervising change management to meet a complex new regulatory environment. Earlier, David was responsible for Quality Systems and HES for Bayer in all Latin America. Before this appointment he was working in Australia in marketing management for Chiron Corporation and Bayer Australia Ltd, utilizing project based strategic management.

His professional roles have included participation in the Asian working groups of AdvaMed, the umbrella group for US medical device manufacturers and EDMA, the European equivalent. He is a member of Ausbiotech and the Australian Organization for Quality.