

Graham Higson, BSc, MsSc

CURRICULUM VITAE

Professional experience

Current position

- Member, NDA Advisory Board 2012 –
- Managing Director, NDA Advisory Services Ltd., 2012 -

Previous positions

- 2010 - 2011, Global Head, Worldwide Regulatory Affairs, GE Healthcare, UK
- 2006 – 2010, VP and Global Head, Worldwide Regulatory Affairs, AstraZeneca, UK
- 2003 – 2006, VP, Worldwide Regulatory Affairs and QA, Pfizer Global R&D, UK
- 2000 – 2003, VP, Regulatory Strategy, Policy and Registration, Pfizer Global R&D, USA
- 1995 – 2000, Director, Regulatory Strategy and Submissions, Pfizer Central Research, UK
- 1991 – 1995, Senior Director, Regulatory Affairs and QA, Gensia Europe Ltd., UK
- <1991: Head of Regulatory Affairs, Sandoz UK; Senior Scientist, Ciba-Geigy Pharmaceuticals, UK; Senior Scientist, Travenol European R&D Centre, Belgium; International Registration Co-ordinator, Synthelabo, France; Scientific Officer, Travenol, UK and Belgium.

Areas of Expertise

Regulatory

- Global strategic regulatory input to development
- Global submissions and approvals
- Scientific Advice
- Health authority interactions
- Trade association interactions

Non-Regulatory

- Leading global regulatory functions
- Corporate Governance and Oversight
- Drug Development Governance
- Integration and merger activities

Major projects

- EFPIA (Scientific, Technical and Regulatory Policy Committee)
- PhRMA (Regulatory Affairs Co-ordinating Committee; Japan Technical Committee)
- EFPIA (Future Medicines Legislation Priority Action Team)
- PhRMA (International Regulatory Affairs Committee)
- PhRMA (Co-chair of European Registration Team)
- EFPIA (member of Regulation 2000 Priority Action Team; member of Regulatory Affairs Ad-hoc Group; member of EFPIA/EMA Project Management Group).
- Board member, AstraZeneca Pension Trustees Ltd
- Chair, AstraZeneca UK Compensation and Benefits Committee

Associations

- Member of Society of Biology
- Chartered Biologist
- Fellow of The Organization for Professionals in Regulatory Affairs
- Member of CMR International Regulations Advisory Board
- Member of TOPRA Advisory Council

Publications