



# Dave Gilbert, BSc (Hons)

## CURRICULUM VITAE

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### Professional experience

#### Current position

- NDA Advisory Board Member

#### Previous positions

- 2002-2003, VP and Head of Regulatory Affairs, Europe, Pharmacia, UK
- 1995-2002, Head of EMEA Liaison and Regulatory Intelligence, Novartis, Switzerland
- 1998-2002, Director, Novartis Europharm Limited
- 1994-1995, TA Head Dermatology, Sandoz, CH
- <1994: Registration Manager (Sandoz), Deputy Head of Regulatory Affairs (Napp Laboratories), Head of Pharmacology and Biochemistry (Smith & Nephew Research), Experimental Biology (Glaxo).

### Area of Expertise

#### Regulatory

- EU strategic regulatory input to development
- EU submissions and approvals
- Scientific Advice
- Orphan Drugs
- Oral explanations at EMA
- Health authority interactions
- Trade association interactions

#### Non-Regulatory

- Re-engineering regulatory processes and departments
- Integration and merger activities
- Balanced Scorecard
- Team Facilitation

## **Major projects**

- 12 Centralised NCEs. Mutual Recognition, Referrals, Arbitrations.
- Former chairman of the EFPIA Regulation 2000 Priority Action Team.
- Former member of EFPIA Trade Mark ad hoc group
- Former member of EFPIA Pharmacovigilance ad hoc group
- Former member of EFPIA Transparency ad hoc group.
- Leader of global regulatory integration team during Sandoz/Ciba merger.
- Regular presenter and session organiser for DIA and TOPRA
- Recipient of DIA Outstanding Service Award

## **Associations**

- TOPRA
- DIA

## **Publications**

Numerous publications and presentations on Centralised Procedure, MR procedure, Pharmacovigilance, Regulatory reform, Variations, Regulatory Strategies. The complete list can be provided upon request.