

## BIOGRAPHY

### **MICHAEL H. ANISFELD**

Michael H. Anisfeld is a senior consultant for Globepharm Consulting specializing in GMP/Quality activities for the healthcare manufacturing industries. In his current position he numbers among his clients United Nations Agencies (WHO, UNFPA, UNIDO), national regulatory agencies (including the US-FDA, Australian TGA) and over 260 pharmaceutical, medical device, biotechnology and bulk pharmaceutical companies in the Americas, Africa, Europe and Asia.

Mr. Anisfeld has established and directed quality control, quality assurance, production, research and development administration, materials management and supply chain functions in the industry, and has instituted innovative, cost-effective auditing programs for his clients, ensuring they pass regulatory inspections first time.

Performing over 25 full scale mock inspections annually (to United States FDA, British MHRA, Canadian HPFBI, Australian TGA, and ISO 9000 standards), including audits whose reports are evaluated directly by national regulatory agencies as part of product approval, Mr. Anisfeld has served on both sides of the fence: Inspector and Inspectee!

With over forty years expertise in the healthcare industry, he has held senior management positions in International Technology Transfer, Quality Assurance and Production and in the course of his career, he has designed pharmaceutical, medical device and active pharmaceutical ingredient (API) facilities in seven countries. A member of the adjunct faculty of the University of Illinois, where he lectures in Pharmaceutical Technology and Drug Quality issues, Mr. Anisfeld holds higher degrees in Pharmaceutical Technology (M.Sc.), Business Administration (MBA), Management (MSM) and holds a Diploma in Middle Eastern Studies (DMES).

An active member of many European and American regulatory and technical associations, he has served on the Board of Directors of the Parenteral Drug Association, and been Chairman of its Quality Control and Aseptic Processing Task Groups. An acclaimed international lecturer on the subject of GMP and Quality topics, Mr. Anisfeld is also a prolific author on these topics. He is the editor/author of many books on the subject including: "International Drug GMPs", "International Device GMPs", "Keyword Guide to 21CFR", "Guide to FDA International Inspections", "Sterile Pharmaceutical Manufacturing", and PDA's monograph "Validation of Aseptic Processing of Liquid Drug Products", and "International Comparative Pharmacopoeia". He is currently Vice President of the Industrial Pharmacy Section of the International Pharmaceutical Federation (FIP).

He consults with companies, professional associations, international organizations and governments worldwide on all matters pertaining to Good Manufacturing Practices (GMP), Good Warehousing/Distribution Practices (GWDP) and Quality Assurance Systems in the pharmaceutical and medical device supply chain. He provides "expert witness" testimony in court cases involving the implementation and interpretation of pharmaceutical GMPs and medical device QSRs; and for several years has donated four weeks a year pro-bono working with government agencies and professional associations in lesser developed nations to improve drug quality in those countries (including Cuba, Ghana, Kenya, Mongolia, Nigeria, and Sri Lanka).

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