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, national regulatory agencies (including the US-FDA, Australian TGA) and over 60 pharmaceutical, medical device, biotechnology and bulk pharmaceutical companies in North America, Europe and Asia.

Mr. Anisfeld has established and directed quality control, quality assurance, production, research and development administration, and materials management 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 MCA, Canadian HPB, 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 twenty five 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 bulk pharmaceutical chemical facilities in four countries. A member of the faculty of the University of Illinois, where he lectures in Pharmaceutical Technology, Mr. Anisfeld holds higher degrees in Pharmaceutical Technology (M.Sc.), Business Administration (MBA), and 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 a regular lecturer to companies, professional associations, organizations and governments worldwide on all matters pertaining to Good Manufacturing Practices and Quality Assurance Systems in pharmaceutical and medical device manufacture. Additionally he provides “expert witness” testimony in court cases involving the implementation and interpretation of pharmaceutical GMPs and medical device QSRs.

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