Mitch Cheeseman, PhD
Managing Director, Regulatory & Industry Affairs Department at Steptoe & Johnson LLP

With more than 20 years of experience at the US Food and Drug Administration, Dr. Cheeseman assists manufacturers in achieving and documenting regulatory compliance for products regulated by FDA and EPA. He provides the same assistance to clients marketing such products in the European Union (EU), China, South America, and Asia. Dr. Cheeseman has experience assisting manufacturers with issues regarding both premarket approval and compliance issues as well as postmarket issues including compliance with the Food Safety Modernization Act (FSMA) and implementing regulations. He provides strategic advice in support of product research and development to optimize return on investment with respect to regulatory requirements and market entry.

During his time at FDA, Dr. Cheeseman led FDA's food ingredient and packaging programs and held primary responsibility for the regulation of direct food additives and food contact substances, color additives, Generally Recognized as Safe (GRAS) food ingredients, and bioengineered food. He served as primary contact for advice on regulatory science and policy to all other FDA product centers in areas where FDA's Office of Food Additive Safety had primary or overlapping regulatory responsibility and where FDA/OFAS had specialized expertise in regulatory science. As such, he worked closely with scientists and policymakers in FDA's medical device and drug programs as well as in the Center for Veterinary Medicine and the Center for Tobacco Products. Mitch also provided guidance and negotiated policy on significant issues (e.g. the regulation of colors in medical devices, the safety of plastic materials used in the manufacturing and packaging of medical devices and drugs, regulatory policy on nanotechnology), and the safety of certain substances (e.g. Bisphenol A and phthalates), which cut across multiple product areas.

Mitch has participated in many international meetings, workshops, and working groups speaking on the use of probabilistic risk assessment in the regulation of chemicals and the Threshold of Toxicological Concern (TTC). His work regarding structural alerts for carcinogenicity is the primary basis for the cancer thresholds in the existing TTC approach applied to the regulation of food flavors by the FAO/WHO Joint Expert Committee on Food Additives and by FDA to the regulation of food contact materials. His work is the basis for the current regulatory standards for genotoxic impurities in pharmaceuticals which have been adopted by the European Medical Products Agency (EMEA) and the US Food and Drug Administration Center for Drug Evaluation and Research.