

**AusMedtech2009**

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**Australia's Medical Technology National Conference**

15 and 16 June

Sheraton on the Park, 161 Elizabeth Street on Hyde Park, Sydney

[www.ausmedtech2009.com.au](http://www.ausmedtech2009.com.au)



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Mike Heyl's practice is primarily in the medical device area with an emphasis on post-market enforcement matters. He focuses extensively on post-market compliance issues, including the Food and Drug Administration (FDA)'s Quality System Regulation (QSR), adverse event reporting, and field action requirements. His experience includes assisting in the defense of criminal investigations by the U.S. Department of Justice, responding to FDA

Warning Letters and Form 483s, conducting internal investigations of alleged violations of federal regulations and corporate codes of business conduct, reviewing and drafting standard operating procedures, assisting clients with import and export issues, conducting regulatory due diligence and assistance with negotiation of corporate mergers and acquisitions and initial public offerings, creating and implementing corrective action plans, and providing general advice on a variety of device-related regulatory issues.

Mike also is a frequent speaker at medical device seminars and conferences.

Prior to joining Hogan & Hartson, Mike served as Senior Manager of Government Relations for the Synthetic Organic Chemical Manufacturers Association (SOCMA). In this capacity, he represented and advocated the interests of batch and specialty chemical producers before U.S. Congress and numerous administrative agencies. Before joining SOCMA, Michael provided business accounting services to a small health care trade association. He has also been involved with numerous political campaigns, including serving on the advance team of a presidential campaign in 1996.