

Creating Global Solutions



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AUSBIOTECH 2010 NATIONAL CONFERENCE SPEAKERS' PROFILE

Michele Yelmene **Regulatory Affairs & Quality Assurance – Advisor to Industry** **California, United States**

Ms. Yelmene has over 25 years of operational and project management, clinical and scientific research and regulatory affairs experience in the biotechnology and pharmaceutical industries. Prior to consulting for industry, she held executive positions at numerous biotech and pharmaceutical organizations. During her career, Ms. Yelmene has been responsible for clinical development, preparation, and presentation of 14 FDA-approved products and over 30 investigational new drug applications (INDs) for both pharmaceutical and biologics-based therapies in the areas of viral infections, respiratory, CNS, metabolic and endocrine diseases, vaccines, and lysosomal storage disorders. She has participated in meetings with the FDA at all phases (pre-IND through Advisory Committee) of clinical development. Ms. Yelmene is a member of the Regulatory Affairs Professional Society, Drug Information Association and Co-Chair of the FDA Committee at BIOCOM in San Diego. She received undergraduate degrees from Rider University.

