

# Joint International Conference and Expo on Industrial Pharmacy & 5<sup>th</sup> Global Pharmacovigilance Summit

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## Combination Products – The Paradigm shift

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Combination products present a unique challenge globally for industry and the regulators regardless if you consider pharmaceuticals or biologics, devices or diagnostics. As the US and Japan have expressed their views in the form of draft guidance and regulations, organizations are working towards a streamlined process that best meets their needs. Combination products present challenges that need to be evaluated to better prepare for the future and to demonstrate an organization's compliance. Let us consider how to develop integrated cGMP and Regulatory Strategies for combination products. With two or more components; two Quality Systems; two or more databases; one or more Postmarketing Safety Report(s) what Is an Organization to do? How does the organization set up the right culture? Some best practices to consider. Risk based safety assessments may be a solution.

## Biography

Khaudeja is a Physician with a Masters in Clinical Research (UCSD), Pharmaceutical engineering Certification, an Oracle DBA, and a certified Project Management Professional. She is an Abbott President's award winner, avid Toastmaster and certified coach. Khaudeja has more than 25 years professional experience, including clinical practice. She has held several global safety positions at Abbott Vascular, Abbott Diagnostics, Abbott Established Pharma Division and now AbbVie Inc. Her career in safety includes global leadership roles in devices, diagnostics, pharmaceuticals and combination products.

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