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Navigating The Quicksand Of Device/Drug Combo Products

Join former FDA Investigations Branch Director Ricki Chase – now with Lachman Consultants – as she draws on her 16 years of agency experience to bring you the latest insights into the complexity surrounding combination device/drug products.

February 12: PART 1

In this first podcast, Ricki will define combination products, and review related regulations and guidance documents. She will highlight the varying types of combo products, definitions unique to device design, and how combo product manufacturers differ from the typical medical device or drug firm. Also: Risk management concepts will be introduced.

February 19: PART 2

Next, Ricki will delve into unique medical device concepts, including human factors studies, biocompatibility issues and design changes. She'll also point out pre-market and post-market pitfalls to avoid, and some strategies for successful combo product compliance.