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Challenges of cGMP implementation at different CMO's - Role of quality agreements

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Current GMP requirements for pharmaceutical development and IMP manufacturing are not always the same as those for marketed pharmaceutical products. ADRES is working with dozens of startup companies from the Biotech industry; most of these small companies outsource the entire manufacturing process to Contract Manufacturing Organizations (CMOs). Sometimes the different CMOs have different interpretation of the cGMP requirement and they are not always appropriate to the clinical phase that the company is in. In these cases, the Quality agreement has a crucial role in clearly assigning the responsibilities between the parties and discussing various critical issues like: notification on deviations, client involvement in Investigations etc.

This presentation will briefly discuss cGMP compliance requirements in the different development and clinical phases include various examples of CMO requirements and will demonstrate how a Quality agreement can prevent disagreements between the parties that could lead to loss of time and money.

Biography

Rivka Zaibel is an expert regulatory, quality and project management consultant primarily to the biotech and medical device industry. Rivka Zaibel worked for 21 years in Bio-Technology General (Israel) Ltd and served as the Vice President of Regulatory Affairs and Quality Assurance and now Ms. Zaibel is the owner and CEO of ADRES, Advanced Regulatory Services Ltd., Israel established on 2009. Ms. Zaibel has extensive experience in worldwide registration of medical devices, recombinant products and vaccines; quality systems; GMP and quality assurance; clinical and toxicological issues; development of biotechnology-based products and medical devices; project management; lean systems.

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