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A blueprint for outsourcing audits of approved GxP validations

A retrospective review of an approved GxP pharmaceutical validation carries unique risks, and often requires the assistance of outside subject matter experts experienced in this work. Approved GxP validations may have been already been submitted to health authorities, may have been used to support the approval of GxP data, or may have supported the release of GMP product to the market. If you must audit an approved GxP validation, and need outside auditing consultants, you should have a documented plan that specifies: (1) what is to be audited, why audit, and the risks of auditing; (2) who will do what (3rd party auditor/client); (3) selecting the auditors and documenting their qualifications; (4) how and where the audit will be executed, and the timeline; (5) how gaps will be documented, categorized, and reported; (6) how conflicts will be handled; (7) the plan may also include how confirmed gaps will be remediated. This practical blueprint steps through who, what, when, where, why, and how of using a third party for auditing approved GxP pharmaceutical validations.

Biography

Michael D Spangler has founded Spangler Consulting LLC in 2009. His clients engage him for assessments and remediations of quality systems and QMS programs, as well as for his CMC and analytical development expertise. He has direct clients, and also provides his services through larger consulting firms like The Quantic Group and QSC. His consulting value draws from his 25 years of pharmaceutical industry experience in analytical development, as a Senior Principal Scientist, CMC Author, People Manager, Project Team Leader, and as a participant in a Consent Decree Remediation. He is well published, presents regularly, and has invented several novel testing techniques. He holds a BS Degree in Chemistry and MS Degree in Industrial Pharmacy.

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