

Compliance Case Study #6 Process Validation Failure—Liquid Product Batch Size Increase

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A case study involving a batch size increase for a liquid solution product is described. The batch size increase was considered to be a relatively simple change because other similar products at the site were already manufactured at the same increased batch size and the equipment to be used was “identical” to other site equipment. Manufacturing was started and the formulation ingredients did not dissolve in the product solution—The validation performance qualification was a failure. Mixing in the tank was not sufficiently rigorous. The supposedly identical tank did not have the same...

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