

Case Study #3—Process Validation Failure of a Liquid Product Batch Size Increase—“Identical” Manufacturing Tanks

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A case study involving process validation of 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 thought to be identical to other site equipment. Manufacturing was started and the formulation ingredients did not dissolve in the product solution. The validation performance qualification (PQ) was a failure. Mixing in the tank was not sufficiently rigorous to dissolve the...

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