

## Validation Sampling Plans



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A recurrent challenge in process validation is how to set up a sampling plan to collect enough data to determine the outcome of the validation without necessarily measuring every part produced or looking at all the process data. These sampling plans have to be able to be justified statistically, as they will be examined by regulatory authorities, both during initial submissions, on site audits, and potential changes to the process and revalidation. What is Sampling Sampling is the ability to make a quality determination on a large number of things without direct examination of each thing...

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