Title:	General Guidance for Process Validation Sampling				
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General Guidance for Process Validation Sampling

Introduction
This guidance addresses recommendations for good sampling practices. Validation sampling plans must be specified or referenced in the protocol.

The purpose of this guidance is to provide guidance on the cGMP requirements for validation sampling. Successful validation is dependent on the proper selection, identification, handling, storage and tracking of test samples. Missed or lost samples can result in the need to repeat a portion of, or the entire, validation study. In order to avoid these types of problems and to ensure data integrity, a number of considerations are listed.

Recommendations and Rationale for Recommendations
cGMP Requirements for Sampling:

The GMPs mention samples, sampling plans, or sampling procedures or methods repeatedly and the main themes that occur throughout these references are as follows:

a) **Sampling Plans**: Sampling plans and methods shall be predetermined and documented (for example, in a SOP or validation protocol). Sites should be able to provide scientifically sound rationale for the sampling and testing plan. The sampling plan should identify (where appropriate):

- Sampling rationale and acceptance criteria.
- Sample locations, sample size, sample frequency, and types of samplers to be used.
- The tests or evaluations/assessments required and how the data should be analyzed.
- Those qualified parties responsible for taking samples.
- Appropriate container/closure systems to be used, consider the amount of allowable headspace.
- Specific instructions for sampling.
- Any special precautions to be observed, especially with regards to: − Sterile products.
  − Hazardous materials.

