

# G(QC)LP

6

## Sampling Plans

This module reviews the theory and application of statistical and practical sampling plans, as well as some related special problems associated with active or inactive “chemicals”, printed or unprinted packaging, in-process materials, process water and finished product.

### Objectives:

- Describe considerations for setting up sampling plans
- Read and interpret an attribute sampling plan
- List special cGMP requirements for sampling chemicals, printed matter and components
- State the cGMP expectations for sample protection and pooling
- Set up targetted sampling plans for a purified/WFI water system

# Course Outline

## INTRODUCTION

- o Introduction
- o Purpose of sampling
- o Sampling requirements
- o Sampling steps
- o Sampling plans
- o Review

## READING ATTRIBUTE SAMPLING PLANS

- o Introduction
- o Defining an attribute
- o AQL I
- o AQL II
- o Parameters I
- o Parameters II
- o Parameters III
- o Reading plans I
- o Reading plans II
- o Reading plans III
- o Try some sampling plans
- o Review

## CGMP REQUIREMENTS FOR CHEMICALS

- o Introduction
- o Chemicals requirements
- o Supplier qualification
- o Chemical testing plans
- o Microbial testing plans
- o Review

## CGMP REQUIREMENTS FOR PRINTED MATTER

- o Printed matter requirements
- o Review

## SAMPLING TECHNIQUES AND POOLING

- o Introduction
- o Content uniformity
- o Liquids sampling issues
- o Pooling/compositing rules
- o Sampling frequency
- o Zero Acceptance Number
- o Review

## TARGETED SAMPLING PLANS

- o Introduction
- o Limitations
- o Targeted sampling
- o Water samples
- o Sampling points
- o Review

## CONCLUSION

- o Summary