

How To Use This Kit

Each subject of the Survival Kit is comprised of nine (9) training sections: (1) Reason for training; (2) Introduction; (3) The Regulation; (4) Discussion; (5) Activity; (6) Presentation; (7) Closing Activity; (8) Summary; (9) Excerpted 483 Citations.

A brief description of the training sections is described below. This section format lends assistance to the trainer as they utilize the kit to their best advantage and attain the desired training result.

(1) Reason for Training

This section is provided for the trainer to specifically inform the class of the reason their attendance is required.

For example: "...execution of the site training plan" or, "...as mandated by the corporate offices".

Experience has shown that students are more apt to become involved and focus their attention if they understand "why" they are in the room.

(2) The Introduction

This is the initial opportunity for the trainer to remark about the training topic and to provide a common informational background for all students.

(3) The Regulation

Relevant sections of the Code of Federal Regulations are referenced in support of the training topic. The training presentation will be more effective when students are able to relate the need for compliance to the specific regulatory requirement.

(4) Discussion

The questions in this section are designed to engage the group and define the immediacy of the GMP issue at hand. This discussion helps the group to parallel their real life and work situations to the compliance topic and whets their interest in the subject.

(5) Activity

The opening activity is an excellent subject “set up” designed to foster student attention and support of the subject. Utilizing this tool will establish the validity of the subject as it relates to employee responsibility for Good Manufacturing Practice compliance.

(6) Presentation

This is the actual core of the compliance message with its content designed in a logically sequenced format. Trainers should strive to embellish core information by drawing upon their subject matter knowledge and sharing their compliance experiences. Introducing real-life information stimulates student interest and learning.

(7) Closing Activity

The message derived from the use of this activity at the close of the session serves to link all subject learning points. This activity is the catalyst that stimulates awareness of the impact of individual behaviors on GMP compliance.

(8) Summary

This is the opportunity for the trainer to summarize the key learning points of the training session and reiterate their importance in support of Good Manufacturing Practice compliance.

(9) Excerpted 483 Citations

This section contains information obtained from actual FDA 483 citations. The content depicts examples of the ramifications of failure to follow the GMP regulations and its applied penalties.

Discussion of these citations refocuses the group’s attention causing them to reconsider the impact of their work performance on regulatory compliance.