The DIRTY DOZEN

IN HEALTHCARE QUALITY

STUDY BOOKLET

KEY2COMPLIANCE®
Compliance Training Network

EN1711 130805b

The DIRTY DOZEN
IN HEALTHCARE QUALITY

STUDY BOOKLET

Inspiration and instruction for 12 short training sessions on quality and GMP (Good Manufacturing Practice) which helps the organization to create and renew its commitment to quality work and GMP.

1. Lack of Communication
2. Complacency
3. Lack of knowledge
4. Distraction
5. Lack of teamwork
6. Fatigue
7. Lack of resources
8. Pressure
9. Lack of assertiveness
10. Stress
11. Lack of awareness
12. Norms

Centerfold: Form for training documentation.
Can also be downloaded from our web site (pdf):
www.key2compliance.com/en1710.htm

Introduction

This study booklet is meant to be used together with the twelve ”The Dirty Dozen in Healthcare Quality” posters. The concept originates from the aerospace industry in Canada where Gordon Dupont developed the model in 1993 when he worked for Transport Canada. The idea of the model was to highlight a number of key factors underlying the so-called ”human factor” : there is usually something that causes the human errors we make and one needs to understand them in order to prevent and minimize errors.

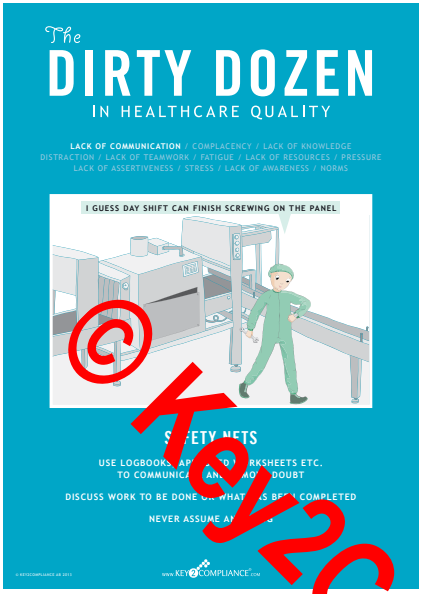
We have used the original model but have customized the content and examples to the general principles for quality used in the pharmaceutical and medical device manufacturing industries. We believe that both the posters and this study booklet can be used to recall and discuss the importance of quality and how to reduce the risk of errors. This, in turn, contributes to higher quality, more efficient production, and lower costs for troubleshooting, rejection or rework.

The posters can be placed at appropriate locations in the operation, break rooms, locker rooms, corridors etc. Then use this study booklet for arranging short discussion sessions (30-60 min). It may be appropriate to discuss one topic at a time. Some topics may be more or less appropriate depending on what work functions the group have, so it is up to the instructor to decide.

Note that the concept is based on understanding and identifying the factors underlying our errors. Quality requirements, GMP and your own quality procedures obviously works as built-in safety nets to prevent errors. In connection with these exercises, it is appropriate to discuss the procedures, rules or instructions already in place that are applicable in each area.

The form at the back of the booklet can be used as a supplement to your own sign-off lists for the training and provide documented evidence of both the training effort and the preventive quality work.

Good Luck!



Session 1

About communication

Communication [kəˌmjuːnɪˈkeɪʃn]

The exchange of thoughts, messages, or information, as by speech, signals, writing, or behaviour.

Discuss

- How is our communication working? Have we encountered incidents or deviations due to lack of communication?
- Discuss unconditionally and do not be too quick to judge or find scapegoats. The key is to identify areas where it can go wrong.

Write down

The procedures and documents we have describing how and where we communicate.

To improve

Write down a couple of suggestions on how to improve and reduce the risk of misunderstanding and lack of communication!