Leader's Guide

Batch Record Review Overview Training

Please print and read this document prior to class. It informs you how to produce the other documents and components of this program.

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Leader's Guide: Batch Record Review Overview Training

Table of Contents

Program Information

Program Title:

Batch Record Review Overview Training

Program Description:

The primary purpose of this program is to provide an overview of the batch record review process.

Program Objectives:

At the end of this program participants will be able to:

1. Explain general information regarding the batch record and the review process.
2. Explain what the regulations say about batch record review.
3. Identify good documentation practices with regard to batch record review.
4. Identify the contents of a typical batch record.
5. Explain the processes of Issue Resolution, Final Review and Disposition.

Intended Audience:

All company employees.

Recommended Audience Size:

15 to 20 participants

Training Frequency:

Deliver to new employees and/or employees with investigation responsibilities.

Estimated Presentation Time:

2.0 hours (Includes time for presentation, questions and answers, and assessment)

Estimated Preparation Time:

1 hour

Presentation Materials:

- PowerPoint slide deck: Batch Record Review Overview Training
- Knowledge Assessment
- Knowledge Assessment Answer Key
- Training Sign-in Sheet (not provided in Leader's Guide)

Presentation Equipment:

- Slide projector
- Computer
- Screen
- Pens/pencils for participants
- Flip chart/markers

- Room to accommodate 15-20 people

Presentation Format:

- PowerPoint presentation
- Large group discussion

Assessment Requirements:

☐ Knowledge Assessment

☐ Knowledge Assessment Answer Key

☐ 80% completion for passing grade

Program Implementation

Program Preparation

Prepare the Materials

In addition to this Leader's Guide, there are three pieces to be developed for this program:

1. Slide handouts
2. Knowledge Assessment
3. Knowledge Assessment Answer Key

To produce the Slide handouts:

1. Open the PowerPoint file.
2. Go to *File*, then *Print*.
3. Once the Print command box comes up, make sure to check for these settings:
   - Print Handouts 3 slides per page
   - Print Range: **All**
   - Number of Copies: **(enter total for the number of class attendees)**
4. Left click on *OK*

It is suggested that you print one copy of the worksheet and use a copy machine to duplicate copies for each program participant. It is a good idea to have a couple of additional copies of each worksheet available for participants who attend the presentation at the last minute.

To produce the Knowledge Assessment

You may print a copy from the Appendix OR:

1. Open the Word document.
2. Go to *File*, then *Print*
3. Once the Print command box comes up, make sure to check for these settings:
   - Print Range: **All**
   - Number of Copies: **1**
4. Left click on *OK*

It is suggested you print out one copy of the Knowledge Assessment and use a copy machine to duplicate copies for each program participant. It is a good idea to have a couple of additional copies of the assessment for participants who attend the presentation at the last minute.

To produce the Knowledge Assessment Answer Key

You may print a copy from the Appendix OR:

1. Open the Word document.
2. Go to *File*, then *Print*
3. Once the Print command box comes up, make sure to check for these settings:
   - Print Range: **All**
   - Number of Copies: **1**
4. Left click on *OK*

Prepare the Classroom

Visit the room where you will be making the presentation ahead of time. Make sure the projection system and computer are plugged in to the electric outlet, connected to each other and operate properly. Make sure the screen operates correctly. Place a flip chart at the front of the room.

Prepare Yourself

The program consists of a Lesson Plan to guide you through the presentation. You should "walk" through the presentation at least once to ensure you are familiar with the presentation and what you will say. A Lesson Plan is provided to guide you in the important points to cover and discuss with the participants.

Program Presentation

Follow the provided Lesson Plan. If you do, you'll be sure to make a complete presentation.

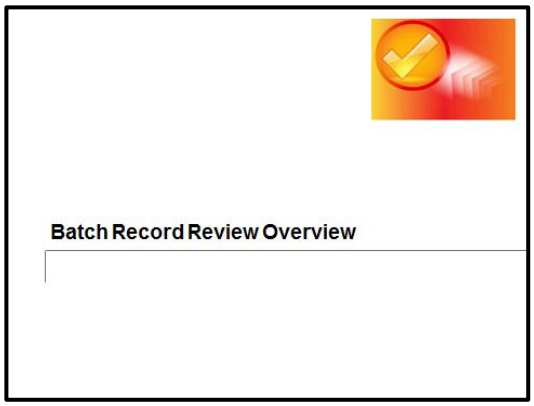
Prior to beginning the program, hand out copies of the slides to the participants. These pages have space for the participants to use to take notes during the presentation. Also, make sure that each person has a pen or a pencil to take notes.

Program Wrap-Up

Administer the Knowledge Assessment at the end of the training program. The Facilitator will grade the assessment, with 80% a passing score. If remediation is required, review the material with the participant, and re-administer the test.

Lesson Plan

Slide 1

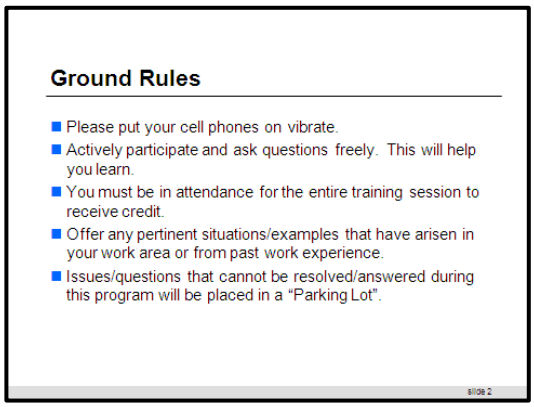


Introduce yourself (if necessary) and then introduce this training program by saying:

Welcome to our Batch Record Review Overview training.

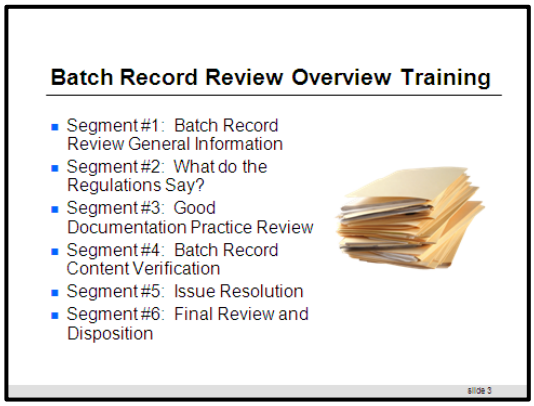
This program will provide you with an overview of our batch record review process – why it's important, how it works and so-on.

Slide 2



Review ground rules.

Slide 3



Now say:

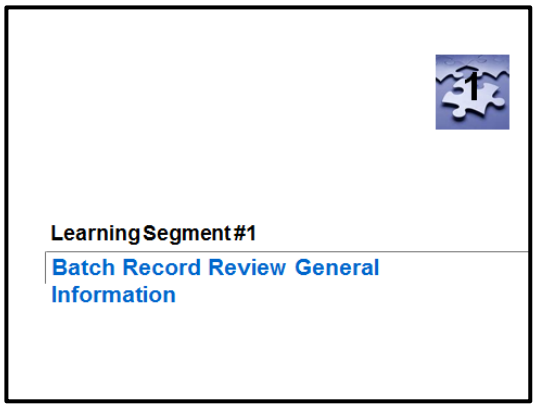
In today's Batch Record Review Overview training, we will discuss information broken into six learning segments.

Review slide to identify learning segments.

Then say:

Now let's move on to the first segment!

Slide 4



Introduce the first learning segment by saying:

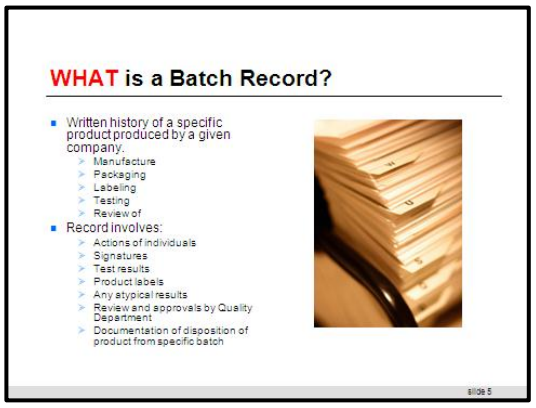
In this first learning segment we'll look at what a batch record is, what kinds of information it contains and a little bit about the batch record review process.

Then ask:

What is a Batch Record?

Record response on flipchart.

Slide 5

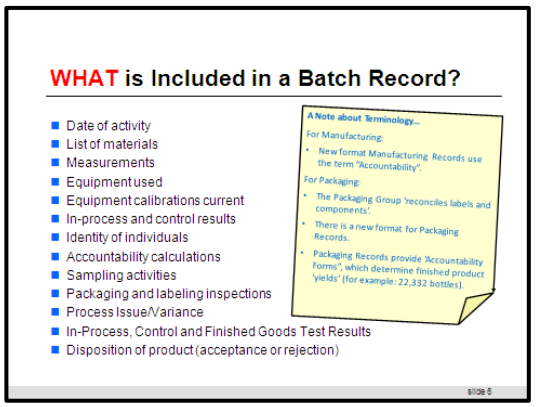


Compare responses on flipchart to slide. Then say:

A batch record is the written history of the manufacture, packaging, labeling, testing and review of a specific product produced by a given company.

This record involves actions of individuals, signatures, test results, product labels, any atypical results, review and approvals by the Quality Department and documentation of the disposition of the product from the specific batch.

Slide 6



Now say:

Since the batch record is the history of a specific batch of product, it is necessary that key pieces of information be included.

Review slide to identify contents of a typical batch record and offer examples as necessary.

Then ask the question:

What types of batch records exist out there?

Record responses on flipchart.

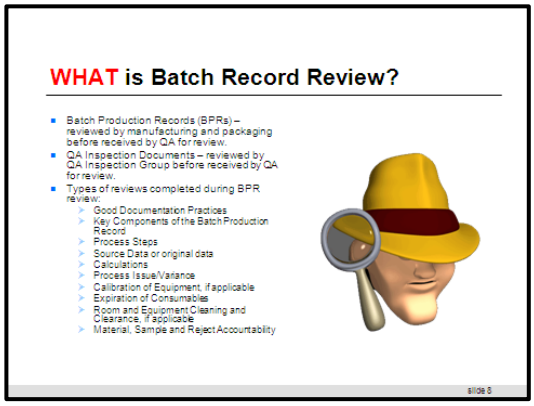
Slide 7

Compare responses on flipchart to slide and then say:

There are batch records for all major operations in the manufacture of a final drug product.

These include Active Pharmaceutical Ingredient (API), bulk drug manufacturing, finished product manufacturing, and labeling and packaging

Slide 8



Explain Batch Record Review. You might say:

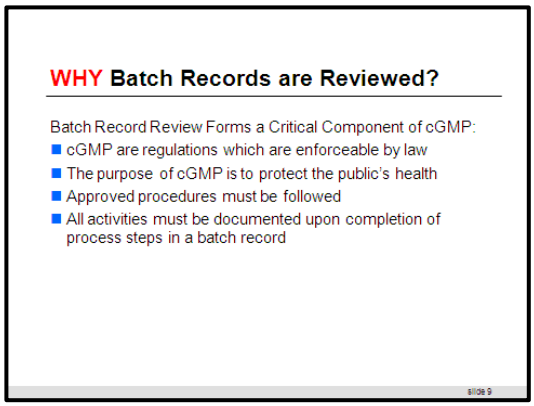
Batch Production Records – BPRs – are typically reviewed first by manufacturing and packaging personnel before they are received by QA for review.

QA Inspection Documents are reviewed by the QA Inspection Group before they are received by QA for review.

There are many types of reviews completed during a BPR review.

Review slide to identify types of reviews completed during a BPR review.

Slide 9



Explain why batch records are reviewed by saying:

Batch Record Review forms a critical component of cGMP. We review batch records because:

- *cGMP are regulations which are enforceable by law*
- *The purpose of cGMP is to protect the public's health*
- *Approved procedures must be followed*
- *All activities must be documented upon completion of process steps in a batch record.*

Then ask:

So, who do you think reviews and approves batch records?

Slide 10

Now say:

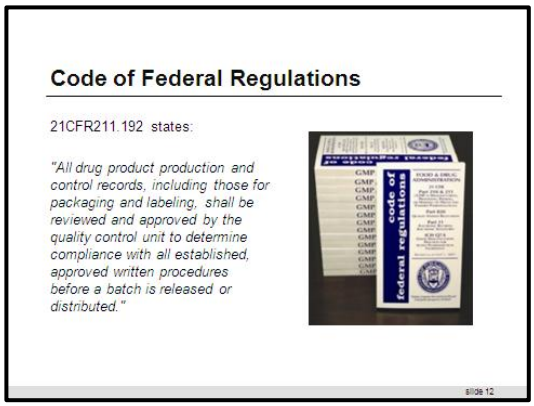
Batch Production Records must be reviewed and approved by qualified individual(s) within manufacturing, packaging and quality assurance.

Slide 11

Then say:

Now let's look at what the regulations say about Batch Record Review.

Slide 12



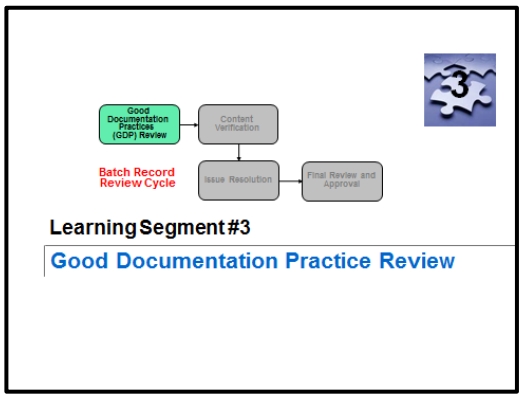
Review slide. You might say:

21CFR211.192 states that:

"All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed."

As you can see, the regulation is very specific that we conduct our Batch Record Review properly.

Slide 13

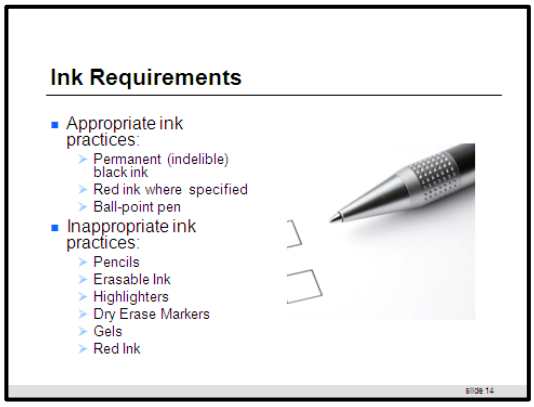


Introduce Learning Segment #3 by saying:

The regulations say we need to conduct a proper review of our batch records. So how do we do that?

The first step is Good Documentation Practices.

Slide 14



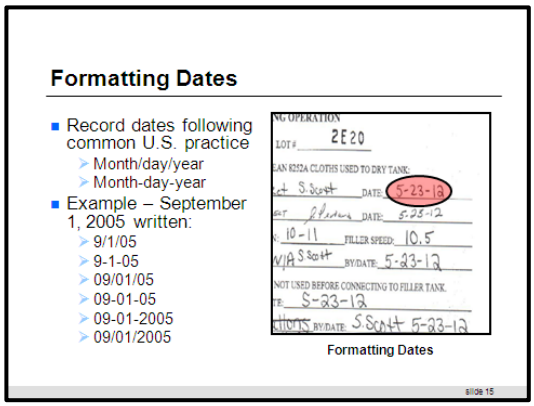
Then say:

First of all, we need to utilize proper ink practices when completing documentation.

Review slide to identify appropriate and inappropriate ink practices.

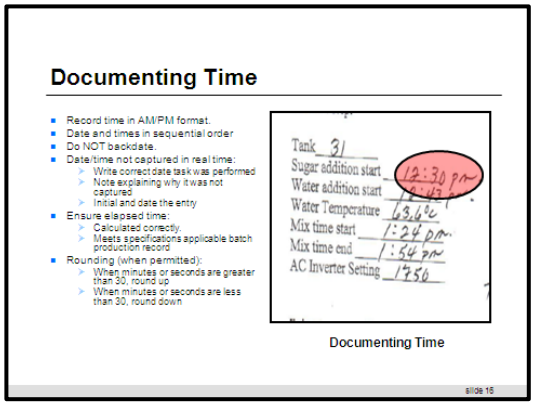
Offer examples as necessary.

Slide 15



Review slide to explain date formatting requirements.

Slide 16

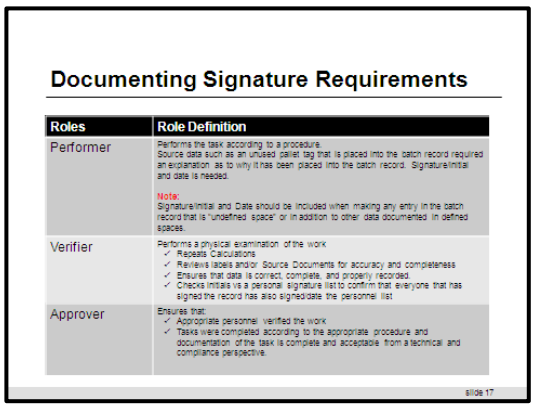


Then say:

Time documentation is another critical piece of Good Documentation Practices. We document many things during a batch – process start time, pump times, cleaning times, etc.

Review slide to explain time documentation requirements.

Slide 17

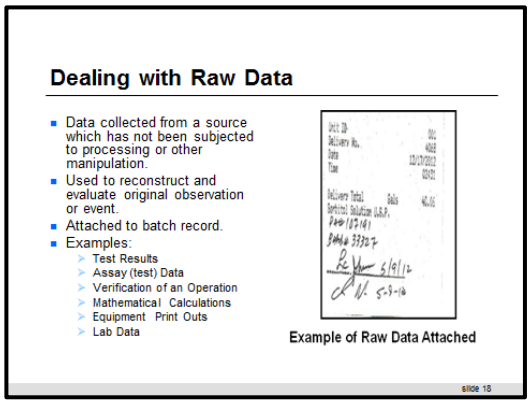


Now say:

We also have requirements for documenting signatures. Each person (or role) involved in a document has different requirements.

Explain signature requirements/roles using slide.

Slide 18



Then say:

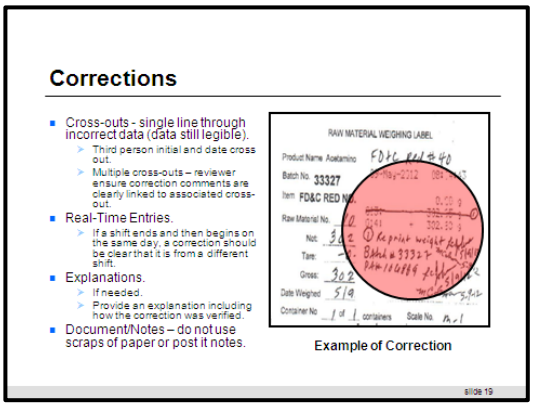
Raw data is something else we deal with in a batch record.

Raw data is a term for data collected from a source which has not been subjected to processing or any other manipulation. It is used to reconstruct and evaluate the original observation or event.

When collecting raw data, be sure all necessary raw data is attached to the batch record.

Raw Data may include but is not limited to Test Results, Assay (test) Data, Verification of an Operation, Mathematical Calculations, Equipment Print Outs and Lab Data.

Slide 19

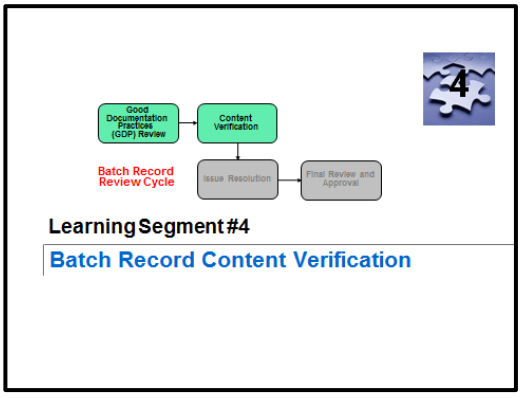


Explain requirements for corrections by saying:

And finally, Corrections. Regardless of how careful everyone is, there will come a time for corrections. When they are needed, they must be done the right way.

- *Cross-outs. Single line through the incorrect data (data still legible) and a third person's intial/date. When multiple cross out are present, the reviewer should ensure that correction comments are clearly linked to the associated cross out.*
- *Real-Time Entries. If a shift ends and then begins on the same day, a correction should be clear that it is from a different shift.*
- *Explanations. If needed, provide an explanation including how the correction was verified – such as "Line down for retirement party for Larry…" or "Carol went to give blood".*
- *Document/Notes. Do not use scraps of paper or post it notes as documents or notes.*

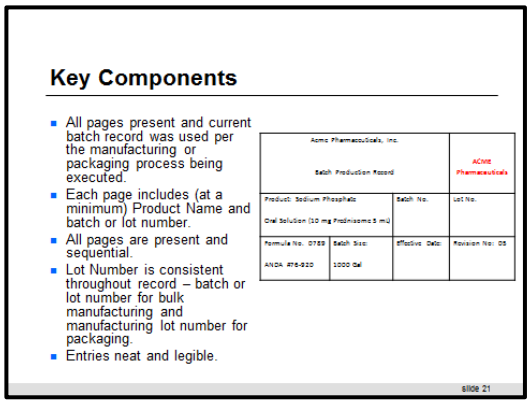
Slide 20



Then say:

This fourth learning segment deals with verifying the content of the batch record.

Slide 21



Now say:

First, you'll need to verify that all of the key components are present.

It is important to make sure that whether the BPR is electronic or in hardcopy format that all pages of the BPR are present and the current BPR was used per the manufacturing or packaging process being executed.

Once the batch record is received for review:

- *Review each page from top to bottom and on both sides – each page should include at a minimum the Product Name and batch or lot number.*
- *Verify all pages are present and sequential.*
- *Ensure Lot Number is consistent throughout the record – batch or lot number for bulk manufacturing and manufacturing lot number for packaging.*
- *Ensure entries neat and legible.*