	Knowledge Assessment Answer Key Batch Record Review Overview

1. **True or False.**

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

   a. True

   b. False

2. In what type of format is the BPR presented? **(Fill in the blanks)**

   The batch production record may be either in an **Electronic** or **Hard Copy** format.

3. What are Types of Batch Records? **(Circle all that apply)**

   a. Active Pharmaceutical Ingredient (API)

   b. Bulk drug manufacturing

   c. Finished product manufacturing

   d. Labeling and packaging

4. **True or False.**

   Batch record entries are required to be entered using pencils:

   a. True

   b. False

5. **True or False:**

   Reprocessing of any kind does not need to be approved by the Quality Unit,

   a. True

   b. False

6. **Circle the correct response.**

   Which of the following CFR regulations addresses Batch Record Review?

   a. 21CFR211.345

   b. 21CFR211.192

   c. 21CFR211.102

   d. 21CFR211.457

	Knowledge Assessment Answer Key Batch Record Review Overview

7. **True or False.**

   All necessary raw data needs to be attached to the batch record.

   a. True

   b. False

8. **Circle all that apply.**

   Which of the following are steps completed during Content Verification of a Batch Record?

   a. Review of Key Components

   b. Review of the Source Data

   c. Review of Calculations

   d. Review of deviation references

9. **Circle the correct response.**

   When reviewing the expiration dates for consumables, which of the following parts of the batch record are used?

   a. The Process Step Section

   b. The Bill of Materials Section

   c. The Reconciliation Section

   d. The Attachments Section

10. **True or False.**

    All rejected materials must be accounted for and documented appropriately on the batch record.

    a. True

    b. False