Batch Production Record Checklist

A Batch Production Record is a detailed, written documentation of the work performed to manufacture or remediate a batch of cannabis or cannabis product. Batch production records include information about the cannabis and non-cannabis ingredients used, the staff member(s) who completed each step, verification that the Master Manufacturing Protocol was followed, and information about the quality control processes used to ensure safety. Batch production records should be detailed as necessary to provide an accurate, indelible, and legible history of the work performed. They must be created concurrently with the performance of each documented manufacturing or remediation activity.

The checklist below will help you verify that your batch production records capture the minimum required information. A complete list of requirements can be found in section 17216 of the Department of Cannabis Control's regulations. (Cal. Code Regs., tit. 4, § 17216.)

Overall information

- ☐ The license number or premises address of the facility where the manufacturing or remediation occurred.
- ☐ The unique identifier (UID) of the final batch of cannabis product.
- ☐ The batch or lot number assigned to the batch.

Ingredients

- ☐ The unique identifiers (UIDs) of the cannabis and cannabis products used in the batch.
- ☐ The identity and weight or measure of all cannabis and non-cannabis ingredients used – A common way of tracking ingredients is by using the lot numbers assigned by the ingredients' manufacturer.

Equipment and processing lines

- ☐ The specific equipment and processing lines used – The specific equipment and processing lines used provides information vital to protect public health if the equipment is determined to malfunction or be a source of contamination.

Production steps

- ☐ The date on which each step of the Master Manufacturing Protocol was performed.
- ☐ The initials of the person who performed each step (e.g., the person who weighed or measured each component, who added each component to the batch, and who verified the addition of components).
- ☐ Actual yield and difference from expected yield at the appropriate phases of manufacturing –The Batch Production Record must record the actual yield for each measurement point and note the percentage difference, if any, from the expected yield at appropriate phases of manufacturing as identified in the Master Manufacturing Protocol.
- ☐ Monitoring Values – If your Product Quality Plan identifies any steps in which monitoring is needed to ensure product safety, the values must be recorded in the Batch Production Record.

Packaging and labeling

- ☐ A copy of the label or other identification of the label to be used.
- ☐ Actual quantity of packages and labels used if the cannabis product leaves the manufacturing premises as a final form cannabis good – If the amount of actual packages or labels used differs from what is expected, the difference from the expected quantity to be used must be recorded in the Batch Production Record. Cannabis products transferred in bulk to another licensee for further manufacturing do not need to include the quantity of packages and labels used in the Batch Production Record.

Quality control steps

- ☐ Quality control review – Documentation that quality control personnel reviewed the batch production record and any monitored operations.
- ☐ Quality control approval or rejection – Documentation that quality control personnel
- ☐ approved/released or rejected the finished cannabis product and the batch for distribution.
- ☐ Documentation of any investigations – If investigations into deviations from expected yield or package and label count occur, the results must be noted in the Batch Production Record.

The Department of Cannabis Control (DCC) licenses and regulates commercial cannabis activity within California. To learn more about the California cannabis market, state licenses or laws, visit cannabis.ca.gov. Email questions to info@cannabis.ca.gov or call 1-844-61-CA-DCC (1-844-612-2322).