Checklist for Batch Production Records

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, verifications that the Master Manufacturing Protocol was followed, and information about the quality control processes used to ensure safety.

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 regulations.

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	occurred. The identity of the product being manufactured. The unique identifier (UID) of the final batch of cannabis product.
Ing	redients
	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 - Records of which raw ingredients were used in which production batches are important when tracing is needed, such as when a supplier issues a recall. A common way of tracking ingredients is by using the lot numbers assigned by the ingredients' manufacturer.
Equ	ipment 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 be a source of contamination.

Prod	uction Steps				
	The date on which each step of the Master Manufacturing Protocol was performed. The initials of the person who performed each step. This includes 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 – The Master Manufacturing Protocol should identify specific steps after which the yield of the in-process product must be measured. 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. These values can provide critical information about possible errors in the manufacturing process. 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 and package. Actual number of packages and labels used if the cannabis product leaves the manufacturing premises packaged for retail sale. Cannabis products transferred in bulk to another licensee for further manufacturing do not need to include the number of packages and labels used in the Batch Production Record. Actual quantity of packaging and labels used – if the amount of actual packages or labels used differs from what is expected, the difference from the expected number to be used must be recorded in the Batch Production Record.				
Quality Control Steps					
	Quality control review – Documentation that quality control personnel reviewed the batch production record and monitored operations, tests and examinations. Quality control approval – 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.				



Key Points to Remember

Records must be accurate, indelible, and legible.
The documentation captured in a batch production record occurs when the activity is
performed.
Batch production records contain the actual values and observations obtained during the production, monitoring and verification processes.

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 <u>cannabis.ca.gov</u>. Email questions to <u>info@cannabis.ca.gov</u> or call 1-844-61-CA-DCC (1-844-612-2322).