

	Doc. Control #			
	Department:		Version:	
	Title:	Control Chart Template	Date Created:	
	Prepared By:		Date Approved:	
	Approved By:		Date Updated:	

Control Chart

COMPANY NAME									
In-Process Control Chart									
lot number									
date									
			a.m.						
			12	1	2	3	4	5	6
	high								
ITEM	target								
(units)									
	low								
tested by									

Instructions

Enter the Lot Number and Production Date at the top left of the Control Chart. Write/Type the name of the test where ITEM is listed. Add the units of measurement under that. Add the target value in the middle green row on the chart, and add the Upper Specification Limit (USL) on the 'high' listing on the upper yellow row. Enter the Lower Specification Limit (LSL) on the 'low' listing on the lower yellow row. For each reading taken during processing, enter the test value in the appropriate box.

Values in the green rows indicate a process that is under control and no further action is required. Values in the yellow rows are acceptable product but the process must be adjusted to bring the next test value back into the green rows. Any test value in a red row is unacceptable product and must either be disposed of or reworked to create an acceptable product.

Attached to this instruction is the Control Chart Template as an Excel Spreadsheet.

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Directions for Using and Understanding the Control Chart

A Control Chart is a powerful tool a Contract Manufacturer (Co-Man) can use to help keep a production process under control, producing in-specification product every time. The goal of the Control Chart is to direct process adjustments during production to ensure the product is always acceptable. The instructions above will inform you on how to set-up the chart and record data. The instructions below are to help you interpret different series of data and the best approach to react.

Understanding the Control Chart

The Control Chart consists of an Excel template with numerous rows of green, yellow and red rows, with time increments across the top of the chart. The template is adjustable so you can put whatever time increment you want across the top. Typically, during a production run, samples are taken every hour which is the default increment on the template. If your run is typically shorter, you can adjust this to every 30 minutes, 15 minutes and so on so you generate sufficient data to best control the process.

The colored rows indicate if the test result is within the given acceptable range (Green), acceptable but borderline (Yellow) and out of spec product (Red).

COMPANY NAME									
In-Process Control Chart									
lot number									
date									
			a.m.						
			12	1	2	3	4	5	6
	high								
	target								
ITEM									
(units)									
	low								
tested by									

You list the test on the ITEM cell, and its units in the cell below. The values for target, high and low are determined by your R&D testing. See the Visual Specification Template instructions for a description on how to set specification limits.

Once you've entered the information above, the Control Chart is ready for use. Typically, this Chart is out on the Production Floor with the Batch Record. The Operator takes a sample at the prescribed time, runs the test and records the result by placing an X in the appropriate cell.

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There are a number of data points that would require action by the operator in the form of a process adjustment. Below I have circled and numbered those areas:

XYZ Cookie Company														
In-Process Control Chart														
lot number - ABC123XYZ														
date - March 13, 2023														

For each circled area, I will discuss what it indicates and what the required corrective actions are. We will use the chocolate chip cookie example.

1. The moisture reading here is 3.2%, above the USL. As a result, this is unacceptable product and must be rejected. Since there is no way to rework this product, and baking further might result in unacceptable color, this product must be disposed of.
2. In the case of 3 or more data points trending in the same direction, regardless of whether they are all in spec or not, the operator must make an adjustment. In the case of the chocolate chip cookies, the adjustment here would either be to lower the temperature of the oven or bake for a shorter period of time. Since most commercial ovens are not humidity controlled, this scenario could happen as the outdoor humidity varies throughout the production run.
3. The moisture reading here is 0.9%, which is below the LSL. In this case, the product is too dry and must be rejected. Since there is no rework procedure for dry cookies, these products must be disposed of.
4. The moisture reading here is 1.0%. The operator made an adjustment when the reading was at 0.9%, and at 1.0% the product is acceptable. Since the operator already made the adjustment earlier, we would wait until the next reading to determine if further action is required.
5. In this case there are three straight readings in the same direction, so an adjustment must be made. Here, it would appear the operator made too large of an adjustment when the product was at 0.9%, resulting in the product moisture trending upwards and quite possible out of specification for the next reading. An adjustment here to increase the oven temperature or increase the retention time would be required.

Note at the bottom of the chart there is a 'tested by' row. Whomever conducts the test is required to initial and date in this cell, indicating they took the sample and completed the moisture measurement. This is a critical step to ensure regulatory compliance.

The Control Chart is a valuable tool to help understand the normal variations of a process, but also to help adjust the process as needed to ensure in spec product is always being produced.