



Connecting Industry to Mathematics Instruction

NSF ATE Award # 1954291

Mind Your Tolerance

Student Activity Sheet

A Process Engineer is responsible for the systems, equipment, and processes involved in the manufacture of products. One of the responsibilities of a Process Engineer is to monitor how accurately items are being produced according to their design specifications, and to report anomalies that could indicate the need for an adjustment in the equipment or process.

During the manufacture of Metered Dose Inhaler canisters, the valves are crimped onto the canister. To ensure integrity of the product, In-Process Checks are conducted on the crimped canisters. Each Canister is measured for Crimp Height (mm), Crimp Diameter (mm), and Net Fill Wt. (g). Results are recorded in the “Sample 1” and “Sample 2” sheets of the Canister Sample Data Student spreadsheet. Answer the following about your assigned Exercise.

1. Analyze the In-Process Check Data in order to determine if any product has one or more measurements that are not within specifications. Record a “flag”, or note, for any canister with a measurement that is outside the tolerance of specified design value:
 - The Crimp Height must be within $0.08mm$ of the design spec of $6.96mm$.
 - The Crimp Diameter must be within $0.10mm$ of the design spec of $17.80mm$
 - The Net Fill Weight must be within $0.30g$ of the specified $6.50g$.
- a. Do you notice any trends in the data? Be sure to examine columns as well as rows. Explain below.
- b. Does the data cluster around a particular value, or is it spread out?
- c. Briefly explain how you identified the information requested above. Could a graphical representation of the data be helpful? What might that look like?

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- d. Compute the mean and standard deviation for each parameter (measurement) in your worksheet.
 - i. Explain what the mean and standard deviation tell you about the crimp height, crimp diameter, and fill weight of a run of canisters.
 - ii. What would you expect the mean to be? Explain.
 - iii. What would you hope the standard deviation would be? Explain.
 - iv. Explain what the mean and standard deviation tell you about each measurement.
- e. What recommendations would you make to the manufacturer based on the results you've gathered?

During the manufacture of Metered Dose Inhaler canisters, the suspension (active medicine along with additives) is recirculated to fill the canisters with the proper drug concentration or mixture. To ensure integrity of the product, In-Process Checks are conducted on the process parameters related to the filling vessel and system. Every 100th canister from the process equipment is checked and the parameters of **Temperature (°C)**, **Stir Rate (rpm)**, **Recirculation Rate (L/min)** are recorded. Results are recorded in the “Remix Sample 3” sheet of the spreadsheet.

2. Analyze the In-Process Check Data to determine if the product is within specifications. Record a “flag”, or note, for any canister with a measurement that is outside the tolerance of specified design value.
 - The temperature must be within 2.00°C of 21.00°C
 - The Stir Rate should be within 5rpm of 200rpm
 - The Recirculation Rate must be within 0.10L/min of 2.50L/min
- a. Do you notice any trends in the data? Explain below.
- b. Can you think of a more efficient way of identifying the canisters that are “out of tolerance” than you described in #1 on the previous page? Explain.
 - i. How could a spreadsheet command help to identify events that are in/out of tolerance?
 - ii. Write a command for each parameter if temperature is stored in E2, Stir Rate is stored in F2, and Recirculation Rate is stored in G2. Add these commands to your spreadsheet.
- c. Compute the mean and standard deviation for these three measurements. What do these results tell you about the mixing process?

Now that you have had some experience with the Process, take a look at the BatchSample sheet of the spreadsheet.

3. How is this sheet different?
4. Will your method from the previous page work well with this new task? Explain.
5. Describe a way that you think the method for identifying readings out of tolerance could be improved over scrolling through the table of numbers. Discuss this suggestion with your partner(s). HINT: The spreadsheet command =OR(E2>15,E2<12) will return a value of FALSE if both inequalities are false (meaning that the value in E2 is not more than 15 and is also not less than 12). If one or both of the inequalities is true, this command will return a value of TRUE.

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Add this feature to the spreadsheet. If you downloaded the data as an Excel spreadsheet, upload it into Google Classroom/Canvas.

6. How do you think you could look for patterns in a data set this large? Did you see any patterns in the data? Speculate on a cause for any patterns that you see.

Reflection Questions

For each of the following data patterns, make a conjecture for each situation.

- a. Near the end of a production run, the Crimp Diameter was increasing over the final 15 samples. What might cause this?
- b. In the middle of a production run, a “clump” of medication clogged the filling valve to the canisters. How might you be able to recognize this event from a set of sample data?
- c. The Crimp Height was below the specified tolerance in the first 18 samples but fell within the tolerance for nearly all the remainder of the samples. What might cause this event?
- d. Every item in five consecutive production samples has been with specifications on all parameters. Is this likely? What might be a cause?