Statistics for Process Validation

Training Master Handbook

Presented By

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How to use this handbook

The handbook is organized to focus on particular skills and revisions.

These lessons allow you to learn and practice the skills used throughout the course.

The following icons are used in this handbook.

	Activity	Revision exercise or written task
	Important	Important points to remember for the assessment
	Quick Link or Tip	A shortcut, tip, or favourite link
	Discussion	Group discussion activity

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1. Activity 1: Process knowledge to understand variability

Read the following background information:

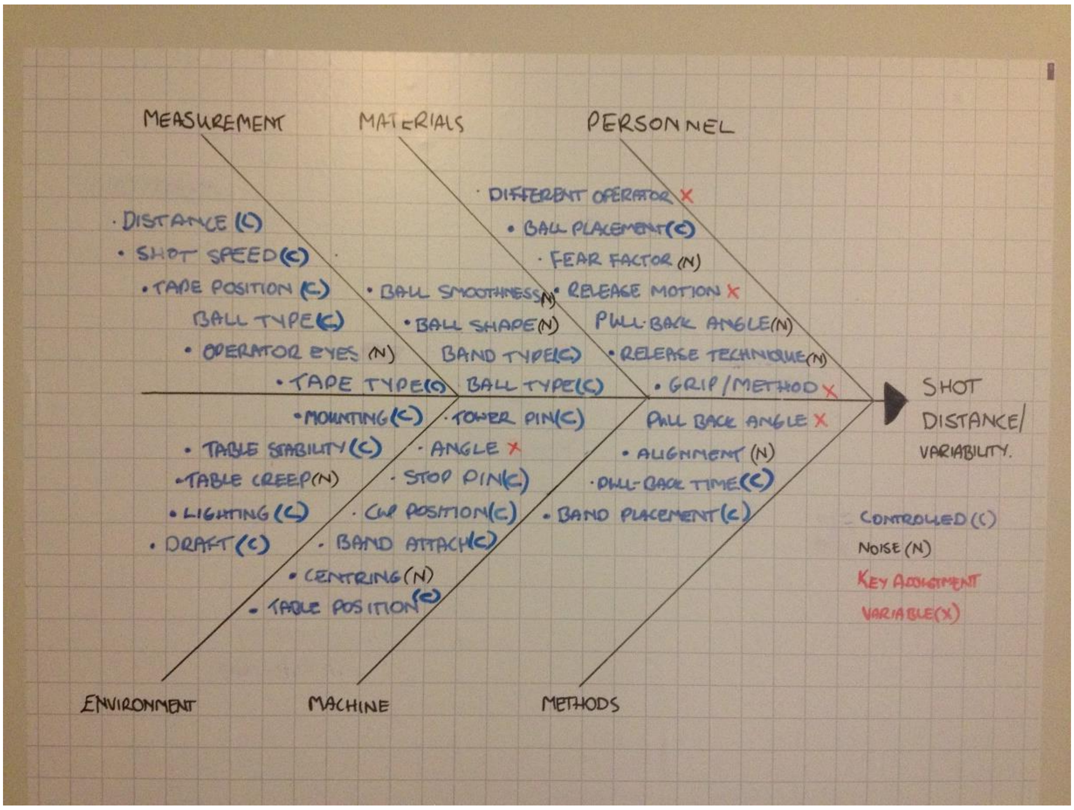
1. The activity will use a catapult as part of an exercise.
2. The catapult is set up as follows:
   a. The catapult is mounted to the table using clamps.
   b. Cup positioned at the top of the catapult arm.
   c. One rubber band is attached below the firing cup.
   d. The tower pin should be located at the top and the stop pin at position 4.
   e. The pull-back/firing angle to be used will be 180 degrees.
3. Select 5 team members to fire the catapult, and two Observers to independently record the distances that the ball has been fired.
4. When instructed, the five team members must to shoot the catapult five times in quick succession using the green rubber ball. Each member should shoot as quickly as possible. Time is money, and high productivity is our goal.
5. The shot data should be entered into Excel (*Activity 1: Quick-fire Initial*) using the template supplied by PharmOut.
6. The spreadsheet will automatically plot the distance fired as recorded by both Observers versus the shot number. The sheet will also calculate the mean, standard deviation and absolute difference between both Observers.

What does the information generated tell you about your processes?
• High Variability (catapult, firing, angle, Operator, Observer etc) • No consistency (no SOP, instructions, diagrams, etc) • No control (no SOP, no training, no target etc.) • Team not organised (no procedures, no training, etc.)

7. Now that you have a little more understanding about your process, work as a team to develop a high-level process map for firing the catapult. You can use the post-its available to map the process on the wall/flipchart or use this handout to document your process flow.
8. Nominate a speaker to describe the process to the group once complete.

What are the main steps that could help with shot consistency?
• Standing position of Operator • Pull-back angle positioning • Waiting a number of seconds before firing • Holding position of the firing arm • Ball position in the cup • Waiting for the Observer • Collecting the ball after each shot

9. Once the process is defined, it is important to be aware of causes of variability. Using an Ishikawa Diagram (or Cause & Effect diagram), brainstorm potential causes of variation in distance of shots fired.



10. Work as a team to develop the diagram. You can use the flipchart or use this handout to document your work.
11. Nominate a speaker to describe the process to the group once complete.

What are the main reasons that contribute to shot variability?
Shooting Technique: • **<u>Grip:</u>** Grip the cup consistently (edge of the cup, arm, wing nut, finger over arm below cup). Best is sides of arm between thumb and index finger. • **<u>Release Technique:</u>** smooth & consistent. The operator should use a smooth and consistent release technique. Don't drag the fingers over the arm, or jerk as the arm is released. • **<u>Pull-back angle measurement:</u>** The pull-back angle is critical. A one (1) degree shift in the angle may change the shot distance by 30cm or more. • **<u>Release motion:</u>** As the arm is released, the operator should take care not to jerk and change the release point. • **<u>The fear factor:</u>** Often the techniques used by the operator change in subtle ways under pressure. Be sure the operator is comfortable with the sequence of activities and executes the shooting action in the same manner each time. • **<u>Ball placement in cup:</u>** Place the ball in the cup gently, without pressing. On some catapults, the ball fits tightly in the cup creating a suction that changes the impact point by more than two 60cm.

- **Arm in slot:** After the catapult has been used for a while, the arm can loosen in the slot. Shot variability seems to increase as the slot spacing increases.

Catapult stability:

- **Mounting:** The catapult should be attached firmly to the mounting surface.
- **Table Creep:** Be sure the table doesn't creep forward or backward as shots are taken. Very small changes in table location can change the down range shot location by several cm.
- **Table Stability:** Flexible tables that move during shooting can influence shot distance.

Rubber band:

- **Stretching:** If the arm is held in an extended or stretched position for a long period of time, the tension in the rubber band will relax. If the pull-back time is increased from 5 seconds to 1 minute, the shot length may decrease by 30cm. The operator should hold the arm back for a given period of time.
- **Heating:** The shot rate also affects shot distance. If we shoot several shots per minute for an extended period, then stop, the next few shots may be longer than before by several cms. Establish a warm-up procedure before shots begin.
- **Linearity:** The rubber band is a non-linear elastomer. Tension does increase as pull back angles increase, but not in a completely linear manner.
- **Tower pin:** As we pull back the catapult arm, the pin in the tower will begin to turn, allowing the rubber band tension to change. The pin often turns for up to 5 seconds after the arm is pulled back. The operator should hold the arm back for a given amount of time i.e. 3 seconds after reaching the final angle.
- **Placement:** The rubber band should pass over the tower pin without binding. It should be aligned before each shot.
- **Centering:** Identify the centre of the rubber band and place it carefully over the pin at the base of the tower.

Measurement Technique:

- **Distance:** The team should use a fractional tape measure to estimate downrange distance.
- **Ball impact location:** The ball impact location is very difficult to estimate. The team should use a mechanism that yields a positive indication of the impact location.
- **Ball impact elevation:** When the impact is more vertical, the impact point is easier to identify.

12. Understand the process CNX (**C**onstant, **N**oise and e**X**perimental variable). On the Ishikawa diagram, label all the bones.
    a. If the factor should be kept constant, label it a **C**
    b. If the factor is noise or cannot be controlled, label it an **N**.
    c. If the factor is a key adjustment variable, label it an **X**.
    d. Are the X variables Process Parameters (PP's) or Critical Process Parameters (CPP's)?

13. Draft a **high-level** SOP for firing the catapult. All factors labelled as "C" must be held constant, the "N" factors must be monitored to ensure they stay within the acceptable boundaries.

What are the main instructions for your SOP?
The catapult should be attached firmly to the mounting surface. If the Catapult is placed on a table, use a c-clamp to hold if firmly against the table surface." "Be sure the table doesn't creep forward or backward as shots are taken. Very small changes in table location can change the down range shot location by several inches." "Be sure the table is reinforced and rigid in construction. Flexible tables that move during shooting can influence shot distance." "As the arm is released, the operator should take care not to jerk and change the release point. "The operator should use a smooth and consistent release technique. Don't drag the fingers over the arm, or jerk as the arm is released. Some teams have added very elaborate mechanisms to aid the grip and release." "The pull back angle is critical. A one-(1) degree shift in the pull back angle may change the shot distance one foot or more. "Be sure the operator is comfortable with the sequence of activities and executes the shooting action in the same manner each time." "Establish a warm-up procedure before shots begin." "The rubber band should pass over the tower pin without binding. It should be aligned before each shot." "Place the ball in the cup gently, without pressing." "The operator should carefully grip the cup in the same way each time, holding the sides of the arm between the thumb and index finger." If the arm is held in an extended or stretched position for a long period of time, the tension in the rubber band will relax. As the arm is pulled back, the pin in the tower will begin to turn, allowing the rubber band tension to change. The pin often turns for up to 5 seconds after the arm is pulled back. The operator should hold the arm back for a given amount of time i.e. 3 seconds after reaching the final pull back angle." "The team should use a tape measure to estimate downrange distance." "The ball impact location is very difficult to estimate. The team should use a mechanism that yields a positive indication of the impact location such as to use aluminium foil in the landing area." "The Catapult can be shot from the floor," **Maintenance Hints** "The team should inspect the rubber band frequently. Small nicks and cracks do influence the shot distance. If the rubber band is changed, shot distances will change significantly. Exercise the new rubber band by extending it fully 50 or more times before conducting your experiment." The team should carefully monitor the state of the pad. If the pad is changed, the shot distances will change significantly. To seat the new pad correctly, you should impact it 50 or more times by pulling back and releasing the arm."

1. Repeat the catapult shots as per Steps 2-6 above but the shot data should be entered into Excel (*Activity 1: Quick-fire Repeat)* using the template supplied by PharmOut and compare the results using the spreadsheet.

The Results:
What was the range of data in the Initial run: __________ What was the range of data in the Repeat run: _________ What was the improvement: __________

2. Activity 2: Analysis of Variance

1. Analysis of Variance (ANOVA) is used to test for significant differences in the means between several different test conditions.
2. In this exercise, we would like to consider other types of suppliers of the ball that is fired during our catapult process.
3. Consider the following items in preparation for the hypothesis test:

Hypothesis	All of the ball types are the same
Alternative Hypothesis	At least one of the balls is different
Significance Level	Significance or alpha (α) level seat at 0.05

4. Before we decide on which type of ball is suitable, we need to test to see if there are differences between them.
5. The catapult is already set up for the correct conditions, as per Activity 1.
6. Shoot 5 shots with each type of ball. You may wish to use the "best" shooter from the last exercise to shoot all of the shots!
7. Record the data on the spreadsheet (*A2-ANOVA Data* tab).
8. The Facilitator will run the data using Minitab.

What did you learn from the results?
• The foam and rubber balls appear similar and result in similar shot differences. • The whiffle ball is different. • What do you recommend doing? • What is the whiffle ball was much cheaper?

3. Activity 3: Gage R&R Test

1. This activity examines the capability of our measurement system and considers the effect on product performance. Assume that the digital calipers is clean, calibrated and undamaged. Three Operators will measure 10 items in a random order.
2. Before taking measurements, press the red OFF/ON button to switch the power on.
3. Press the mm/inch button to select the desired unit of measurement. We will use mm (Display will show: 0.00^{mm})
4. Fully close the jaws of the calipers and press the yellow ZERO button to zero the instrument.
5. Select the item to be measured (follow the Gage R&R spreadsheet as indicated by the Facilitator) and slowly open the jaws of the calipers wider than the width of the item to be measured.
6. Slowly slide the jaws of the calipers closed to tighten against the outside surfaces of the item perfectly.
7. Read the measurements from the LCD display.

8. Fully open the jaws of the calipers and remove the item that was measured.
9. Close the caliper jaws again fully and check that the instrument reading returns to zero.
10. Repeat for all items according to the Gage R&R spreadsheet.
11. Record the data on the spreadsheet (*A3-Gage R&R Data* tab).
12. The Facilitator will run the data using Minitab.

What did you learn from the results?

4. Activity 4: Design of Experiments (DoE)

Read the following background information:

1. This activity examines the basics of designed experiments an demonstrates how data gathered during constructed tests/experiments can be used to build a predictive model of a process
2. This is useful if there is little prior knowledge about a process (catapult) or how many shots it might take to hit a randomly placed target. The model is also useful if the target changes.
3. Having the ability to hit the target right first time, every time would be very useful from a quality perspective, but also a time and cost perspective.
4. We will use the following experiment to construct a predictive model.

Experimental Matrix		Distance green rubber ball fired		
Pull-back angle	Stop Pin	Shot 1	Shot 2	Average
160	5			
160	3			
180	5			
180	3			

5. The shot data should be entered into Excel (*Activity4: DoE Data*) using the template supplied by PharmOut. Note that the order of the shots should be randomised.

6. Follow the instruction in the template to develop a model to predict a shot distance.
7. Once the distance has been determined, place a PharmOut mug at that point take a shot!

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