

# Improvement in sampling methodology and data governance for formulation production units

## BUSINESS CASE

### Organization Trends

- Price erosion in foreign markets due to entry of new competitors and existing competitors launching competing products
- Increased focus on eliminating Cost of Poor Execution (COPE) and Cost of Poor Quality (COPQ)

### Customer trends

- Quality issues not detected leading to:
  - Product recalls
  - Customer complaints

## CHALLENGE

### What is the challenge

- The organization samples every batch of products manufactured to test for quality and ensure compliance
- To ensure that the sampling methodology reflects the actual quality of the product, the organization doubled the samples tested
- There was no scientific method used to ensure that there is no variation in data collected due to human factors basis the sampling methodology

### Where is the challenge

- At two formulation production units

### When was the challenge identified

- In FY 2015

## IMPACT

### What is the impact

- Due to the increase in the sampling sizes, the following impacts were seen:
  - the cost of sampling dramatically increased
  - the time taken to validate the products through the QC labs increased, resulting in delayed dispatches to the customers
- Ultimately it impacted the adherence to the production plan and a drop in customer satisfaction
- Given the premium associated with the products, there was a big impact on the profitability of the production process

## TARGET

### What is the Target

- Implement of following techniques on collected data to improve efficiency and effectiveness:
  - **Cross validation of sampling**  
**Example:** Sampling technique validated using multiple lab analysts and products against baseline average
  - **Repeated trial (Measurement System Analysis i.e. MSA)**  
**Example:** Each sampling instance repeated twice by each lab analyst for each product
  - **Aggregation and decomposition**  
**Example:** Overall sampled data broken down by lab analyst and product
  - **Pairwise attribute visualization**  
**Example:** Boxplot of product against lab analyst and of product against trial instance

## OUTCOMES

### Operational outcomes

- Robust sampling methodology ensuring actual quality of product is reflected in the samples
- No variation in product quality data due to human factors
- Data analytics practices implemented in the two production units

### Business outcome

- Decrease in percentage of products failing in stability tests from 2.6% to 1.4%
- Reduced the sample sizes back to the original sizes, reducing cost by over US\$ 3.3 million

## Delivered using:

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**KINDUZ Services:** Data Analytics | Continual Improvement | Leadership Augmentation

