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CASE STUDY AUDIT:

PHARMACEUTICAL SYRINGE IMPROVEMENT PROJECT

THE CLIENT

The client, a global pharmaceutical manufacture of large and small molecule medicines, and a major leading pharmaceutical supplier of glassware to the pharmaceutical and healthcare industry.

THE CHALLENGE / BACKGROUND

Luer-lock syringe barrels for the filling of pre-filled syringe applications of various lifesaving medicines were sourced from an international recognized manufacturer in Germany. These syringe barrels are processed at multiple facilities during production operations.

“Black Spots” were detected in the syringe tip with varying distribution on several batches.

Though this flaw was initially characterized as “Minor” because of the lack of patient safety impact, the pharmaceutical manufacturer implemented a 100% pre-use visual inspection of all syringe barrels received. This inspection was to remain in place until such time as corrective actions could be proven effective at reducingthe occurrence of the black spot flaw to acceptable levels.

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THE APPROACH

The project “Black Spots” was conducted using the 5 phase Six Sigma method DMAIC (Define, Measure, Analyze, Improve, Control).

Define phase: Describe the business pain and the full arguments for the project. At the end of the define phase a completed project charter is to be presented to the project sponsor for approval.

Measure phase: Collect and test information/data. Various analytical tools are used here to collect information and to test the quality of this information. If not enough information is collected, this increases the probability of a beta error (saying nothing is wrong, when in fact there is). If the information is of poor quality, this increases the probability of an alpha error (saying there is something wrong when in fact there is not).

Analyze phase: Make a decision. Based on the information collected in the measure phase, decisions are made here as to what is causing the business pain described in the define phase.

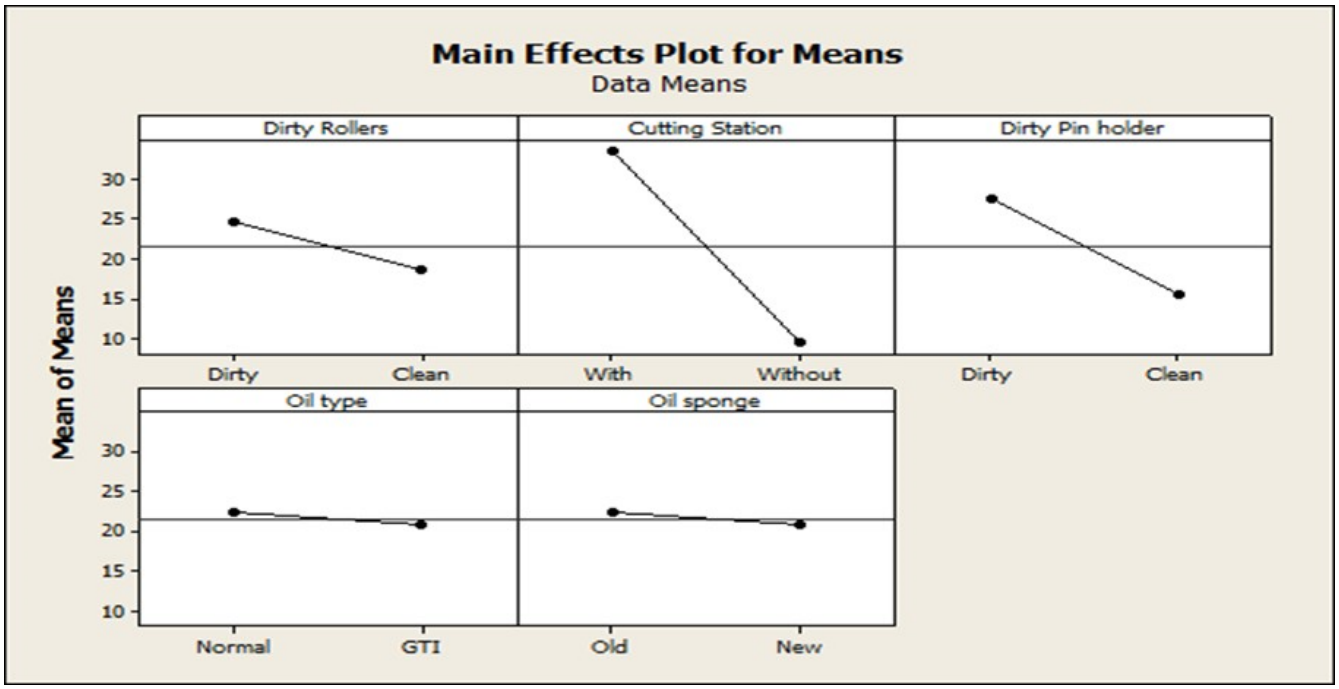
Improve phase: Fix/improve the process. Various possible solutions are analyzed and tested to confirm elimination of the business pain.

Control phase: Stable and predictable process. PDCA (Plan-Do- Check-Act) process controls are placed within the process to react on leading indicators (found during the analyze phase) which have a direct impact on the business pain (lagging indicator).

THE RESULTS

ROOT CAUSE

After having conducted a Tugushi Design of Experiment, it was confirmed that the black spots are formed by combining opportunity and introduction of a contaminate.



The opportunity, air bubbles and rough surface in and on the syringe tip, are inherent to the syringe manufacturing process by: heating up, roll forming, and cutting the glass.

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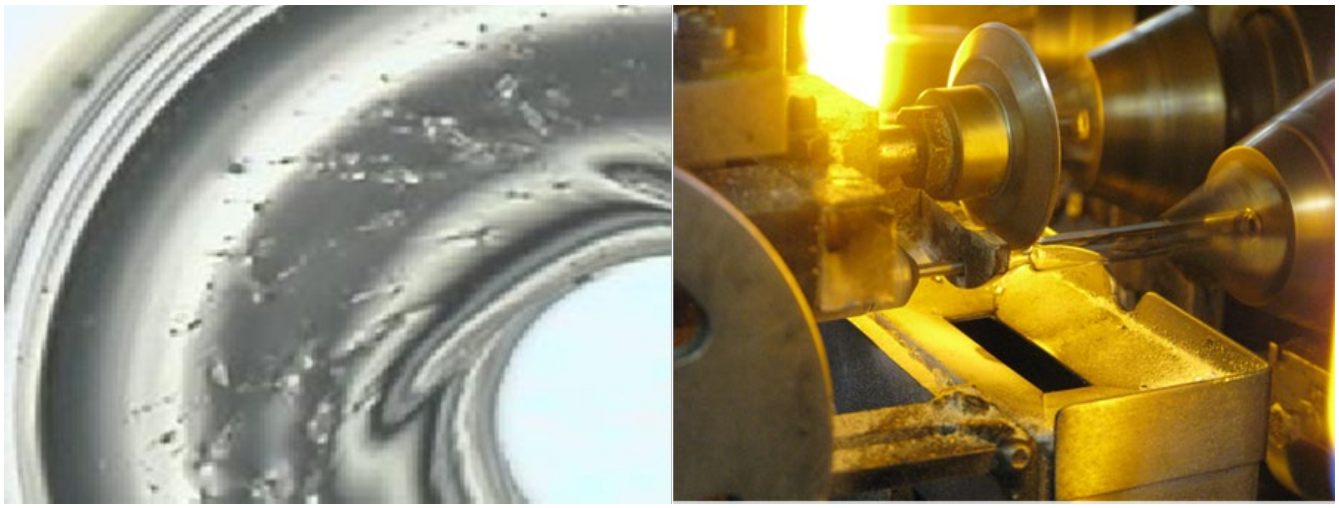

When these tiny air bubbles and rough surfaces come in contact with a surface contaminant, such as the lubricated on forming rolls and lure cone forming station, the contaminant is then transferred to the syringe tip. The contaminant, oil lubricant, is also inherent to the syringe manufacturing process. Oil lubricant must be used on forming rollers to avoid glass sticking to rollers.

To reduce the probability of providing the opportunity, the following improvements have been made:

Proper flame adjustment (heat and position of flame)

- Position (up-down, left-right, front-back)
- Heat (gas-oxygen ratio)

Cutting station
- Exchanging and sharpening actual cutting wheel at predetermined intervals

To reduce the probability of providing the contaminant, the following improvements have been made:

Cleaning and maintaining roll forming station at predetermined intervals

- Exchanging oil lubricant sponge
- Removing built-up oil lubricant deposits on forming wheels

Cleaning and maintaining lure cone forming station at predetermined intervals

- Exchanging forming needle
- Removing built-up oil lubricant deposits on forming needle holder

Ensuring proper and clean oil lubricant is used

Final Results

From an initial 100'000 ppm defect rate (10%), a goal of 100 ppm's (0.001%) defect rate was set. Final process capability of 38 ppm's (0.00038%) was accomplished.

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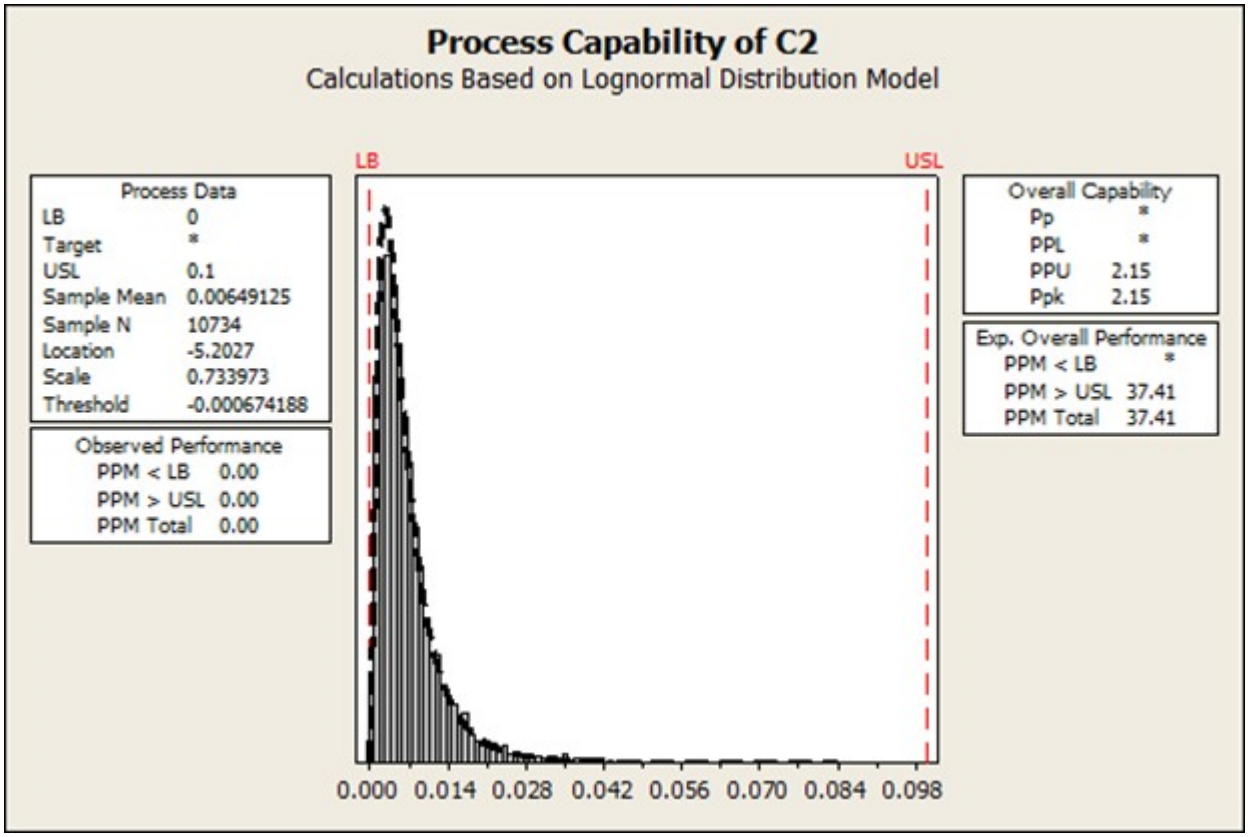

Client testimonial

"In an effort to ensure patient safety and meeting health authority requirements, this matter was costing us millions of Swiss Francs a month. SECORA was able to contain, pinpoint, resolve, and eliminate this issue without interfering with operations. The structured way and data driven decisions SECORA used to remove this problem convinced the FDA the issue was resolved, which allowed us to continue to supply the market and of course the ultimate safety to patience".

Project Sponsor