

# Design Improvement and Installation of Syringe-Feeding Machine to Satisfy new FDA Standards



**STERLING**  
PHARMA/MEDICAL DIVISION

## SITUATION

Due to a change in requirements by the FDA, an improved process for transferring glass syringes was necessary. The change mandated that there would be zero tolerance for any damaged units.

- The existing machine would occasionally crack or shatter a glass syringe.
- The new FDA regulations required their handling process, which had previously been operating within code, to be improved.
- They did not have the engineering capabilities required to design and implement the changes necessary to continue operating legally.

## STERLING SOLUTION

After careful evaluation, a plan was implemented to redesign the syringe-handling portion of the assembly machine.

- The handling portion was completely redesigned in 3D with the collaboration of the client and lead builder.
- In addition to the redesign, Sterling Engineers oversaw the fabrication and installation of the new section of the machine.

## RESULTS

The redesigned syringe handling section of the machinery met the strict new FDA regulations mandating zero tolerance for any damage to the units. In addition to meeting these standards, the new design had the additional benefit of increased efficiency because the machine no longer had to be stopped to remove broken glass.

## PROJECT SNAPSHOT

- ❖ *New FDA regulations forced a medical products company to update its syringe manufacturing process.*
- ❖ *Sterling redesigned and assisted with implementing the updated portion of the machinery.*
- ❖ *With the new design by Sterling, their process met the updated FDA regulations, and had a positive side-effect of increased production efficiency.*

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