

Pharmaceutical Anti-Counterfeiting US Federal Law Requires Pharmaceutical Packaging to have Unique Serial Numbers by Nov. 2017



SITUATION

Several clients, who are leading pharmaceutical manufacturers, are retrofitting all their packaging lines globally to meet the new serialization requirements.

- US deadline is November, 2017. If Packages are not serialized by the deadline, the products cannot be sold.
- Several countries such as China, Turkey, South Korea, and Brazil have serialization requirements earlier than the US deadline.
- Increasing demand for personnel with expertise in this area and the large scope of projects needed to meet these requirements, are impacting available resources. Companies are competing for the available resources. As implementation deadlines approach, some companies will be left without the resources necessary to meet the requirements.

STERLING SOLUTION

Prove program management for the overall projects.

- Created a team including mechanical controls, and packaging equipment and packaging design engineers.
- This team supports projects worldwide to meet the US and rest of world serialization requirements.

RESULTS

Sterling has been able to provide the program management and the expertise to complete the projects before the various deadlines.

- Providing leadership to develop multi-year budgets and schedules to meet the governmental requirements.
- With Sterling Engineering's strategic alliances, a customized turnkey serialization solution can be provided.

PROJECT SNAPSHOT

- ❖ *Set up global teams of integration engineers to address a significant number of line upgrades in a very limited amount of time.*
- ❖ *Provide project management for serialization projects.*
- ❖ *Packaging lines modified with vision cameras, printers, and line level software.*
- ❖ *IT systems implemented to obtain serial numbers from SAP and load to line level software.*

SEI PROJECT#: 12168