

## Customer case

Type of production	Filling and terminal sterilization of nested syringes
Project	Phased implementation of loading/unloading of sterilizers, starting with manual handling and continue to fully automated handling. Green-field project.
CL's scope	<p>Conceptual study and flow analysis</p> <p>The scope of delivery included:</p> <ul style="list-style-type: none"> <li>- Value Stream Analysis of existing production line</li> <li>- User Requirement Specification</li> <li>- Functional Specification</li> <li>- Future work flow based on the result of the Value Stream Analysis</li> <li>- 2D &amp; 3D Layouts</li> <li>- Capacity calculation</li> <li>- Controls architecture</li> <li>- Detail drawings of interest; i.e. Grippers</li> <li>- Risk analysis - GMP requirements</li> <li>- Fixed price Quotation (from Detailed design to take over on site)</li> <li>- Quality and Project plan (draft) (with IQ /OQ, FAT/SAT activities)</li> <li>- Recommendations (Important issues, next phase – Key timeline)</li> </ul>
Project time	8 weeks for pre-study
Results achieved	A good basis for budgeting and RFQ not only from a technical perspective but also from a GMP perspective and project execution perspective.
Effects	<p>The 2D and 3D drawings became an important input to the business case to for management visualize the future manual handling and fully automated handling.</p> <p>One effect of the pre-study was global coordination between the Europe site and the US site. The global coordination enabled the possibility to have future global standardization and standardized procedures.</p>
Challenges	<p>The customer's organization was initially situated in France but during the project the new organization was built up in US. During the time period for the pre-study a handover was done between the existing and the new organization. This created challenges such as stakeholders divided to different continents, requirement changes late in the project and potentially difficulties to get requirements confirmed. The challenge was identified during the project risk assessment and already in an early phase of the project risk reduction actions. With CL's experience from global projects, existing routines and project execution model this risk could be eliminated.</p> <p>The facility was under construction for the time of the pre-study which included challenges such as coordination with re-building project and basic requirements that changed during the projects time line.</p> <p>Another challenge for this pre-study was to find a method for a phased implementation that was possible to implement, test and validate during an ongoing manual handling.</p>