

Dr. Gunther Roiss Version 2022		Project Management, LEAN, OPEX, 6-Sigma, Stabilizations, Continuous Improvement, OEE, RFT, Pharma, Automotive, Medical Device, SOP Training, Lead Time Reduction, Productivity Improvement, Interim Management, GMP, Solida, Quality Management, DIN EN ISO 13485:2016				More info: www.roiss.ch
Selection of representative projects of the last 15 years						
Project No.	Period	Category	Project title	Project description	Activities	Results
14	4 months	Production, Quality Assurance, GMP	Throughput time reduction of quality events (deviations, capas, etc.) in a pharmaceutical plant (Solida)	At a pharmaceutical contract manufacturer, quality events led to delivery delays. The situation was to be analyzed and a new effective system for faster processing of quality events was to be designed and implemented.	Voice of the Customer analysis, employee survey, on-site problem analysis, setting up a change management process. Introduction of basic LEAN methods, introduction of a store floor management system, communication exercises, development of key figures, training of employees.	Both the processing speed and the quality of the processing have improved significantly. Prioritization has been significantly reduced.
13	5 months	Chemical-pharmaceutical analysis laboratory, GMP	Process organization in a pharmaceutical-chemical laboratory under GMP conditions	Process improvements were to be implemented in a chemical analysis laboratory for pharmaceuticals. The focus was on internal communication and prioritization of tasks.	Voice of the Customer analysis, on-site problem analysis, implementation of a change management process. Introduction of basic LEAN methods, introduction of a store floor management system, problem solving processes, new planning system in the laboratory using T-cards and magnetic boards, training of employees, training of coordinators.	Communication between the management level, coordinators and employees has become significantly faster and improved. This has resulted in faster sample throughput and fewer organizational quality events.
12	12 months	Medical Device, GMP	Engineering: Process development of an automated visual quality control in the micro range for a 3-shift operation	In a physical analysis laboratory, the production of microcomponents for heart implants was to be optically monitored with a high number of personnel. The task was to develop a standardized, fully automatic optical inspection machine, finalize the specifications and initiate the order.	Familiarization with microtechniques, familiarization with testing procedures, preliminary analyses carried out, use of artificial intelligence for analysis evaluated, analysis of worldwide companies for optical microanalysis, error catalog drawn up, specifications for feasibility study drawn up, selection of several companies, visits to companies, trial work carried out and evaluated, specifications and quotation for testing machine drawn up, quotations evaluated, ordering of testing machine order including validation initiated.	The testing machine was delivered approximately 12 months after the order was placed.
11	5 months	Packaging, GMP	Task force packaging of pharmaceuticals	At a well-known drug manufacturer, the head of packaging (production, 6 packaging lines) dropped out at short notice. The transition had to be guaranteed until a new person was appointed. For this purpose, all processes and current problems had to be recorded and evaluated for real risks on several levels.	Process analysis, organization analysis, analysis of GMP relevant steps, documentation analysis, SOP analysis, customer analysis. All lists, problems, to-dos, etc. were brought together. Afterwards an own prioritization system was developed and the processing was coordinated with 6 subproject managers. In parallel, the planning of the packaging machines was changed. Reporting to the plant management.	Slowly, the delivery situation improved. The new packaging manager was able to continue the system set up and stabilize the packaging.
10	17 months	Physical analysis laboratory, GMP	Ensure permanent audit readiness of a chemical laboratory.	One physical laboratory had repeatedly attracted negative attention during audits. It was necessary to restore an audit-proof overall condition. This was done by visual store floor management including planning management.	Voice of the Customer analysis, on-site problem analysis, setting up a change management process. Introduction of basic LEAN methods, introduction of a store floor management system, introduction of visual basic planning. Rework of SOPs, training of employees in workshops and Powerpoint. GEMBA tours with management and customers. Training of employees to react flexibly and in a structured way to customer requests.	The lab received positive praise in two independently conducted audits and now serves as a best practice example of positive change management plant-wide.
9	17 months	Laboratory, GMP	Interim laboratory manager	In a chemical-physical laboratory with a focus on medical devices, the laboratory manager function was carried out on an interim basis for several months.	Management of approx. 10 employees, evaluation of analysis results, preparation of SOPs, CAPA processing, evaluation of deviations, ordering, budget control, outsourcing of analyses, safety officer.	Laboratory operations were successfully maintained until a new laboratory manager was appointed.

8	10 months	Laboratory, GMP	Throughput time reduction of analyses in a pharmaceutical-chemical laboratory under GMP conditions	In a chemical laboratory in daily operation with approx. 20 employees, which is responsible for the release tests of the production, the lead time of the individual releases should be reduced significantly.	Process analysis, organizational analysis, analysis of GMP-relevant steps, documentation analysis, SOP analysis, customer analysis. After the analysis phase, the project had to be divided into 2 projects, both of which ran for several months. Selection of personnel, support of personnel development, customer negotiations, redesign of SOPs, simplification of tests, processing of CAPAs, facilitation of documentation, development of a uniform communication structure, development of structured time modules, development of a store floor management system including whiteboard, management of laboratories, training of laboratory managers.	Turnaround time was reduced by 8 days and 60% respectively at the end of the two projects. See attached graphs.
7	13 months	production, GMP, machine optimization	Bottleneck management in a production plant of the pharmaceutical industry and production increase in the GMP area	A packaging machine for pharmaceuticals had only 30% OEE availability and was therefore the supply-determining bottleneck in the entire plant network. Internal departmental measures taken in advance were ineffective.	Training of employees, preparation of training documents, management and coordination of a 3-shift operation, technical weak point analysis, organizational weak point analysis, FMEA analyses, realistic target setting, action plan, monitoring of the implementations in the GMP area, presentation of the results to the plant management.	Resolved the bottleneck, increasing OEE availability to 70%.
6	5 months	production, GMP	Create and conduct departmental training series.	For the onboarding within the department, a training plan as well as several training courses necessary for the department were to be created and carried out. For this purpose, the existing technical knowledge, such as onboarding and offboarding, correct dressing, as well as production-specific knowledge, was to be prepared in a didactic manner and effectively conveyed.	Analysis of the existing training concept. Preparation of the SOPs in PowerPoint slides and in practical preliminary exercises. Setting up various mockups for training purposes. Selection of several internal and external co-trainers. Establishment of a new training culture for employees and managers in production. Cooperation with the TWI institute. Audit-compliant documentation.	The training concept was successfully implemented and is still in operation today. Other departments have copied this onboarding and training system because of its success.
5	16 months	production, GMP	Increase right-first-time rate in a galenic pharmaceutical plant under GMP conditions (solids).	In a galenic mass production in 3-shift operation with a total of approx. 120 employees (with high personnel fluctuation), the error rate was to be reduced and thus the Right-First-Time (RFT) rate increased.	Urash analysis using Fischbone, evaluation with Pareto and creation of a value stream. Simplification of key figures. Making key figures transparent. Timely (daily) informing of key figures. Weekly problem discussion and follow-up training in small groups. Processing CAPAs, supervising batch releases, establishing structured communication on the store floor. Gradual integration of support and neighboring areas such as maintenance and quality control. Training of basic elements in leadership behavior with foremen and supervisors.	The error rate was reduced by 90% within the 9 month project period. The Right-First-Time (RFT) rate increased by several 100%.
4	12 months	Production, automotive	Reducing a shift in an automotive environment (United Kingdom).	In a production plant with approx. 500 employees, savings were to be made in order to remain marketable. For this purpose, a 3-shift operation had to be reduced to a 2-shift operation while maintaining the same output.	Balancing project with classic project structure (time, capacity, budget). The takt rates deposited in the finance department were checked by an actual survey and the new financially required takt rates were determined. Then each clock cell was analyzed individually, optimized and then re-clocked out. Bottleneck processes were outsourced to a side line. Supply logistics were completely segregated and adapted.	The conversion was successful. The required savings were realized. The company is still in the market today.
3	12 months	Planning, automotive	Planning of a factory for fuel cell drives with unknown sales figures.	At a German car manufacturer, the sales department was unable to provide target figures for fuel cell vehicle sales. There were too many unknown factors in this new segment. The board still needed a ready plan for a factory in case demand increased.	Analysis of the various strategic customer and sales scenarios. It was impossible for the sales department to realistically evaluate this new market segment. The plant, hall and production planners urgently needed an estimated sales volume to be able to plan a new factory. Strategic storage areas including delivery systems (JIS, JIT, Kanban) were designed. Analysis of stakeholders and their interests. Establishment of a decision-making body. Involvement of international experts. In numerous rounds of talks, a modular production method based on LEAN methods was implemented. Study trips abroad to similar production methods (of different products). Creation and presentation of a white paper and construction of a modular production line as a mockup.	The new planning concept attracted attention and approval throughout the group. A module was realized as a mockup and presented to the management (board).

2	9 months	Production, automotive	Technology transfer of technical equipment between two sites	A German car manufacturer needed to move a complex processing line from a domestic site to a foreign site. The ongoing production of the downstream customer process was not to be jeopardized.	Analysis of different production and sales scenarios. Risk analysis in case of non-delivery. Set-up of a strategic parts warehouse. Compilation of the transfer team, training of future employees at the German site. Preparation of the new site. Set-up of the daily project workshop. Supervision of the dismantling work. Supervision of the transport. Supervision of erection at new site. Commissioning of the plant. Start-up schedule of the plant. Various adjustments to local mentality and conditions at the new location. Monitoring of total costs. Flexible troubleshooting. Transfer of project shop floor to line shop floor.	The plant was successfully relocated. The key production figures were achieved. The downstream process (customer process) was not disrupted.
1	24 months	Production, Laboratory, Machine Optimization	Improvement of quality and productivity of various technical machines.	Several projects were carried out to increase the quality of the product or the productivity of the (partly interlinked) production or analysis machines.	Various 6-Sigma and LEAN methods such as as-is analyses, multi-moment surveys, SAKT, QCO, SMED, target analyses, Ishikawa analyses, Pareto analyses, action lists, 5S, 3W, PDCA cycles, stabilization phases, training of employees, presentation of results.	In all projects, significant success was achieved in the area of quality improvement and/or productivity increase.