TARGUS Expertise in Pharmaceutical and Medical Devices Industry

Successful with tailored solutions

TARGUS works.

TARGUS Management Consulting

TARGUS Expertise

Pharmaceutical and Medical Devices Industry

Our aim is to be the industry's leading consulting company for operations in the pharmaceutical and medical devices industry. Since its founding in 2001, TARGUS has gained substantial experience and expertise in more than 100 projects covering the entire value chain. The selected project examples in this brochure provide an overview of our experience and way of working.

TABLE OF CONTENTS

Proven Benefits through Top Performance

Success through tailored solutions and implementation focus

Competitive advantages cannot be gained with standardized approaches or theoretical concepts. Long-term success requires individually designed solutions and strong, target-oriented implementation skills.

Being ready for the future

Within the past few years, worldwide sales of prescribed medicines and medical devices have increased steadily with CAGRs of 3-5%. Projections show a stronger increase for the next years with the main growth driver being the US market.

Nevertheless, companies in the pharmaceutical and medical device industry are facing major disruptions in the market. Regulatory authorities – foremost the FDA – are raising standards in manufacturing practices and documentation while introducing new requirements like serialization. Organizations must develop new skills and capabilities to stay compliant in this heavily regulated industry.

Sales of generics and biosimilars are growing rapidly in the pharmaceutical industry, attracting competition and increasing cost pressures. Furthermore, the constant customization / specialization of drugs is reducing batch quantities and lowering economies of scale in manufacturing.

The aging population, driven by declining fertility rates and increasing life expectancy, represents a major demand driver for medical devices. Growing markets are attracting competition and driving new innovations. Today, many segments in the medical device industry are facing disruption by rising technologies like 3D printing and wearables. These innovations will force many companies to rethink their manufacturing strategies and to build new capabilities like Big Data.

Given the traditionally high margins and cash reserves of major players, mergers and acquisitions are a constant factor in both the pharmaceutical and the medical devices industry. To manage M&A activities professionally, companies have to develop specific skills and the capability to ensure proper execution. With tailored approaches, methods and tools, we have helped numerous companies in the pharmaceutical and medical devises industries improve the competitiveness in the market. Our clients range from well-known global conglomerates to mid-sized, hidden champions in the field.

Sustainable results are a matter of tailored solutions and strong focus on implementation. Our experienced consultants bring both management consulting and management expertise.

General Project Expertise

- R&D
- Procurement
- Production
- Quality / Compliance
- Logistics / SCM
- Sales
- Due Diligence and PMI
- Factory Planning and PMO Strategy

Experience in Pharmaceutical industry

- Solid dosage forms
- IV drugs
- Standard solutions
- Parentaral nutrition
- Enteral nutrition
- Components

Experience in Medical devices industry

- Medical instruments
- Infusion devices
- Disposables
- Transfusion systems
- Dialysis machines

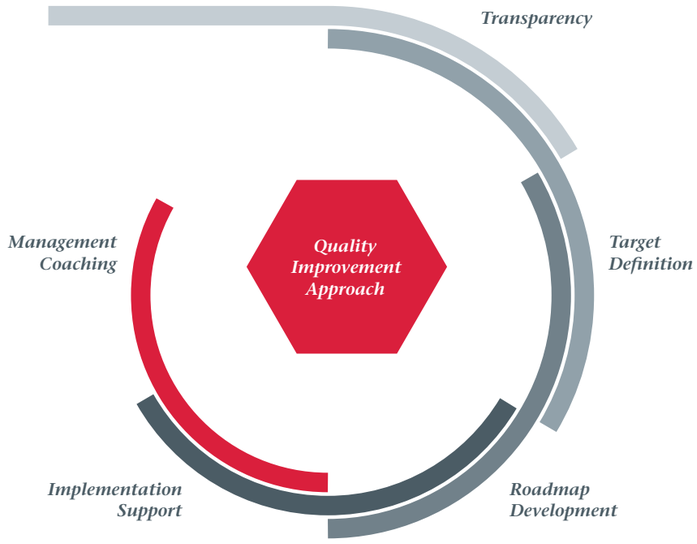
Quality Improvements

Sustaining competitiveness is critical in today's pharmaceutical world beset with market shortages and market consolidation. It is necessary to maintain an efficient and streamlined quality organization to provide high-quality products to the market on time. We have supported US pharmaceutical organizations by setting up initiatives with their quality management teams that have yielded multiple new product approvals from the FDA since the completion of the project.

We began by focusing on creating overall transparency of the current quality organization to identify deficiencies in processes, quality metrics & reporting structure. Together with management, we identified Time-to-Release and "Right First Time" as the as the KPIs with the greatest impact to the organization. We developed activity roadmaps around each key measure. We supported the managers to drive these changes in their departments to ensure sustainability of the new standards.

Project results

- Quantitative transparency of release performance
- Defined quality KPI system with monitoring and visualization
- Improvement roadmaps leading to 45% increase in batches without deviations
- Reorganization concept of MQA to ensure more floor oversight



Roadmap for Success

A European pharmaceutical and medical device company's American facilities have shown insufficient results. Key performance indicators in the manufacturing, quality and supply chain area were decreasing over several years.

To turn around the negative trends, TARGUS supported the plant teams to develop and implement a roadmap to success. After an initial screening and assessment of the plants, the key areas for improvement have been aligned with the management team. The main action fields were to improve manufacturing productivity and yield, production planning, and speed of batch releases.

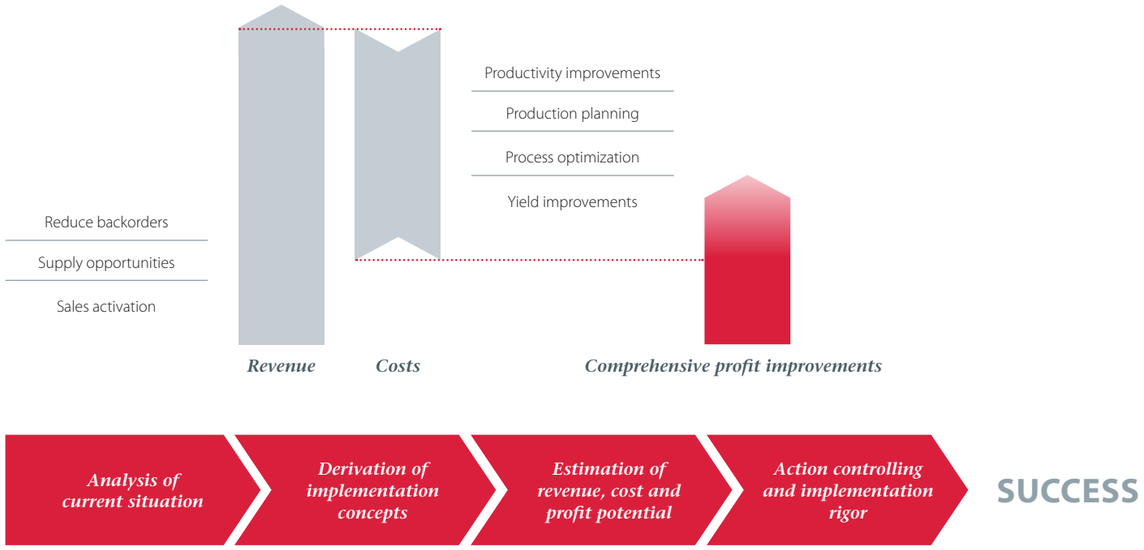
Transparency in key areas was established and losses in the operational execution were quantified and visualized. From this transparency, the facility team could develop their roadmap for success. To underline commitment, the team signed the roadmap and submitted it to the global leadership team.

The roadmap was challenging and involved organizational changes as well as technical and process-related improvements.

Based on the improved planning and performance, the plants were capable of supplying the market demand and also fulfill short term drug shortages.

Project results

- 35-40% output increase with existing equipment
- Back order reduction of > 80%
- Batch release process improvements
- Improvements in all relevant quality KPI
- Roadmap process integrated in annual strategy cycle



Material Cost Management in Pharmaceutical Plants

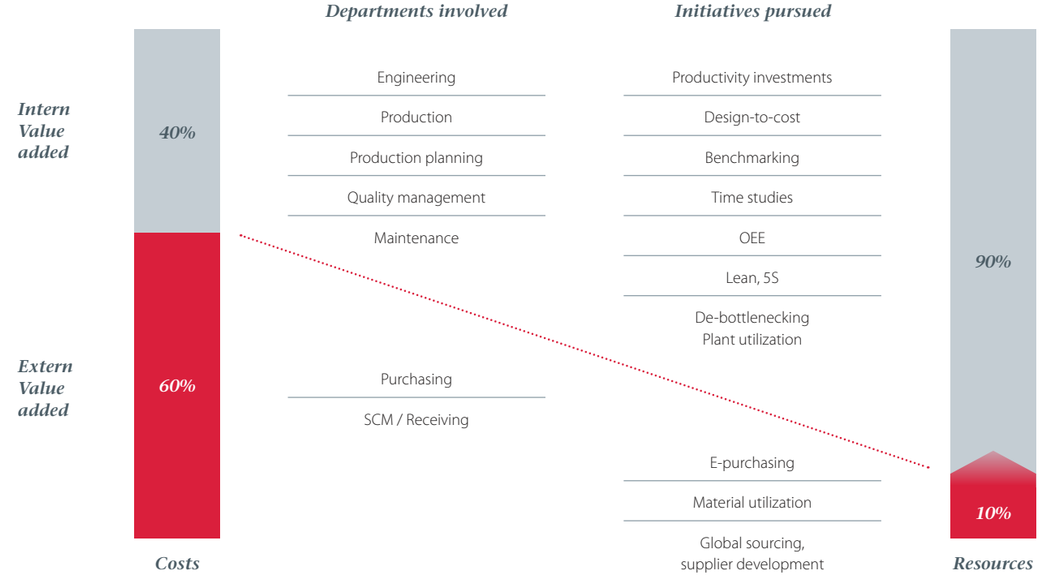
Finding ways to reduce costs in heavily regulated environments can be challenging, however our projects to reduce external spending are always successful. The benefits extend beyond just cost reduction, as our holistic approach engages a large cross section of cost-stakeholders leading to synergies outside the balance sheet success stems from the mobilization of the entire organization across all departments such as R&D, filling, and quality. Our proven, stringent approach allows for fast savings, efficiencies in production planning and management, and performance.

In the pharmaceutical industry complex initiatives are more difficult to change quickly due to regulatory hurdles. Still, we have proven in many projects around the globe that significant savings can be found if all levers (consumption, technology and sourcing) are investigated thoroughly by cross-functional teams guided by our experienced consultants.

Overall reductions in external spend of 5% to > 20% have been realized in projects such as medical device components, glass vials, and packaging materials. The execution needs to be planned with a 1-3 year horizon and efficient and detailed savings monitoring must be implemented and managed by the client.

Project results

- Reductions in external spend of up to 20%
- 1-3 year realization of savings
- Operational synergies across engineering, sourcing, manufacturing, and quality



Operational Due Diligence

Mergers and acquisitions are vital to the growth of pharmaceutical companies, yet roughly half of all M&As fail to achieve expectations. M&A decisions are often based on traditional disciplines: commercial, financial and legal factors when operational performance and development potential are often underestimated.

Based on our substantial experience in operations in the pharmaceutical and medical devices industry, TARGUS offers a different view on transaction targets. We focus on core operations which are crucial for the future success of the business.

Through management interviews and plant visits the current status is being evaluated. Based on the individual circumstances of each deal structure and the parties involved, we focus on core operational performance and improvement potential which have significant impact on the revenue and cost basis of the company.

Frequently used screenings are:

- Material cost reduction potential in procurement
- Product cost evaluation and improvement potential
- Manufacturing processes and strategy
- Plant network evaluation
- Process performance in indirect areas
- Supply Chain Management

Based on these initial screenings, strengths and weaknesses in the operations of the company are identified and provide further information to derive conclusions on transaction value.

In the following pre- and post-merger integration phases, TARGUS has setup PMI offices for clients and guided those organizations through an efficient and goal-oriented integration process.

Project Results

- Quantified improvement opportunities in operations
- Strengths and weaknesses profile in each area
- Status quo evaluation
- Capability assessment
- Risk profile overview

Organizational Design for R&D

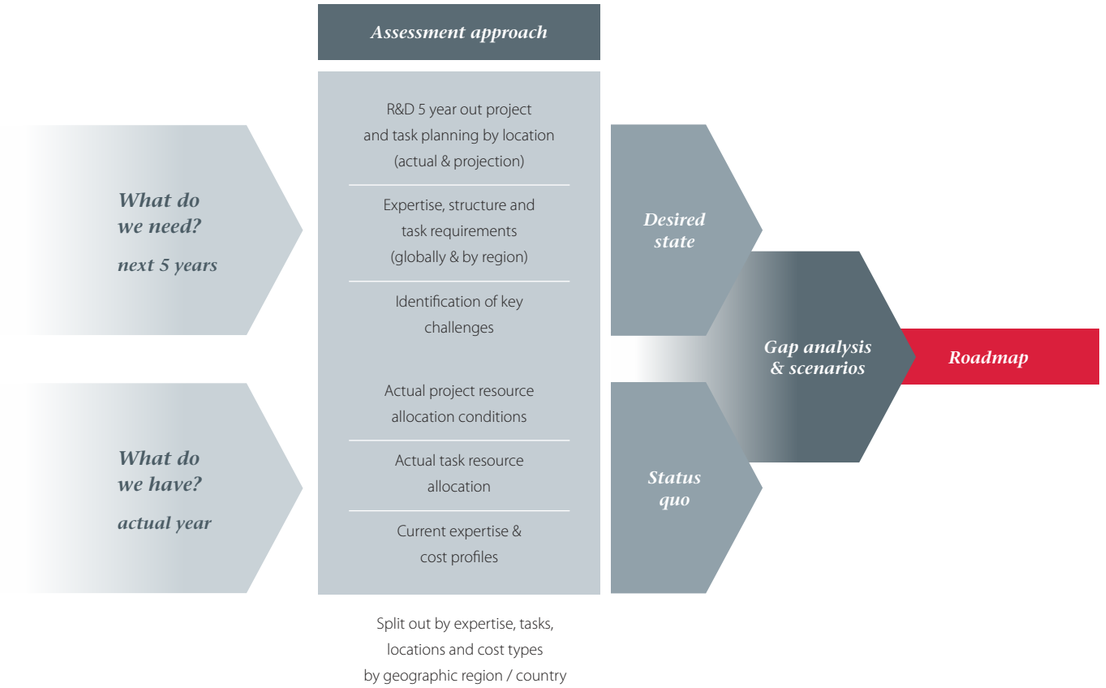
R&D is often described as the motor of growth for any pharmaceutical company. A critical asset which is not always transparent in its performance or the justification of its costs in both budget as well as headcount.

Many pharmaceutical companies struggle understanding the adequate resource needs of R&D and the global network which supports it. In many cases, the optimal design of the R&D network organization will play a crucial role in achieving industry leading results. Our methodology enables performance through timely delivery of the planned product pipeline, ensures efficiency by executing launches on time and in-budget, and builds equity, reinforcing R&D as a key driver of overall sustainable company value.

We accomplished this at one customer through a three-step methodology: Create transparency of the global R&D network with regard to resources, capabilities, capacities, and costs. Make a gap analysis between the status quo and the desired state and propose a scenario that enables the development of a roadmap to close the gap.

Project Results

- Total cost transparency of R&D
- Capability and knowledge profile
- Capacity evaluation and requirements
- Capacity utilization improvement
- Performance enhancement and efficiency improvements
- Network concept for geographic expansion
- Global R&D management structure



Project Management Office

In this growing industry environment, it is necessary for companies to execute strategic growth projects, while concurrently managing their day-to-day business. To do this, it is important to have experts or external support who can smoothly connect the existing critical operations of the business with the long-term vision of the organization as it grows its footprint.

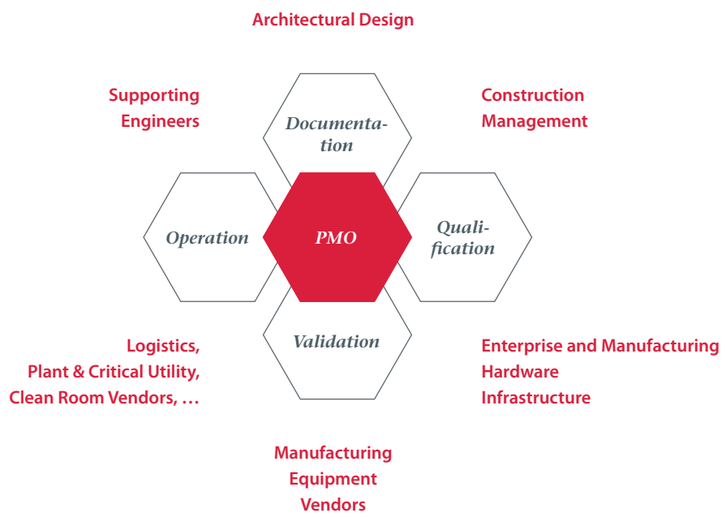
The TARGUS PMO portfolio has been well established in the pharmaceutical industry with successful factory planning and process optimization project accomplishments. We have led several expansions and new construction projects involving standard solution IV drugs to single and multi-dose generic and specialty medicines.

Our team is capable of managing plant design, critical utility layout, clean room design, as well as complex line designs involving filling, formulation or lyophilization equipment.

We have successfully managed entire projects from design through validation and qualification of new lines, navigating teams through the complexity of FDA documentation requirements. Our strength is that we link the pharmaceutical experts with the necessary plant design architecture to bring the new facility to a world class level on schedule.

Project Results

- Full transparency of project status
- Active critical path management
- Clear project success metrics
- Forward looking project management routines
- Target group focused visualization



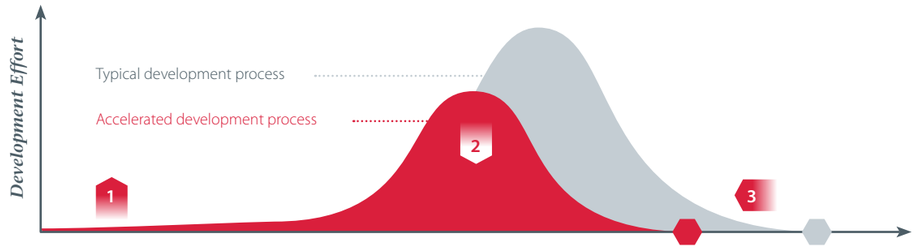
Lean Innovation and Efficient Product Design

In the face of a steadily increasing complexity, it becomes harder and harder to meet the time and budget goals of development projects. The problem is even more evident if you have several projects running in parallel. Therefore, it is of utmost importance to focus on the reduction of "waste" in the course of the projects. "Waste" may appear in form of unnecessary process steps or duplication work-steps due to redundant project components.

In order to counter "waste" in your projects, we offer the method "Efficient Product Development" (EPD). With EPD you optimize the use of your resources and increase the efficiency of your R&D efforts. By increasing the efforts put into the project setup, e.g. in standards and process definition, you obtain a robust framework for your project. In consequence, we are able to reduce the average total effort of R&D projects and their duration by 20-40%.

Project Results

- Shortened project run time by up to 40%
- Reduction of Technical and engineering resource
- Smoother adoption of the project plan
- Increased speed to market and project turnover



1. Increased initial efforts

- Clear targets for time and results
- Effective basic design
- High level of concept quality
- Improved process steering
- Definition of standards

2. Reduction in total effort

- Reduction of technical changes (which can account for up to 40% of total cost)
- Early involvement of upper management
- Support of creativity and methodology

3. Shortened project run time

- Interdisciplinary networking
- Process parallelization
- Early identification of problems and measures
- Use of hidden resources, e.g. expert knowledge

Project Management System

Often, numerous and parallel projects in R&D, sales, production, and supply chain are the norm in medical device organizations. This requires a fact-based project initiation and implementation supported by a solid decision structure with specific routines. Resource allocation over the whole organization is an important task that requires special attention due to the interdisciplinary nature of almost any major project.

To support this task, we developed a holistic approach to multi-project management based on PMI / IPMA standards. The system is realized as easy-to-use Excel-based software solution which serves management with core information specific to each project. Inside the software package, there are templates for project initiation with fact-based decision logic, project planning and follow-ups based on task dependencies, financial targets, and resource planning. Other visualized topics include critical risk, financial, task, and resource statuses. All of these can be replicated over multiple departments within a greater company level project.

The tool is the basis for productive project team discussions and top management decisions. Once introduced and, if used consistently, it defines the standard for successful project management in the company.

Project Results

- Simplified executive communication tool
- Visualization of project task and metric tracking
- Identification of executional and financial risks
- Simple and sustainable status dashboard for all management levels

Cultural Change and Turnaround in Operations

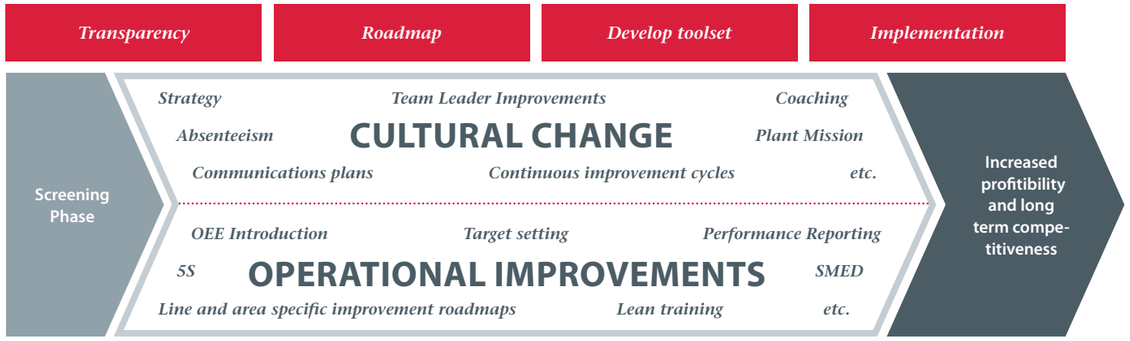
An international acting producer of medical devices acquired a plant for blood processing products. After the acquisition from a non-profit organization, a project was launched to improve the operational performance in production and TARGUS was asked to support the change process. After the clearing phase, it became very clear that in addition to operational improvements, intensive work had to be invested in the cultural transformation of the plant.

We started the project with the implementation of selected modules from the TARGUS OpEx toolbox, such as OEE performance measuring, 5S and SMED. Additionally, several measures to change the culture and to improve the organization were set up. Successful examples are a team leader improvement plan, a communication plan, an absenteeism reduction campaign and the launch of a new employee scheme system “Ideenbus”.

Together with the management team a new mission statement was developed and communicated to all employees.

Project Results

- Successful Cultural Change
- Absenteeism reduction from 15% to 5%
- Productivity increase by 5-15%
- Implemented set of OpEx Tools
- Significant productivity increases leading to lower personnel costs



Lean Overhead

As pharmaceutical and medical device manufacturers grow through acquisitions and rapid expansion, the ballooning corporate structure will lead to duplication of resources and redundancy throughout the greater organization. Removing this redundancy and finding efficiency improvements are the key drivers for a Lean Overhead project.

Targus consultants analyze the project scope with a function matrix to gain a solid understanding of current processes. This is followed by a collaborative effort with the customer team to unearth hidden inefficiencies. Following the identification and elimination of “waste” (non-value-added activities), the organization is reduced to its essentials. Top management must be involved from the start and engaged throughout the process in order to make such an initiative a success. Hence, clear targets and comprehensible reasoning from top management are integral factors for success and increase organizational acceptance. Our years of experience implementing lean initiatives enable optimized customer processes and improve organizational acceptance.

Especially successful have been projects in the field of QA/QC. The transparency driven approach reveals undisputable savings potentials in all critical processes.

Project Results

- Reduction of overhead costs by up to 30%
- Cost reduction by eliminating non-value-added activities
- Efficiency increases through process streamlining
- Clear definition of roles and responsibilities within the target organization

Indirect Spend

Even though most pharmaceutical and medical device manufacturing organizations take action on long-term investments, cost management activities across organizations mainly focus on direct materials such as APIs, primary / secondary packaging, and device components to directly support the business purpose and keep the daily business running. As well in other industries, indirect spend volumes such as IT, marketing, travel etc. are unclear. In reality, they vary between 30 and 40% of total corporate expenses. Analyzed systematically using the indirect spend optimization approach, 15-20% savings potential has been realized in several project examples. Based on our experience this applies in the same way to pharma and medical devices businesses.

The reasons for this situation are varied: Silo thinking rather than coordinated joint approach, lacking integration of purchasing down lack of qualified staffing and lacking acceptance of purchasing in general.

An indirect cost reduction project starts with a preparation and transparency phase in which we analyze the total spend volume in scope and identify all hidden cost reduction potentials. Through applying the three levers price, specification and consumption across 100% of the total baseline, we, together with the client's team, develop ideas to reduce indirect costs. These ideas are transferred into a roadmap to implement the savings.

Project Results

- Savings of 15-20%
- Realization of savings over the 3-5 years
- Roadmap to execute short and mid term measures
- Regular savings of ~3-5% per year

Preparation	*Concepts and idea generation*	*Implementation and preparation of next phase*
Team setup	Cost transparency and baseline definition	Operational implementation support
Data mining and analysis	Create cost awareness at consumer level and identify incentive	Support implementation of KPI and reporting routines into business warehouse
Survey to identify gaps and most promising levers in purchasing organization	Systematic ideas generation workshops	Planning and setup of upcoming waves (team setup, data mining, and analysis)
Setup of reporting structures and project controlling	Training and coaching of team leaders according to identified gaps	Driving definition of standards and global roll out of sustainability concept
Identify strategic boundary conditions		

Plant Network Optimization

As a result of M&A activities as well as individual expansion projects, many pharmaceutical and medical device companies operate with a production network that has grown up indiscriminately rather than through design. This leads to a combination of unused capacity and duplication of expensive production and laboratory assets, and even potential regulatory issues.

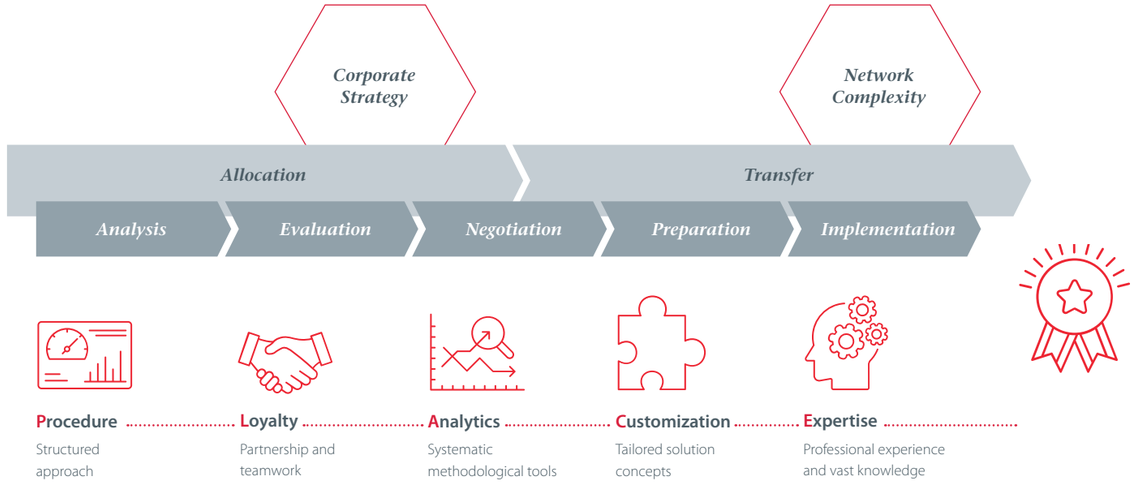
TARGUS has refined a holistic network design model to streamline the entire production footprint and significantly reduce costs. We look at all aspects of production sites and value chain, from raw material inputs through to plant utilizations.

We accomplish this by first building a comprehensive overview over all products and production including pricing, distribution, equipment, personnel and relative cost positions. Then, define several possible future scenarios using a comprehensive allocation model which evaluates utilization of all facilities. For each scenario, the main financial measures such as NPV, capital requirements and one-time-costs are calculated. An optimized scenario is proposed based on customer funding requirements and constrains which includes a product transfer overview.

The improved design results in an optimized production network consisting of clearly focused plants playing to their respective strengths and delivering value to the bottom line.

Project Results

- Data driven evaluation of optimum network design
- Cost optimized manufacturing network design
- Detailed implementation planning of stock levels, equipment, human resources, etc.
- KPI driven project implementation management
- 12% average overhead cost reduction
- 25% reduction in CAPEX



About us

Our commitment for your success:

Effective advisory, fast results and sustainable change

Who we are:

- > 50 professionals
- > 70% with background in engineering and natural sciences
- 50% have a long term industry background
- Creative thinkers with hands on mentality
- In average 10 years of experience
- In total > 500 years of experience in management and consulting

Where we work:

- In > 35 countries on 5 continents
- Wherever you need us

Our locations:

- Ratingen, Germany
- Madison Heights, USA

Quick results and real changes

Our value added

Maximum returns for our clients is the sole focus of our consulting projects – before, during, and after the conclusion of the project. We offer real value added which clearly distinguishes us from other management consultants. We ensure returns on TARGUS projects exceed the project cost by a wide margin.

The right project preparation

… is a part of our success. During a TARGUS pre-project, you have the opportunity to get acquainted with us and our methods. We use the results acquired in this step to fine tune our approach for the main project to your specific needs. This way our consultants require very short orientation time to your business.

Toolbox plus

You profit from the innovative concepts developed by our consultants which enhance our TARGUS Toolbox. Using our unique combination of many time-tested methods, we utilize synergies in your business and achieve additional savings.

TARGUS tailored

The methods from our TARGUS Toolbox are unique. They are based on proven approaches which we continually refine and enhance with our know-how. We use these concepts in detail to customize each project to your organizations needs.

Speed

We work in mixed interdisciplinary teams of experienced managers, consultants and your employees. With this bundling of proficiency we quickly achieve substantial results.

Sustainability

Developing solutions through intensive cooperation and partnership with your workforce solidify sustainable changes in your organization long into the future.

TARGUS works.

TARGUS
Management Consulting

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