

**>> MEDICINE FOR THE PHARMACEUTICAL
INDUSTRY. CUTTING COSTS IN INFRASTRUC-
TURE PROCESSES.**

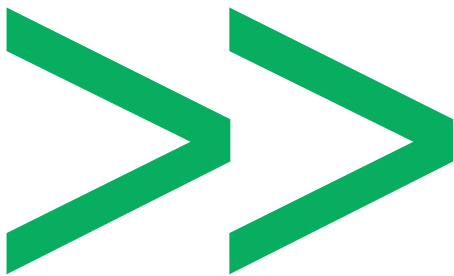
Infraserv Höchst's partnership program

>> EXECUTIVE SUMMARY.

To stay competitive, pharmaceutical companies have to explore every cost-cutting opportunity. They have already made some progress by outsourcing research, development, contract manufacturing and administrative non-core business processes to established partners.

Infrastructure processes offer additional opportunities for optimization, but they rarely receive the attention they deserve. This will have to change soon. Several pharmaceutical companies have already begun to follow in the footsteps of the chemical and manufacturing sectors and are steering their corporate ships into more cost-efficient waters.

As they embark on this new venture, pharmaceutical companies should minimize their interfaces with service providers. After all, the potential for cost-cutting correlates closely with the extent of transferred responsibility. It makes sense to partner with an infrastructure specialist such as Infraseriv Höchst, who can cover a wide range of services – as it has been doing for Sanofi, Sandoz and other partners for a long time.



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>> MEDICINE FOR THE PHARMACEUTICAL INDUSTRY.

Cost-cutting pressures affect many sectors. However, in few industries do they impact innovativeness and long-term competitiveness as immediately as in pharmaceutical manufacturing.

Much of the blame falls on the regulatory environment. Laws such as the German Pharmaceutical Market Reorganization Act (AMNOG) have greatly restricted the industry's freedom to set prices – all in the name of cutting healthcare costs. Public-sector research and development incentives are declining as well. As a result, many companies can simply no longer afford traditional research pipelines. And for highly innovative producers, the situation has only been exacerbated by the burgeoning generics market.

Conventional approaches no longer deliver enough benefits to enable pharmaceutical companies to succeed in the market. They have to slash costs across the board and streamline processes along the entire value chain if they want to survive in a highly competitive environment. This requires responsibilities to be efficiently shared with carefully chosen partners. In a word: outsourcing. Many companies have already discovered the benefits of outsourcing manufacturing, research and development processes.

However, partnerships in infrastructure processes can be just as successful, as illustrated by Industriepark Höchst. At this deeply integrated industrial estate, Infraserp Höchst, the site operator, provides services such as pharmaceutical-grade utilities, pharmaceutical production logistics and clean room services. This is an established model that transfers readily to other pharmaceutical sites and companies. We have made it our mission to share our experience and portfolio with the pharmaceutical industry in Germany, as we have done for UCB in Monheim and Novartis Vaccines in Marburg. Pharmaceutical companies can cut costs by up to 20 % if they devote their attention to their core processes and rigorously outsource non-core processes.

We hope you find this white paper to be illuminating, enlightening and informative.



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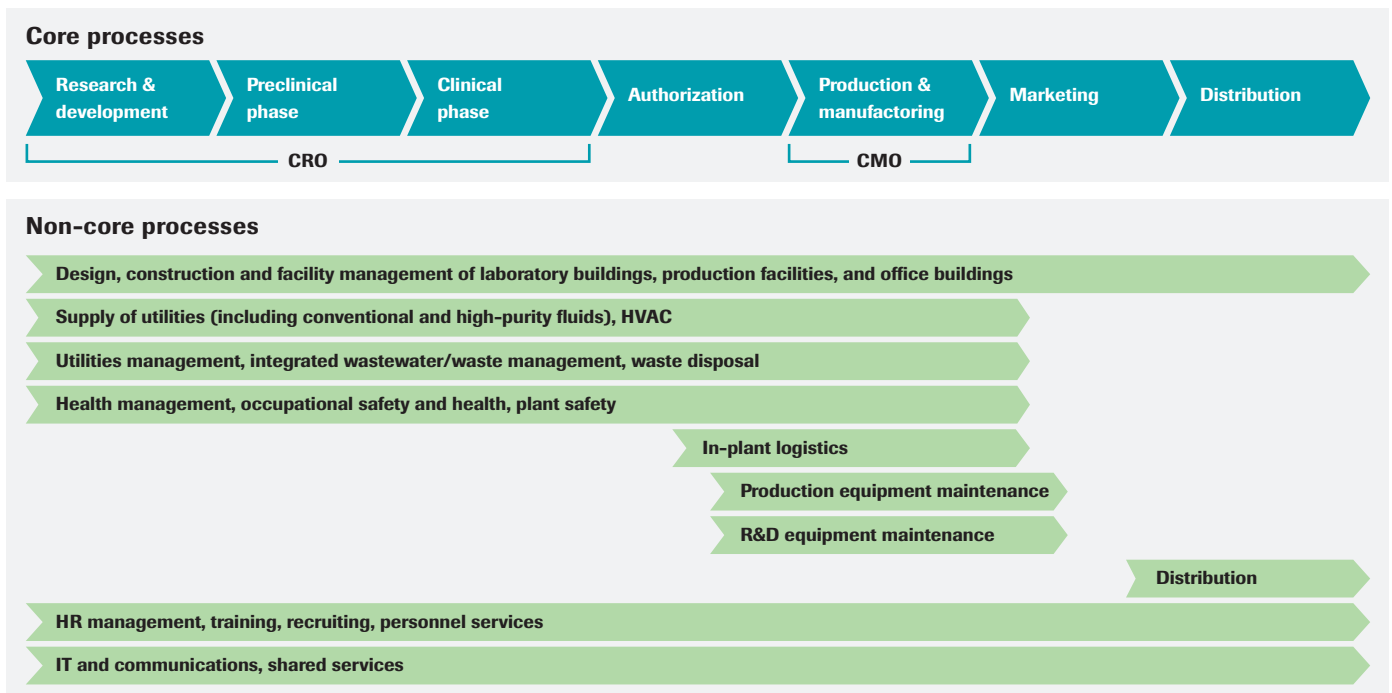
>> THE ALL-IMPORTANT QUESTION: MAKE OR BUY?

Successful partnerships have been established for many relevant core processes in the pharmaceutical industry.

Contract research organizations (CROs) can take on processes in research, product development and end-to-end execution of clinical studies, including staffing. They provide services ranging from monitoring trial sites to completely managing projects to administering the vast, complex and confidential data stocks required for the marketing authorization process. As their products move on to commercial-scale production, many pharmaceutical companies hand off the manufacturing and packaging of APIs and drugs to contract manufacturing organizations (CMOs) that are required by their customers to follow strict guidelines. These partnerships are particularly advantageous when the pharmaceutical company has not even made the product yet. It can leverage its partners' special technologies to accelerate the process instead of spending years developing the products on its own.

The pharmaceutical sector has thus demonstrated that it has the structure, organization and maturity to build and benefit from partnerships in its core processes. Industry players are now well aware of the cost savings offered by core business partnerships.

Pharmaceutical value creation, however, also involves countless non-core processes of varying complexity. Partnership models have long been established for some of these conventional non-core processes, especially administrative ones.



Typical core and non-core processes in the pharmaceutical industry

Partnerships in IT, human resources, bookkeeping, accounting, and similar processes have unleashed enormous savings. The optimization potential of non-core facility and infrastructure processes, by contrast, remains largely untapped. Here, pharmaceutical companies will ultimately have no choice but to institute the same reforms already adopted by the chemical sector and many other industries.

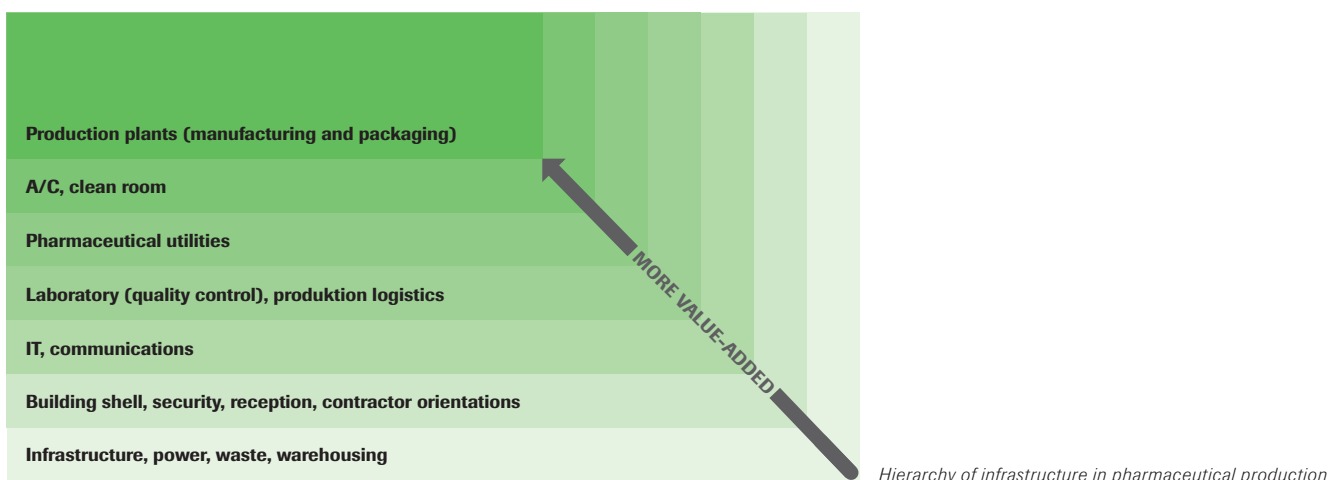
Infraserv Höchst has identified countless effective cost levers in infrastructure processes. It is time to use them. Some pharmaceutical companies have set the right course for the future and taken steps toward outsourcing site services or implementing alternative utility supply solutions. However, not all of them have embraced infrastructure optimization. This has several reasons. First, the data is spotty; there are no benchmarks. Second, most of these non-core processes have little to do with pharmaceuticals – and that does not increase companies' willingness to invest time and energy in enhancements and optimizations. Finally, existing levers are often underestimated even though infrastructure costs harbor considerable potential for savings: They account for up to 10% of production costs.

>> INFRASTRUCTURE SERVICES: IT IS ALL A MATTER OF FINDING THE RIGHT PARTNER.

Only a highly specialized partner like Infracerv Höchst can operate non-core processes to the pharmaceutical industry's demanding standards.

Since we specialize in infrastructure services, not only can we manage these processes far more efficiently without compromising on safety or sustainability, but we also have the in-depth field experience needed to identify additional cost-cutting opportunities that an insider might not see. Overall, we view ourselves as a sparring partner who helps customers focus on their core business.

OUR SECRETS: SPECIALIZED KNOW-HOW AND INDUSTRY EXPERTISE



What does it take to meet all the pharmaceutical industry's requirements for non-core processes and successfully support the shift to an outsourcing paradigm? First, customers require uncompromising adherence to product quality and availability requirements from the very beginning of the transition. Such a high standard is unattainable for all but the most experienced, capable service providers who can combine profound process expertise with the willingness to integrate seamlessly with the customer's organization. Speed, responsiveness and the resources to flexibly meet all requirements are just as important as a healthy outside perspective that can identify and exploit potential synergies and economies of scale.

Thanks to these characteristics, Infracerv Höchst can help customers reduce vertical integration so they can focus completely on their core business.

IDEAL SCENARIO: ONE PROVIDER FOR ALL YOUR NEEDS

Every partnership and outsourcing strategy should aim to reduce complexity – and thus costs – in non-core processes by minimizing interfaces to external providers and avoiding excessive fragmentation. In an ideal world, the pharmaceutical company will find capable, reliable partners who can provide and integrate as many services as possible.

Some companies have already adopted this strategy and transferred complex service packages to specialized service providers along with the associated personnel and service contracts. They have thus taken the first unavoidable step toward boosting their productivity instead of merely cutting isolated costs.

These demanding service packages require a sophisticated service portfolio like Infracerv Höchst's. It is modular by design so the depth and breadth of the processes can be tailored to the customer's needs, resources and requirements.

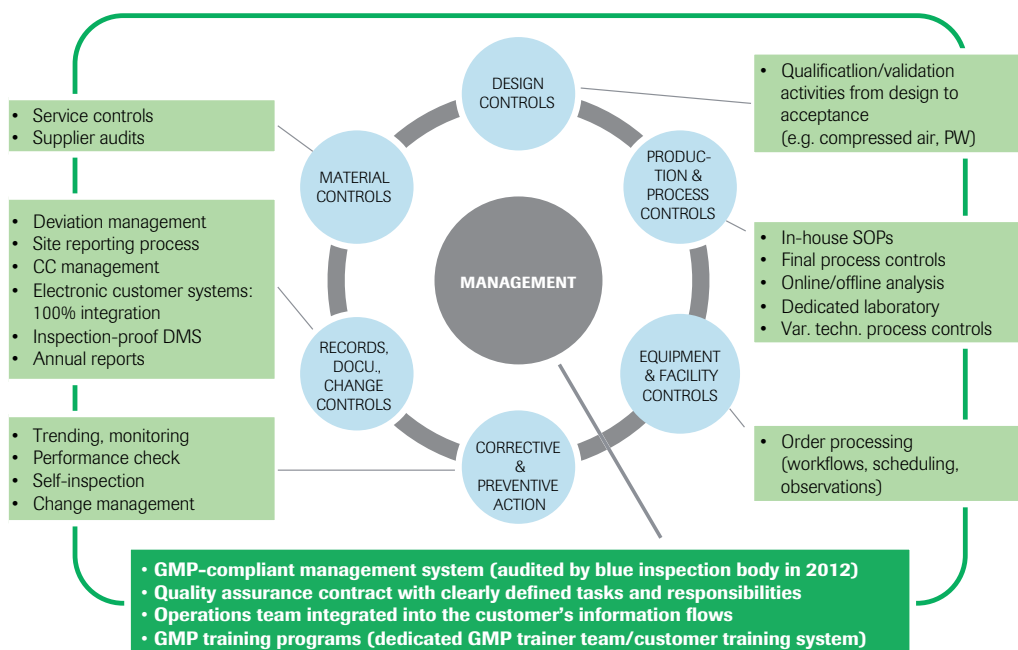
>> EXPERTISE REQUIRED: GOOD MANUFACTURING PRACTICES.

In addition to the above fundamentals, the pharmaceutical industry requires compliance with all regulatory standards, guidelines and laws. In API and drug production, this boils down to three letters: GMP or, rather, GxP. InfraserV Höchst has the capabilities to integrate with a pharmaceutical company's production-related areas without compromising the integrity of the customer's GMP validation.

Purified water example: InfraserV Höchst supplies Sanofi and Sandoz with purified water. This water, produced in strict compliance with all relevant regulations and industry standards along the entire value and supply chain, is delivered as a finished product. Regular audits and certifications by the customer and InfraserV Höchst demonstrate that the water fully conforms to all GMP requirements.

Product-related equipment example: Sanofi produces clinical samples containing APIs that are tested on patients in clinical studies. All the samples are produced at Sanofi's research and development pilot plant at Industriepark Höchst. The entire facility and its product-related equipment are operated by InfraserV Höchst. Obviously, all its work in sterile areas, on ventilation systems and around clean rooms has to comply with GMP requirements. For that reason, InfraserV Höchst is fully integrated into the customer's quality management system, which is an enormous responsibility that requires faithful compliance with the customer's regulations. InfraserV Höchst's employees are extensively trained and follow the customer's standard operating procedures (SOPs).

A certified, transferrable system: We supply many pharmaceutical customers in Höchst with product fluids such as compressed air, N2 and purified water along with facility management services in production areas. To satisfy stringent requirements, InfraserV Höchst has developed and implemented a system that was certified in 2012 by blue inspection body, an accredited GMP auditing firm. It covers the entire Good Manufacturing Practices cycle in the pharmaceutical industry and enables us to provide flexible, performance-driven site services near and even in controlled environments. With this system, we can integrate directly and completely with our customers' GMP organizations. InfraserV Höchst has the experience and capabilities needed to take on wide-ranging service portfolios at other pharmaceutical sites as well.



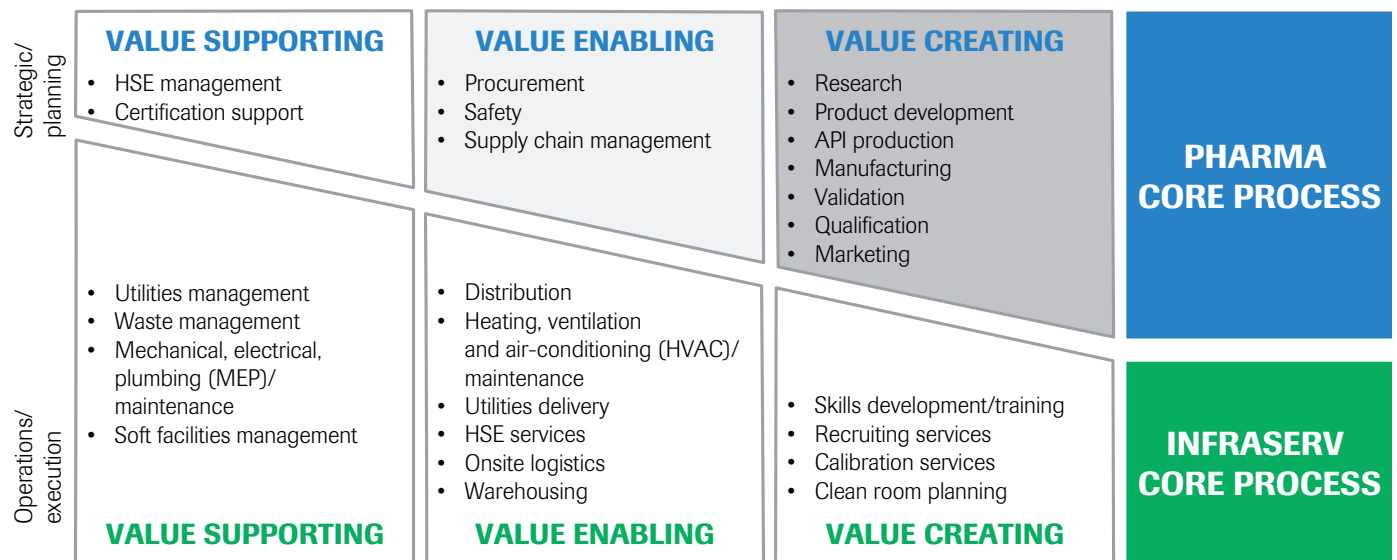
Integration with the customer's GMP organization – active cooperation is essential to success

>> IMPLEMENTATION: FOCUSING ON THE STRATEGIC CORE BUSINESS.

In the pharmaceutical industry, processes can be grouped into three general categories:

value-supporting, value-enabling and value-creating.

Outsourcing decisions cannot, however, be made simply based on a process's value contribution. While there are more value-supporting processes that lend themselves to outsourcing than value-creating ones, all three categories contain processes over which the company should retain complete control – and processes that virtually beg to be outsourced. The diagram shows what processes dovetail with Infraser serv Höchst's capabilities.



Core business boundaries in the pharmaceutical industry

Any pharmaceutical company that decides to focus more on its core business should be prepared for significant change. And change is only possible if the prospective partners have previously formulated a clear vision for the scope of their partnership as well as a roadmap for the transition process.

Drawing on its extensive experience as a service provider, Infraser serv Höchst has developed a specific process for jointly defining and successfully implementing a vision and roadmap. We will establish a modular, simple and manageable relationship with you in which our experts serve as sparring partners and show you options that may not be apparent to you as a company insider.

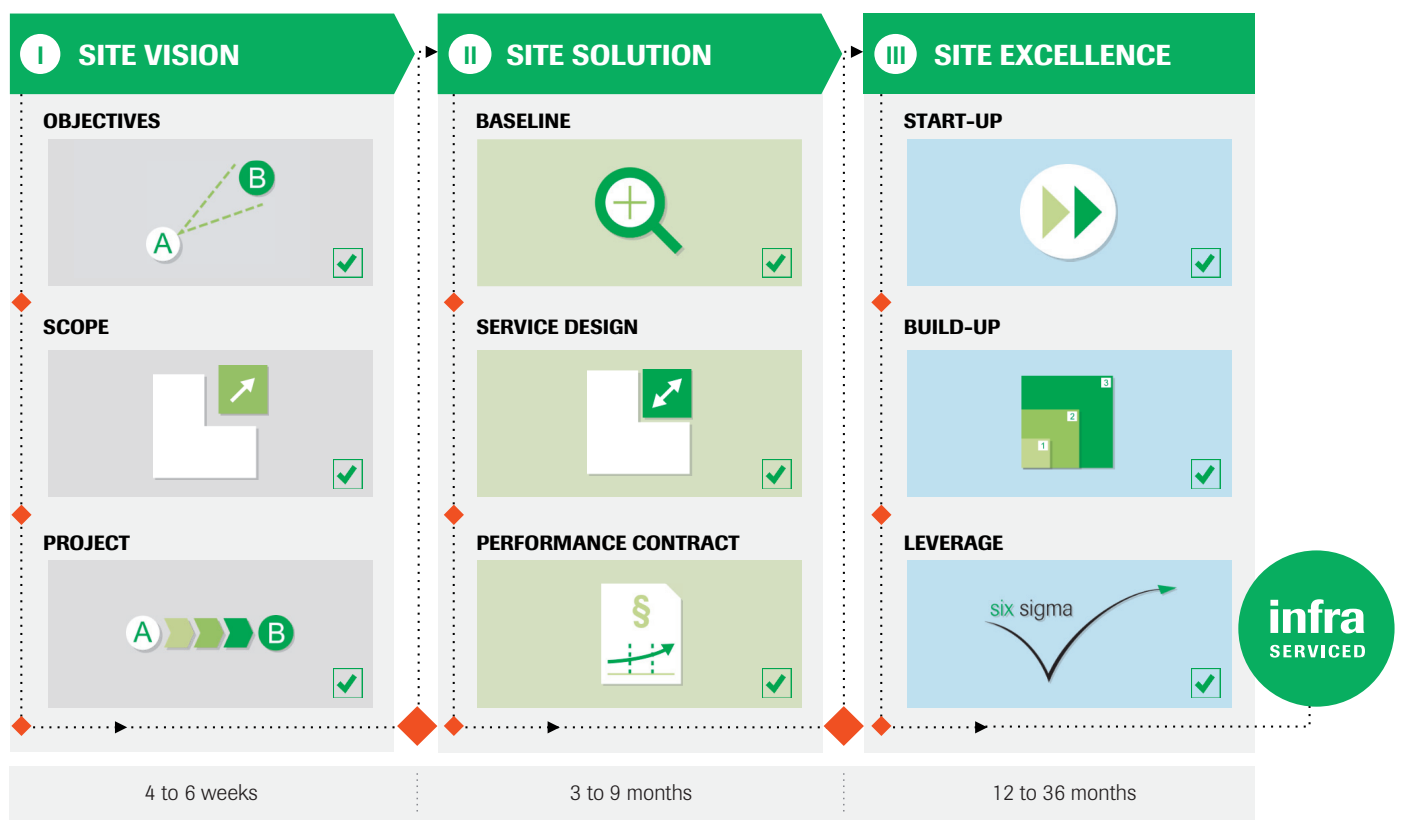
We call this method our **SITE EXCELLENCE PROCESS**.

>> A PROVEN APPROACH: SITE EXCELLENCE PROCESS.

The **SITE EXCELLENCE PROCESS** is a proven method for jointly developing and implementing custom solutions one step at a time. It leads to targeted, sustainable and highly effective partnerships for safely, efficiently and economically operating advanced infrastructure. We call solutions that reach this stage “**infraserviced**.”

SITE EXCELLENCE delivers high levels of customer satisfaction due to the simplicity with which our customers achieve their objectives and the reliability with which InfraserV Höchst delivers savings and quality.

The process consists of three distinct phases with defined goals: Site Vision, Site Solution and Site Excellence.



Site excellence process

PHASE 1: SITE VISION

In this initial four to six week phase, we work closely with customers to define their medium-term goals (Objectives), the ideal breadth of services (Scope) and the project plan (Project) for the partnership. In the “Objectives” module, we define our starting point and desired ending point, identify possible obstacles, and define specific KPIs for tracking our progress. The “Scope” module identifies all relevant non-core processes and evaluates their outsourceability using special methods that we have developed ourselves. In the “Project” module – the final step in the “Site Vision” phase – we draw up a concrete roadmap with milestones that identifies all the next steps in a decision-ready format and proves to all stakeholders that the project is technically and economically feasible, transparent and manageable.

PHASE 2: SITE SOLUTION

This second phase, lasting roughly three to nine months, is also subdivided into three modules. The “Baseline” step identifies current services, processes, interfaces and employees. It provides the certainty and transparency needed to make a variety of site-specific decisions. In “Service Design”, we work with your functional departments to develop concrete solution scenarios that can be presented to management for a decision. This is the step in which we define and review detailed service levels and the associated KPIs; migration activities and staffing changes are planned in this stage as well. Finally, we work up a “Performance Contract”. It defines the partnership’s long-term goals and is binding on both partners. The contract’s effectiveness throughout the relationship is monitored through regular audits.

PHASE 3: SITE EXCELLENCE

“Start-up” transfers operations and responsibilities based on the plan made in previous phases. Since the customer entered into the partnership with the ultimate goal of cutting costs, Infracerv Höchst recommends making the partnership as comprehensive as possible. Case studies show that the more responsibility is transferred to the partner, the more costs can be cut. As such, once Infracerv Höchst has established itself at the operational level, it aims to quickly develop the partnership into a tactical and strategic alliance.

We call this phase “Build-up”. In the course of the partnership, we tirelessly optimize every process transferred to us. This module, known as “Leverage”, utilizes the Six Sigma efficiency enhancement methodology which Infracerv Höchst has long applied to every level of its own organization.

SAVINGS OF UP TO 20 %

Ultimately, there are only two criteria for determining whether the partnership has achieved its desired goal: What costs have actually been cut – and how satisfied is the customer with the outcome? In our experience, if customers outsource large service packages within our areas of expertise, they can achieve savings of up to 20 % without adversely affecting regular operations, let alone putting core processes at risk.

>> INFRASERVICED: WE DELIVER SITE EXCELLENCE.

Infraserv Höchst's SITE EXCELLENCE PROCESS has proven its worth time and again and consistently delivers high levels of customer satisfaction. This pragmatic, manageable and transparent method enables our customers to reliably achieve their goals.

The process, with its defined milestones, lays out a cautious, fully customizable approach that allows for extensive planning and auditing. The SITE EXCELLENCE PROCESS, in other words, lays a solid foundation for a mutually beneficial, forward-looking partnership. Its long-term approach to goal-setting enables strategic planning.

Transferring processes to a seasoned service provider such as Infraserv Höchst – based on profound best practice experience – simplifies the transition, while meticulous implementation and process flexibility ensure the benefits will last for a long time. High efficiency also keeps the time axis lean.

The business benefits are clear: transparent costs, fast and substantial cost reductions that will earn the approval of employee representatives, more capex for the core business, better financials, variabilization of fixed costs and a reduction in head count.

WHAT OPTIMIZATION OPPORTUNITIES DOES YOUR SITE HAVE?

The first step in any partnership is to make contact and get to know one other. We would be happy to come by your company to share our ideas and explain how the SITE EXCELLENCE PROCESS applies to your unique circumstances. At the same time, we could also present references of relevance to your situation. We are confident that Infraserv Höchst is the perfect partner to guide you into a future of cost-optimized production infrastructure.

CONTACT US FOR DETAILS.

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>> REFERENCES: SUCCESSFUL IN AND BEYOND HÖCHST.

OPERATION OF INDUSTRIEPARK HÖCHST

In 1997, Infracerv Höchst began operating Industriepark Höchst, one of Europe's largest and most successful chemical and pharmaceutical sites. New and established tenants – particularly biotechnology outfits, start-ups and research centers – consistently invest large sums in the park year after year. Infracerv Höchst has aimed to build infrastructure that would meet the pharmaceutical industry's needs from the start. Among other things, it built the world's largest central purified water plant and continues to ensure proper disposal of pharmaceutical waste. As a result, Industriepark Höchst has become a global production center for insulin and antibiotics. Its tenants include leading pharmaceutical lights such as Sanofi and Sandoz.

FACTS AND FIGURES:

460 ha (1,137 acres), over 90 companies, approx. 22,000 employees, total investment of EUR 5.2 billion (since 2000), over 800 buildings, 120 production plants, 72 km of roads, 57 km of railway tracks, 800 km of pipelines, 2 mn t of cargo handled per year

INSULIN PEN PRODUCTION PLANT FOR SANOFI AT INDUSTRIEPARK HÖCHST

Sanofi-Aventis, one of the world's leading pharmaceutical companies, wanted to build a new production facility for insulin pens – the products would be assembled and packaged in four halls. It also required testing labs, administrative offices, an incoming goods center, a high bay warehouse and a temperature-controlled storage aisle. Infracerv Höchst completed the project in a record-breaking 15 months without interrupting operations and demonstrated world-class expertise in design, permitting, construction and operation.

In addition, Infracerv Höchst developed a facility management system to ensure GMP compliance during operations and an implementation strategy for transitioning from the trial run to regular operations. The industrial service provider also agreed to manage all aspects of the facility, including heating, ventilation and air-conditioning (HVAC), utilities, waste disposal and plant management. It conducts regular audits as well since it has assumed responsibility for quality management.

FACTS AND FIGURES:

Total area of 28,000 m², 15,000 positions in the high bay warehouse

OPERATION OF CREATIVE CAMPUS MONHEIM

Infracerv Höchst has been operating Creative Campus Monheim for UCB, a biopharmaceutical multinational, since April 2012. Located between Cologne and Duesseldorf, Creative Campus Monheim features an outstanding infrastructure for currently fifteen tenant companies in the pharmaceutical, biotechnology and life science industries.

Thanks to its extensive experience with multi-user sites, Infracerv Höchst is able to enhance the efficiency of many infrastructure processes in order to make research and manufacturing companies more competitive.

UTILITIES SUPPLY FOR THE NOVARTIS VACCINE MANUFACTURING FACILITY

To satisfy the growing demand for vaccines, Novartis Vaccines significantly expanded its production capacity for rabies and TBE vaccines in Marburg. To finish the project, however, it needed a reliable supply of utilities. The company entrusted the conceptual design of its infrastructural facilities and the design and commissioning of its central utilities plant to Infracerv Höchst as a professional service provider with expertise and experience in site design and operation.

>> ABOUT INFRASERV HÖCHST.

Frankfurt-based Infracerv Höchst operates advanced technical infrastructure for companies in the chemical, pharmaceutical and related process industries. Infracerv Höchst leverages its experience and capabilities in site operation, management and consulting to deliver site excellence for its customers. The company, which operates Industriepark Höchst among other industrial estates, provides site services, utilities, waste management and logistics services.

The Infracerv Group's wholly owned subsidiaries include Infracerv Logistics, Provadis Partner für Bildung und Beratung and Technion, a pilot plant service provider.

Infracerv GmbH & Co. Höchst KG has 1,900 employees and 149 trainees on its payroll. The Infracerv Höchst Group has 2,700 employees and 174 vocational trainees. In 2011, Infracerv Höchst and its subsidiaries generated approx. EUR 1.2 billion in revenues.

Industriepark Höchst is home to around 90 companies in pharmaceuticals, biotechnology, basic and specialty chemicals, crop protection, food additives and services. Some 22,000 people work at Industriepark Höchst. The site covers 460 hectares (1,137 acres); 50 hectares (123 acres) are still available for use. The companies at the park invested approx. EUR 383 million in the site in 2011. Total investments made since 2000 amount to around EUR 5.2 billion.

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