

>> YOUR SITE EVOLUTION:  
**PHARMA SITE EXCELLENCE.**

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NEXT LEVEL SITE  
DEVELOPMENT

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SITE OPERATION  
SITE MANAGEMENT  
SITE CONSULTING

HOW WE SUPPORT YOUR SITE'S EVOLUTION



## >> EXECUTIVE SUMMARY

Changing business models are constantly pushing pharmaceutical companies to re-engineer their processes, redeploy their resources and focus more intently on their core businesses. Integrated outsourcing strategies have proven an effective choice for contracting out not only secondary commercial processes, but also core processes such as research, development and manufacturing.

Outsourcing's short- and medium-term benefits extend to site services as well. Here, too, an integrated partnership model promises cost savings by minimizing the number of interfaces. Infracore Höchst is a capable, flexible site specialist with a long track record of successfully supporting pharmaceutical firms and providing a wide range of on-site services tailored to its customers' needs.

Our **SITE EXCELLENCE PROCESS** is a proven, well-defined methodology to chart and pursue a common path toward a rewarding partnership. Step by step, this process identifies and leverages opportunities while ensuring feasibility, transparency and manageability at all times. In the first module, **SITE VISION**, we work with you free of charge to develop a project proposal that enables you and your senior managers to decide on your next steps.



Infraserv Höchst is the partner who can help you evolve your sites. Its preferred path: the **SITE EXCELLENCE PROCESS**.

## >> PHARMACEUTICAL INDUSTRY IN TRANSFORMATION: ARE ALL YOUR SITES AT THEIR BEST?

Today's economy is characterized by relentless competitive and cost pressure. The pharmaceutical industry, however, faces several additional factors that command decision-makers' full attention:

- A paradigm shift in production fueled by an explosion in biotechnological products and processes
- Intense pressure to innovate and radically reduce times-to-market amid rising research and development costs
- Cost pressure caused by expiring patents and competition from generic manufacturers
- Challenge of optimizing production and manufacturing in GxP conditions
- A progressive shift of business to emerging markets amid declining pharmaceutical sales in the former European core market

To make matters worse, market players have to juggle different products, markets, production sites and corporate divisions at different stages in their lifecycles. In many cases, the only way to tackle these challenges without sacrificing long-term competitiveness is by trimming costs and overhauling traditional business models.

### FOCUS AND STRATEGIC PARTNERSHIPS

Companies can respond proactively by focusing on their core business and building up powerful supplier networks. Many providers specialize in pharmaceuticals: Contract manufacturing organizations (CMOs) produce and package drugs and active ingredients. Clinical research organizations (CROs) provide joint research and product development and perform clinical studies from start to finish. Both have become vital partners in the increasingly diverse pharmaceutical value creation network.

On the business side, in-house central services or external outsourcing providers handle many conventional non-core processes such as IT, HR, financial accounting and bookkeeping.

### POTENTIAL FOR IMPROVEMENT IN SERVICES AND INFRASTRUCTURE

Underutilized potential is common in site services, particularly facility management and non-core utilities processes. However, these areas, though rich in potential, are rarely targeted for optimization due to their complexity and close connection to regulated operations. Infraserv Höchst, being a seasoned site service provider and site operator, has decades of experience applying best practices to pharmaceutical sites in order to help customers develop successful evolution strategies and leverage this potential without compromising on quality.

## >> SITE EXCELLENCE: DRIVING LASTING COMPETITIVENESS.

In maturing markets you can strengthen your market position by tirelessly refining and streamlining your infrastructure and production plants. In growing markets, however, speed is of the essence and flexibility and agility plays a key role.

In both cases, it helps to have an infrastructure service model that keeps up with current business needs. To pick up the pace, we recommend starting now and developing your infrastructure service model from standalone services to a more expansive approach.

As a highly specialized industry provider serving multiple sites, Infracore Höchst knows how to start out with individual infrastructure services and gradually assume more responsibility through bundling and integration:

- In the short term, bundling, harmonizing and standardizing services delivers operational benefits for customers
- In the medium term, customers enjoy dynamic, sustainable effects from continuous process improvements and growing flexibility within a site partnership that is built to last

### OUR MISSION: TO ADD VALUE FOR OUR CUSTOMERS

Infracore Höchst, as a site operator and general contractor for infrastructure services, understands all its customers' needs in detail. We will not only free you up from secondary processes, but also generate real value above and beyond our original brief by proactively suggesting improvements to help nip problems in the bud. Being fully integrated in the customer's GMP organization, we always run an audit-proof operation – even if inspections are conducted with little or no advance notice. Backed by extensive training and the entire expertise of Infracore Höchst, our people on-site are committed to contributing to your objectives and projects to help make them a success.

This model, which has proven its worth at Industriepark Höchst and other locations, can be readily applied to any other pharmaceutical site and manufacturer thanks to its modular, highly scalable structure. We share our services and experience with pharmaceutical companies across Germany.

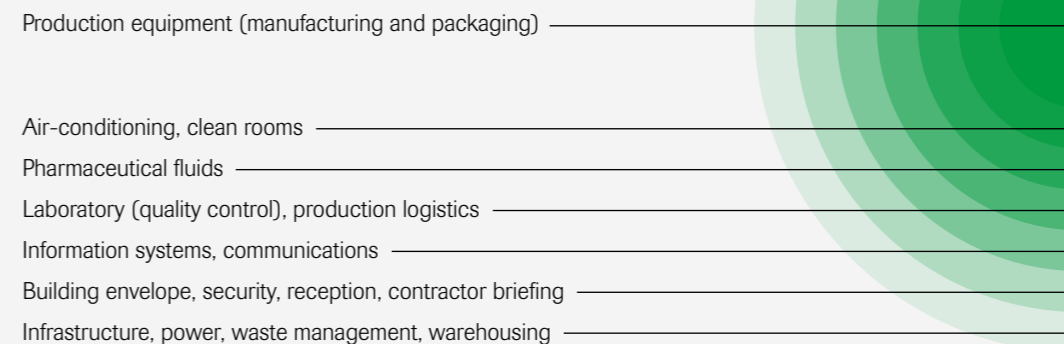
We will jointly define what we can do for you, in what order, and to what extent in the three-phase **SITE EXCELLENCE PROCESS.**



### SITE SERVICES IN PHARMACEUTICAL PRODUCTION

Anything except manufacturing itself: Infracore Höchst supports pharmaceutical manufacturers with a broad variety of services ranging from processes unrelated to manufacturing to those involving direct product contact.

- Low value-added
- High value-added



# >> PROVEN APPROACH: THE SITE EXCELLENCE PROCESS.



The **SITE EXCELLENCE PROCESS** is a modular, transparent and easy-to-manage process for effectively identifying and capitalizing on opportunities to optimize site operations.

Throughout this process, Infracore experts stand by to contribute their expertise in jointly developing solutions that will be implemented step-by-step.

The **SITE EXCELLENCE PROCESS** transitions into a highly focused, highly capable partnership for the safe, efficient and sustainable operation and development of advanced infrastructure and services.

OBJECTIVES	SCOPE	PROJECT	BASELINE	SERVICE DESIGN	PERFORMANCE CONTRACT	START-UP	BUILD-UP	LEVERAGE
Define the starting point (A) and desired goal state (B)	Identify all relevant secondary processes	Prepare roadmap with milestones and concrete next steps	Obtain a detailed snapshot of the current conditions	Develop a concrete solution scenario to submit for a decision	Draft a term sheet to support and simplify the contracting process	Prepare to take over routine operations	Begin operational services	Continuously optimize all processes and interfaces
Identify possible barriers to implementation	Evaluate outsourceability with Infracore's special methodology	Propose a project organization with a joint steering committee	Core issues: costs, services, processes and personnel	Define the service levels and KPIs	Finalize all contract documents, prices and terms	Cross-divisional, mission-critical process	Constantly refine services with customers	Utilize Six Sigma efficiency improvement methodology
Define concrete targets for tracking performance	Define the ideal project scope and service scope	Summarize in a proposal for management decision-makers	Ensure transparency at the site level	Plan migration steps and personnel changes	Sign a contract and agree on regular business reviews	Start-up and on-site team ensure a smooth transition	Expand scope of service in stages	The goal: to establish an enduring win-win partnership

### SUBMIT A PROPOSAL TO MANAGEMENT DECISION-MAKERS IN ONLY A FEW DAYS

In the initial phase, we sit down with you to analyze where you want to end up, what services we can provide, how we can provide them and in what time frame. Your investment is modest: Within 10 days, you will have a finalized proposal to submit to management. Best of all, Infracore Höchst's experts provide this consultation free of charge.

### WATERTIGHT SOLUTION DESIGNED IN 3 – 9 MONTHS

In the next phase, we create transparency, jointly develop an attractive business case and corroborate its feasibility. Then, we spend the next three to nine months developing an optimal solution with you, including services, service levels, KPIs and migration steps. Once the performance contract is finalized, we can start the next stage in our relationship.

### JOINING FORCES FOR A LONG-TERM PARTNERSHIP

The third phase is our joint quest for site excellence. It begins when Infracore Höchst takes over routine operations. However, experience shows that customers stand to benefit even more as the relationship matures and more services are outsourced. As such, we aim to steadily grow our long-term partnership by continuously optimizing and integrating processes: evolution, not revolution.

Infraserv Höchst has translated its extensive experience as a service provider into a clearly defined process for jointly developing, successfully executing and regularly updating a vision and roadmap. It applies a proven method to every step. We call this approach the **SITE EXCELLENCE PROCESS**.

## >> OUR SERVICE RANGE: SITE SERVICES FROM A-Z.

We can essentially provide everything you need to operate and manage any kind of production and research site – from standalone estates to integrated parks to geographically dispersed sites. Our service portfolio supports every phase in pharmaceutical value creation: research and development in laboratories and pilot plants, chemical and biological API production as well as manufacturing, packaging and logistics. We exceed our customers' expectations every day at Industriepark Höchst and the other sites that we manage.

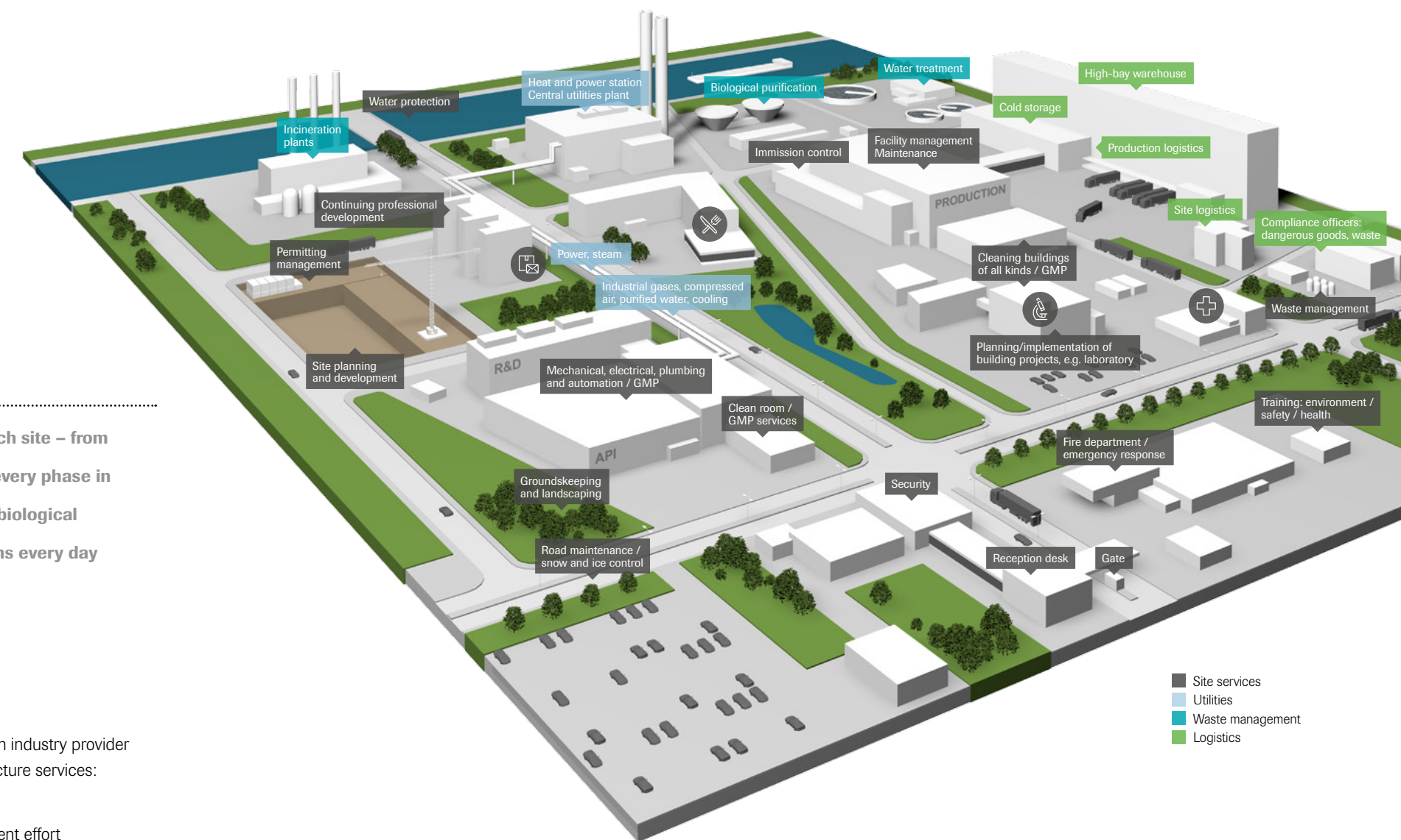
Our services run the gamut from value-supporting activities such as facility management to value-adding processes that are fully integrated with the customer's GMP organization.

What we do does not matter, though. What matters is what you need at each stage in your site lifecycle. Our portfolio extends from support services such as pure facility management to proactive site development to end-to-end operation of your production infrastructure. The better we understand you and your site's specific needs, the better we can support you based on our experience with other customers in similar circumstances.

### WE COMPLEMENT YOUR TEAM

There are many advantages to partnering with an industry provider like Infraserv Höchst that specializes in infrastructure services:

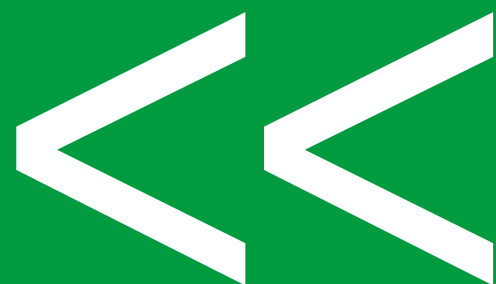
- One contact, one invoice, minimal management effort
- Seamless integration with your GMP organization
- Active support for growth and change processes
- Broad service range, including production-related services
- Multi-site optimization and standardization of service processes
- Ongoing streamlining and refinement



### YOUR SECONDARY PROCESSES ARE OUR CORE PROCESSES

If pharmaceutical companies want to focus more on their core business, they will have to make adjustments. Infraserv Höchst can transition and operate a broad range of process along the pharmaceutical value chain:

	Value-adding	Value-enabling	Value-supporting	
Core processes Pharmaceutical industry	<ul style="list-style-type: none"> <li>• Research</li> <li>• Product development</li> <li>• API production</li> <li>• Manufacturing</li> <li>• Validation</li> <li>• Qualification</li> <li>• Marketing</li> </ul>	<ul style="list-style-type: none"> <li>• Process management and control</li> <li>• Purchasing</li> <li>• Supply chain management</li> </ul>	<ul style="list-style-type: none"> <li>• Safety</li> <li>• Compliance</li> <li>• Human resources</li> </ul>	Strategic ↑ Operational ↓
Core processes Infraserv Höchst	<ul style="list-style-type: none"> <li>• Fluids</li> <li>• Clean room design, installation and services</li> <li>• HVAC/maintenance</li> </ul>	<ul style="list-style-type: none"> <li>• Hard facility management / maintenance</li> <li>• Energy management</li> <li>• Waste management</li> <li>• In-plant transportation</li> <li>• Finished product storage/ in-process storage</li> <li>• Distribution / customs</li> </ul>	<ul style="list-style-type: none"> <li>• Qualification / training</li> <li>• Recruiting services</li> <li>• Environmental protection</li> <li>• Occupational health and plant safety</li> <li>• Health management</li> <li>• Soft facility management</li> </ul>	



# >> OUR REFERENCE SITES: SUCCESSFUL IN HÖCHST AND BEYOND.

As a successor of Hoechst AG, Infracore Höchst has decades of experience driving site evolution at every phase of the site lifecycle by providing expert advice and efficiently and effectively supplying vital infrastructure services. Three examples:

## INSULIN PEN PRODUCTION FACILITY FOR SANOFI

Sanofi planned to build a new production complex for insulin pens with four separate buildings for assembly and packaging. It also required testing labs, administrative offices, an incoming goods center, a high-bay warehouse and a temperature-controlled storage aisle. Infracore Höchst completed the project in a record-breaking 15 months without interrupting operations. It currently manages all aspects of the facility, including heating, ventilation and air-conditioning (HVAC), utilities and waste management.

## SITE OPERATION: CREATIVE CAMPUS MONHEIM

When UCB acquired Schwarz Pharma GmbH, the synergies led to a significant amount of vacant office and laboratory space at its Monheim estate. It decided to convert the campus into a cutting-edge multi-user site for companies in the pharmaceutical, biotechnology and life sciences industries. UCB brought in Infracore Höchst to run the site. This is a change that benefits everyone. Thanks to its extensive experience with multi-user sites, Infracore Höchst can unleash the potential for efficiency improvements in many infrastructure processes in order to make research and manufacturing companies more competitive.

## INTEGRATED SITE SERVICES: NOVARTIS MARBURG

In 2009, Novartis retained Infracore Höchst to commission the central utilities plant at its new vaccine production site in Marburg. Infracore Höchst's specialists succeeded in quickly placing the brand-new plant into service. GIS Infracore, a joint venture and subsidiary of Infracore Höchst, has been operating the central utilities plant and constantly increasing the scope of its services since 2010.

Today, GIS Infracore also operates and maintains other utilities plants (reverse osmosis units and ultra-high-purity steam vacuum pumps). It maintains equipment with product contact surfaces at Novartis's other sites in Marburg as well (e.g. autoclaves and pharmaceutical cleaning machines).

## REFERENCES FOR INTEGRATED SITE OPERATION

### Frankfurt / Höchst Industriepark Höchst

- 460 ha
- Over 90 companies, including Sanofi and Sandoz
- Approx. 22,000 employees
- Scope: end-to-end
- Site operation since 1997

### Frankfurt / Griesheim Industriepark Griesheim

- Production, storage and logistics areas
- 64 ha
- 32 companies
- 1,000 employees
- Scope: end-to-end
- Site operation since 2009

### Marburg Novartis MARS Campus

- Construction of a central utilities plant at an existing site
- 73 ha
- Tenant: Novartis
- Approx. 300 employees
- Scope: commissioning
- Routine operation since 2011

### Monheim Creative Campus Monheim

- Pharmaceutical R&D, production and administration
- 6 ha
- Currently 10 companies
- Approx. 950 employees
- Scope: all site services
- Site operation since 2012



## >> SITE VISION: OUR FREE EVALUATION OFFER.

### I SITE VISION



#### WHAT CAN WE DO FOR YOU?

We want to find out, but we need your help. Hence our offer: Phase 1 in the SITE EXCELLENCE PROCESS – provided free of charge.

#### TRY US AND EXPERIENCE THE DIFFERENCE!

Your time investment is minimal: a one-day workshop at the start. We can hold it at your company or ours, depending on your preferences. Together, we can formulate a common understanding of your medium-term goals (Objectives) and your site's secondary processes (Scope). We will specify the starting point and your desired goal state, identify potential obstacles and define concrete parameters for tracking project performance.

Then, we translate this information into a concrete roadmap (Project) with realistic next steps. You will gain a clear understanding of the overall project and can evaluate its feasibility, manageability and transparency for yourself.

Within 10 business days, you will receive a summary of your SITE VISION and an actionable project plan. Your management team can then use this proposal to make an informed decision to pursue or reject the project. At that point, we can kick off our joint project and immediately move on to Phase 2, SITE SOLUTION.

#### We look forward to your call!

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Partnership requires absolute trust. That is why all our activities depend on full integration with your GMP organization.

**Frank Pauli**  
GMP Compliance Manager  
Infraserv Höchst



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