YOUR SITE EVOLUTION: PHARMA SITE EXCELLENCE.

NEXT LEVEL SITE DEVELOPMENT
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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. Infraserv 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.

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.

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.

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.
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, Infraserv 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

Infraserv 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 Infraserv 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 Indusitriepark 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.

SITE SERVICES IN PHARMACEUTICAL PRODUCTION

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

- Production equipment (manufacturing and packaging)
- Air-conditioning, clean rooms
- Pharmaceutical fluids
- Laboratory (quality control), production logistics
- Information systems, communications
- Building envelope, security, reception, contractor briefing
- Infrastructure, power, waste management, warehousing

We will jointly define what we can do for you, in what order, and to what extent in the three-phase SITE EXCELLENCE PROCESS.
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, Infraserv 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 Infraserv 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 are in a position to grow our long-term partnership by continuously operating and integrating processes, evolutions, new solutions.
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 in every step. We call this approach the SITE EXCELLENCE PROCESS.

Our services cover 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 processes along the pharmaceutical value chain:

Core processes Pharmaceutical industry

- Value-adding
  - Research
  - API production
  - Manufacturing
  - Distribution
  - Marketing

- Value-adding
  - Quality management and assurance
  - Project management
  - Supply chain management

- Supply chain
  - Raw material management
  - Packaging material

- Purchasing
  - Facility management
  - Market research

Core processes Infraserv Höchst

- Facilities
  - Design, engineering, installation
  - Maintenance

- Waste management
  - Hazardous waste
  - Non-hazardous waste

- Security
  - Infrastructure

- Safety
  - Environmental protection
  - Occupational health and safety

- Soft facility management
  - Facility services

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 SERVICE RANGE:
SITE SERVICES FROM A–Z.

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As a successor of Hoechst AG, Infraserv 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. Infraserv 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 Infraserv Höchst to run the site. This is a change that benefits everyone. Thanks to its extensive experience with multi-user sites, Infraserv 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 Infraserv Höchst to commission the central utilities plant at its new vaccine production site in Marburg. Infraserv Höchst's specialists succeeded in quickly placing the brand-new plant into service. GIS Infraste, a joint venture and subsidiary of Infraserv Höchst, has been operating the central utilities plant and constantly increasing the scope of its services since 2010.

Today, GIS Infraste 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*
  - 480 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
  - 84 ha
  - 32 companies
  - 1,000 employees
  - Scope: end-to-end
  - Site operation since 2009

- *Marburg Novartis MABS Campus*
  - Construction of a central utilities plant at an existing site
  - 75 ha
  - 25 companies
  - Approx. 300 employees
  - Scope: commissioning
  - Routine operation since 2011

- *Monheim Creative Campus Monheim*
  - Pharmaceutical R&D, production and administration
  - 64 ha
  - Currently 10 companies
  - Approx. 950 employees
  - Scope: all site services
  - Site operation since 2012
SITE VISION

OUR FREE EVALUATION OFFER.

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!
+49 69 305-6767

Infraserv GmbH & Co. Höchst KG
Industriepark Höchst
65926 Frankfurt am Main
Germany
kundenservice@infraserv.com
www.infraserv.com

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