

# Changing site concepts in the pharmaceutical industry



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# Content

- **Pharmaceutical production: a decade of massive changes**
- Pharmaceutical Production today: organizational structures
- New approaches: trends and interfaces of the future

# Pharmaceutical production: a decade of massive changes

From classical division of labor to integrated production responsibility

## Production in the late nineties:

- Coined by classical division of labor, highly functional
- Responsibility for finished goods only on factory or even site level
- Optimization of cycle times and reduction of inventories deemed an almost impossible quest

## Turnaround with the new millennium: segmented production along with compatible organizational concepts:

- Clear accountability for finished products or product groups inside the factory
- First sustainable improvements in terms of speed /cycle time, quality and yield as a consequence

# The triangle: production, logistics and procurement

From a strict partition to the modern supply chain concept -

## Again the late nineties:

- Traditional split between logistics and procurement on one hand and production on the other
- No self conception at all to perform as a service provider for production; team work approach as an exception

## Tables turned by start of the new millennium: previous production improvements only „the first step in the right direction“

- ➔ Supply chain improvement projects in nearly every pharmaceutical company; Schering AG: „SCREEN“ 2000 -2002
- ➔ Integration of logistics and procurement into production as a consequence
- ➔ **The modern supply chain as a bridging concept was born**

# Production and engineering

From different corners to a joint organization

**The past:** Central engineering the overall and most common concept

**The nineties:** sustainable improvements in collaboration by

- clear work force allocation
- physical proximity to production

**Again the new millennium:** engineering functions assigned to production:

- corporate engineering
- plant engineering
- maintenance and repair

**Today:** Plant engineering

- either assigned to the factory head
- or embedded in the production segments

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# The modern supply center of today

## The integrated approach to complete supply responsibility

What are the essential characteristics of modern supply centers?

### Taking responsibility towards the commercial organization

- regionwise or globally
  - including secondary packaging
  - either for a group of finished goods
  - or a complete dosage form
- 
- responsibility for the whole supply chain („pipeline supply unit“)
  - or embedded in a central supply chain management network
    - with autonomous production scheduling
    - and clearly fixed inventories

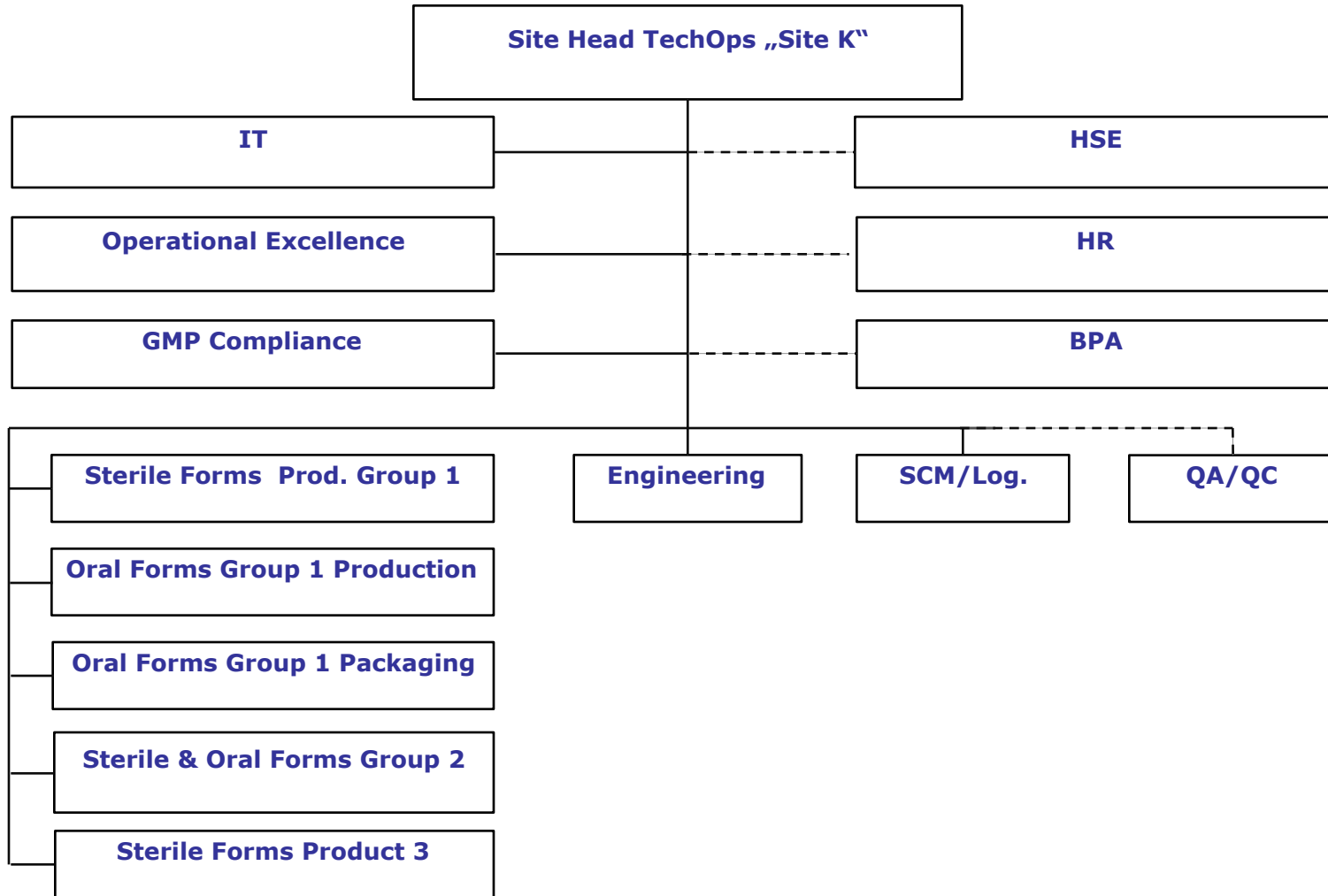
### Engineering as one of the organizational pillars

- machine setting, maintenance and repair
- process optimization, changes and capital investments



Sandoz Site Kundl, Austria

# The modern supply center – a typical org chart example: Organizational Overview TechOps „Site K“

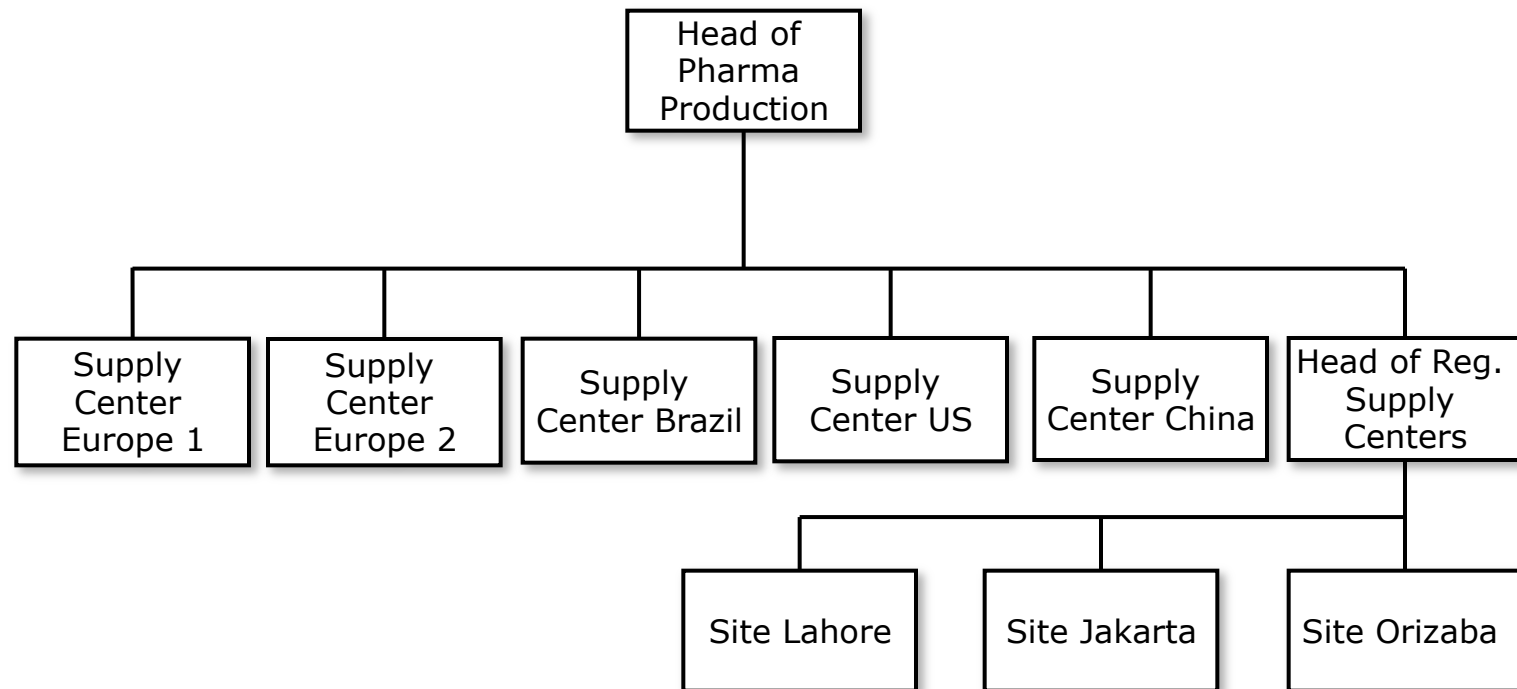




# Pharmaceutical Production – hierarchy of Supply Centers

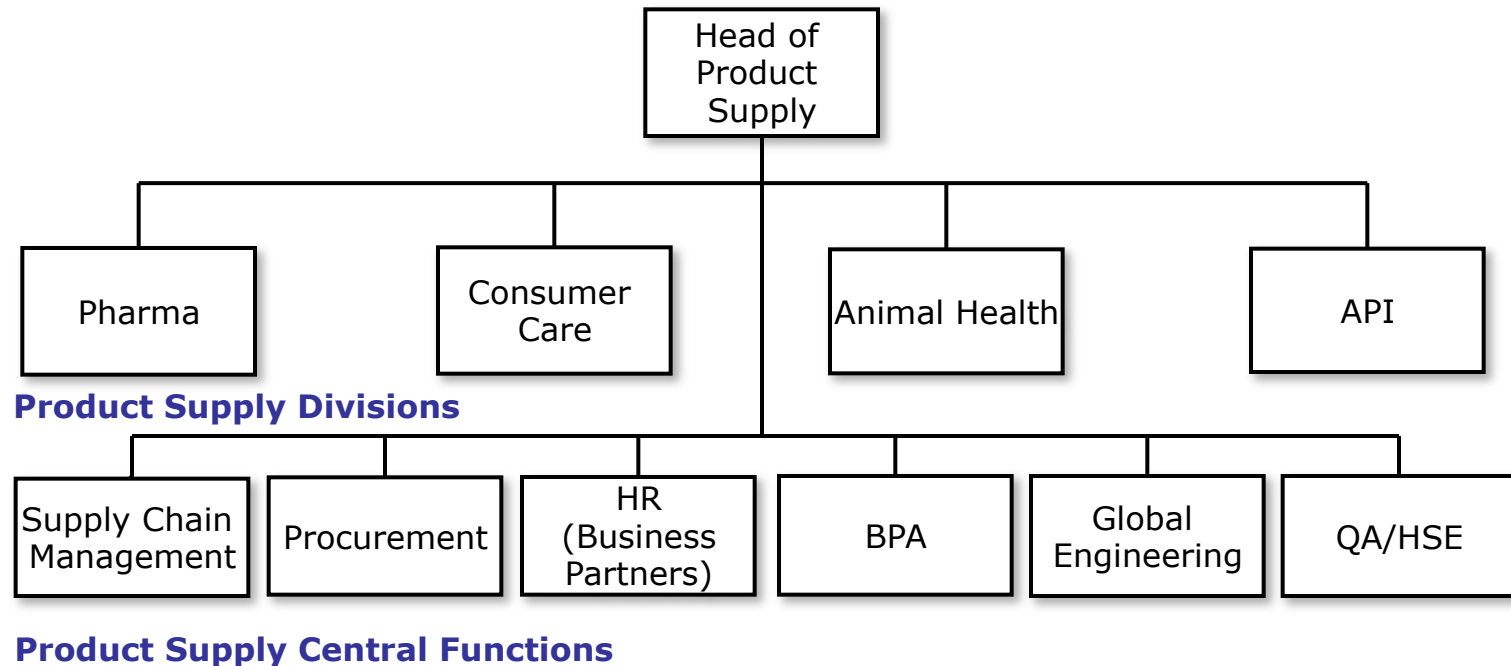
## Supply center heads:

- Direct reporting line to the divisional head of production
- Substructure in case of smaller sites (single country supply)



# Pharmaceutical Production – Global Management Structures

- The general rule: global split between commercial operations and other functions
- Production acting as the global supply chain; its head normally directly reporting to the CEO
- „Healthcare companies“: divisional structure inside production; service functions either embedded or centrally acting

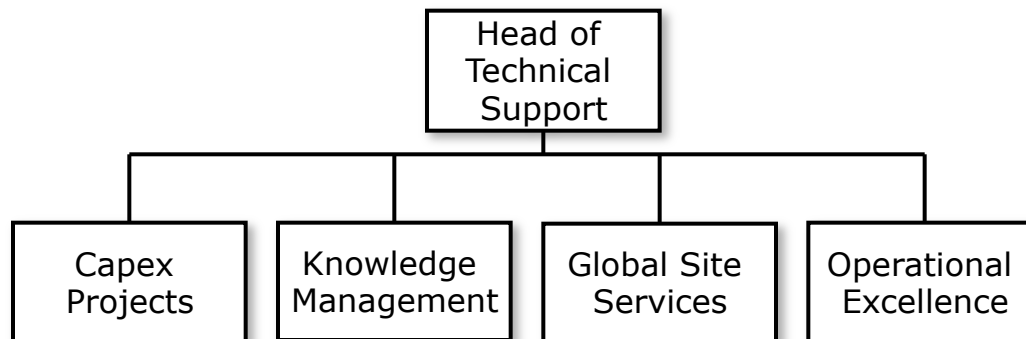


# Pharmaceutical production – the role of global engineering and procurement

Global engineering platform: common in most of the „big pharma companies“

Usual responsibility: project management for the huge capital investment projects; split between local and global responsibility normally budget related: **3 - 5 mio. €**

Example: Bayer Healthcare platform: „Technical Support“



**Future trend: Increasing governance responsibility over the next years**

# Pharmaceutical Production- the role of global engineering and procurement

## The last 5 years: substantial changes for procurement functions

- ➔ Common organizational split between:
  - purchasing of business critical, non standardized items & services
  - standardized, less business specific products and services
- ➔ Both divisions: global acting organizations
  - tremendous loss of power for the local site procurement
- ➔ As a consequence of modern IT-structures:
  - physical proximity of declining importance
  - the „lead buyers“ often spread around the world

## Future trends:

- **Steep increase of global sourcing over the next three years**
- **Platform engineering and central procurement functions: new alliances visible to achieve further cost benefits**

## New approaches for pharma production – trends and interfaces of the future

- ➔ Structural changes of the last 10 years: a quantum leap for the conservative pharmaceutical industry
- ➔ However, pharma production still far away from today's automotive industry with its common partnership network between production, suppliers and service providers
- ➔ Cooperation models in four working areas will change drastically during the next five years:
  - **Production Logistics**
  - **Site and factory infrastructure**
  - **Engineering**
  - **Site Management**

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## Fully integrated production or clear interfaces?

Trends for modern concepts in production logistics

### The integrated logistics organization: a chapter of the past

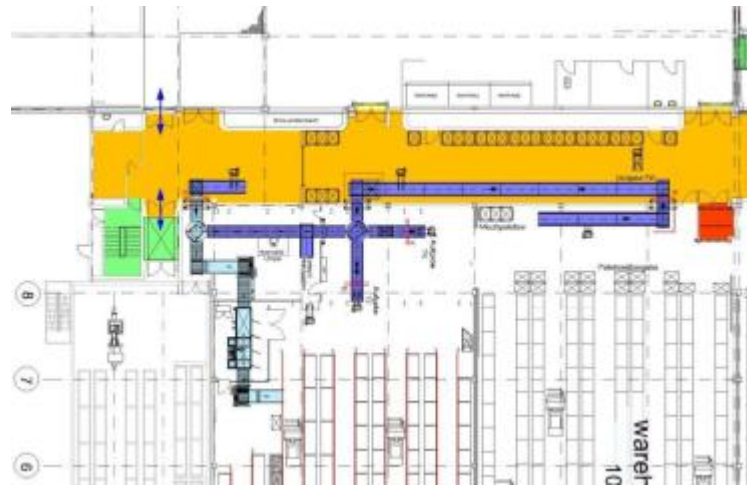
**Site Logistics:** managed by the respective site operator

**Distribution logistics:** in the hands of independent companies

→ with their own certified warehouses and distribution channels for pharmaceutical products

**Production logistics:** still perceived as an integral part of production

Fundamental changes are visible: **new service companies are entering the market.....**



# Fully integrated production or clear interfaces?

## Trends for modern concepts in production logistics

Providers originate either from distribution logistics companies or contract manufacturing organizations (e.g.: Next Pharma Logistics)

If possible in terms of product flow, secondary packaging will be part of the acquisition package

On factory level this package will consist of:

- warehouse operation and management of inventories for all input, packaging and auxiliary materials
- complete material provision at the head of the production line and receipt of the finished goods in the first transport container at the tail





# Fully integrated production or clear interfaces?

## Trends for modern concepts in production logistics

### → **What does it mean for production and plant engineering?**

- Harmonization of IT-systems as a must:
  - ✓ Between provider and SCM on finished good inventory level
  - ✓ Between supply center and provider on inventory and order level
  - ✓ Cut of the previous integrated planning chain for factory logistics and manufacturing
- Installation of a reliable interface for the management of changes, optimizations and investment projects will become mandatory

### → **What does it mean for machinery and plant suppliers?**

- Providers for production logistics will be sitting at the table in nearly every planning meeting „at eye level“
- System suppliers will have significant advantages
  - ✓ By acting as an experienced interface manager
  - ✓ By integrating the logistical interface in their system concepts

# Fully integrated production or clear interfaces?

## Trends for modern concepts in production infrastructure

The magic word „GMP“ impeded expansive technical outsourcing in the past, but:

Classical facility management providers with their roots in building services technology are conquering „new territories“:

### **Technical services for clean rooms and ultra clean media units**



With a steady increase in pharma know-how, they will have a real chance to meet production and supply center heads „at eye level“

### **Next interface in pharma production is already programmed: services and operation of clean rooms, building infrastructure and the supply with clean media**

# Fully integrated production or clear interfaces?

## Trends for modern concepts in production infrastructure

- ➔ What does the new interface mean for production?:
  - Similar to production logistics the quality-assured provision of purified water or other product-relevant media has to be integrated into operations and order management
  - Both parties will need modular and standardized technical interfaces for an easy connection of machinery and plant equipment
  
- ➔ What does it mean for the machinery suppliers? – Two directions possible:
  - The **service provider** will follow the obvious path to become a **product supplier**; in the future **he** will be the discussion partner and customer
  - The **equipment supplier** is trying to generate added value and develops **himself** into the role of a **product supplier**
  - **Machine suppliers have to define their future role model**

# Fully integrated production or clear interfaces?

## Modern service concepts for plant engineering

### The classical domain of the plant engineers: every area of engineering services inside production

- external service support typically provided by smaller, regionally operating engineering offices
- market continuous, but too meager for the big engineering companies; engagement of machine suppliers as engineering partners up to now limited



Know-how for changes, optimization and expansion investments, particularly for interlinked manufacturing: more or less exclusively inside production and its plant engineering

### The future perspective: COGS pressure will lead to further outsourcing

- on shop floor level
- for engineering tasks including equipment qualification

# Fully integrated production or clear interfaces?

## Modern service concepts for plant engineering

### → What does it mean for the future?

- Plant engineer will develop to a „director of technical services “
- As already practiced for facility management, commissioning of services incl. conceptual and detail engineering will go to the full range service providers; This will lead to a minimum of interfaces and joint cost reduction
- Even for this area: experienced companies already on the market; effort and success are growing continuously
- Their know-how and process competence in the respective fields of engineering will increase over the next years

### → What might be the answer of machine suppliers?

- Become **the** continuous and competent discussion partner for the sophisticated engineering jobs in terms of changes, optimizations and expansion investments
- Reinforce the system business:
  - ✓ clear reduction of interfaces
  - ✓ strengthening and encapsulating process competencies

# Fully integrated production or clear interfaces?

## Modern service concepts for site infrastructure

Site utilities and media i.e. common utilities (process steam, electricity, water)

Current suppliers: most commonly the respective site operators

Competitors: often regional energy providers (added value in their business concept)



Big providers of technical services again are entering even this market segment; the interface to the factory is newly arranged, **market power is once more growing**



# Fully integrated production or clear interfaces?

## Operating concepts for pharma sites

The current operating concept of production sites is mainly determined by company size and history:

- The classical **integrated site** (R&D, admin, production): first choice of mid sized and big pharma companies.
- The **chem or industry park** as a typical product of the big multi division companies; Bayer Leverkusen, Hoechst Frankfurt, now operated by Infraser
- The **pharma park**, born either by the sale of a pharma company to several new proprietaries (Behring Werke, Marburg) or by active and focused industrial development policy (Pharma park Dessau)



# Fully integrated production or clear interfaces?

## Operating concepts for pharma sites

### What are the pros and cons with respect to pharma production?

#### Integrated site:

##### Pros:

- all strategic options for further site development can be exclusively utilized for the own company
- Development and implementation of a proprietary site master plan possible
- unique characteristic for branding of visibility and image; no dilutive effects through third parties

##### Cons:

- Operation and (further) site development do not belong to the core competencies of production or other company functions
- site operator is bearing the full risk for all development scenarios, e.g. partnering concepts in case of shrinking or provision of additional resources for infrastructure in case of expansion



# Fully integrated production or clear interfaces? – Operating concepts for pharma sites

## Industry park

### Pros:

- tenants have to pay only for their needs: space, infrastructure, services
- „plug and play concepts“ supported by site operator; installation of supply & service hubs to allow beneficial contracts
- no capital or employee commitments in activities outside production
- contractual agreements both for shrinking and expansion scenarios feasible

### Cons:

- tenants are committed to take particular services, such as energy, security, cleaning; prices are usually not negotiable
- pharma media and technical services may be weak due to industrial and chemical alignment
- loss of the unique characteristic; site has to be shared with third parties and a sometimes opposing visibility and branding

# Fully integrated production or clear interfaces?

Operating concepts for pharma sites -

## Pharma park

Pros:

- tenants have to pay only for their needs: space, infrastructure, services
- plug and play supported; service & supply hubs can achieve bigger synergies
- no capital or employee commitments in activities outside production
- contractual agreements possible both for shrinking and expansion scenarios
- joint „site branding“ for the pharma business will clearly support the image of the respective company
- site operator specialized in pharma infrastructure and services

Cons:

- tenants are committed to take particular services, such as energy, security, cleaning; prices are usually not negotiable

-

# Fully integrated production or clear interfaces?

## Operating concepts for pharma sites

Features Site Concept	Pay what you need	Plug and Play	Capital commitment for Infrastructure	Contractual agreement for development	Unique characteristic	Special. site operator
Integrated	--	0	--	--	++	++
Industry Park	++	++	++	++	-	+
Pharma Park	++	++	++	++	+	++

## Fully integrated production or clear interfaces?

Future trends in operating concepts for pharma sites

### **The pharma park tends to develop as the future global concept for pharmaceutical production sites**

- Unified „site branding“ will support the respective company image
- „plug and play“ concepts are fostered by an experienced pharma site management
- Highest possible synergies achievable for infrastructure and services

The pharma park concept is the ideal choice for the emerging countries, as infrastructure and services are expensive and not easy to develop, particularly in remote areas

What could be site operators next steps for the future?

### **Provision of shell and core for production buildings**

- Usual concept for biotech parks in the lab and development area
- Modular concepts for clean room installation and equipment needed
- **Plug and play concept to be transferred inside the factory**

# Future site concepts for the pharma production – conclusions and outlook

## Pharmaceutical production envisions further structural changes

During the next five years the interfaces for the following areas will be newly programmed:

- **Production logistics**
  - **Factory and site infrastructure**
  - **Technical services and engineering**
  - **Site management**
- ➔ The decision path for new sites leads clearly to industry and pharma parks in particular
  - ➔ This choice will consequently support the progress at the service interfaces
  - ➔ Site operators and providers will be able to install cost beneficial infrastructure and service hubs

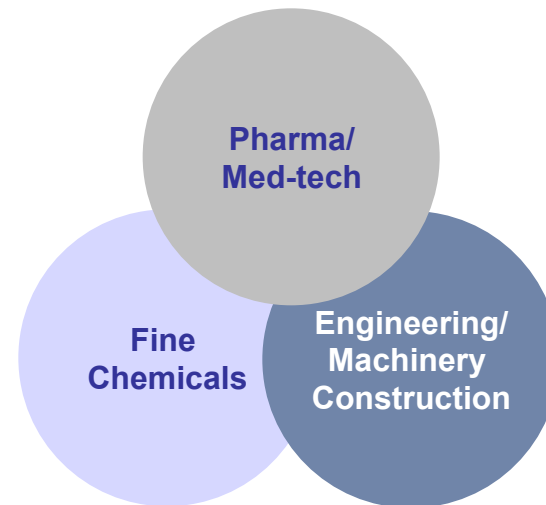
## Future site concepts for the pharma production – conclusions and outlook

- ➔ Machine and plant suppliers will face new and strong customers outside the familiar „pharma family“
- ➔ As they will talk to experienced engineers, there might be some progress compared to the previous and conservative world of the pharmacists
- ➔ According to the development of plug and play concepts inside a factory, machine suppliers should
  - enhance their competencies in interlinked processes and the „system business“
  - think about cooperations with the clean room and clean media manufacturers
  - get in touch and discussion with site operators and the big service providers
  - define their role model for the future: machine or service or „product“ supplier?

**Thank you for your attention!**

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