



Miebach Pharma Study 2016

# Challenges ahead!

Supply Chain Trends in the European  
Pharmaceutical Industry

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The pharmaceutical industry is giving its supply chain and logistics a much greater importance than in the past.

Professional management of suppliers and logistics service providers (LSPs) require key performance indicators (KPIs) and regular audits. Visibility along the supply chain and forecasting are ranked as priorities.

Our European Study clearly shows that most pharmaceutical companies see the European market as a whole region, while national borders are becoming less important, except for specific legislation or distribution channels.

New challenges have to be faced:  
Namely, the increasing volume of refrigerated and frozen products and serialization of product codes.

The Miebach pharma study aims to take a closer and more detailed look at the trends in the area of supply chain management. It points to a number of developments that are of particular interest, since not very many studies to date have focused specifically on supply chain management in the pharmaceutical industry. The results of the study will be compared to the previous Miebach pharma study from 2012 to get further insights about developments in this industry.

Alongside the results of the study, we also aim to provide our readers with useful information and recommendations on how to accommodate these changes.



Martin Eckert



Achim Sponheimer



# Management Summary

# Management Summary

Our learnings from the conducted survey confirm this statement. While in the past issues like national warehousing, outsourcing or regulatory concerns were highly evaluated, the topics with the highest ranking in the 2016 study are very much in line with other industries like FMCG and Automotive – traditionally frontrunners on supply chain innovation.

Some of the most important results are:

- Distribution networks are becoming more European focused and less national. This trend requires some major changes to optimize the supply chain.
- More efficient management of suppliers and service providers, including transports, warehousing and contract manufacturers is needed. Tools like KPIs and audits still need to be fully implemented.
- Lean approaches and general optimization of logistics in manufacturing and packaging are being introduced in many pharmaceutical plants.
- Forecasting is still a major topic along with end-to-end supply chain visibility.

*Today, the pharmaceutical supply chain is more professionally managed than in the past.*

New challenges which have not been priority in previous years:

- **Cold chain**

There is an increasing volume of products requiring cold chain conditions. Many of the pharmaceutical plants and warehouses are still not prepared for this, although the GDP guidelines (2013/C 343/01) are in place for over two years.

- **Serialization to fight counterfeiting**

There is only limited experience with serialization. For Europe, it is a huge project considering the very tight timeline to meet the requirements of European regulations (EU) 2016/161 and 2011/62/EU due on February 9th, 2019.





# Industry Overview

# Industry Overview

*Growth, takeovers, and high volatility shape the development of the global pharmaceutical market.*

The volume of the global pharmaceutical market has more than doubled in the past ten years. By the end of 2014, total revenue was reported at 936 billion euros (Source: IMS Health), with further growth expected until 2019–2020.

The top 20 pharmaceutical companies generated combined 2014 sales of over 400 billion euros, equivalent to more than 40% of the global market volume. Despite increasing tendencies towards concentration, the industry remains highly segmented. During the last four years, mergers and takeovers in the pharma and biotechnology sector have been on record level. This trend is expected to continue in the foreseeable future.

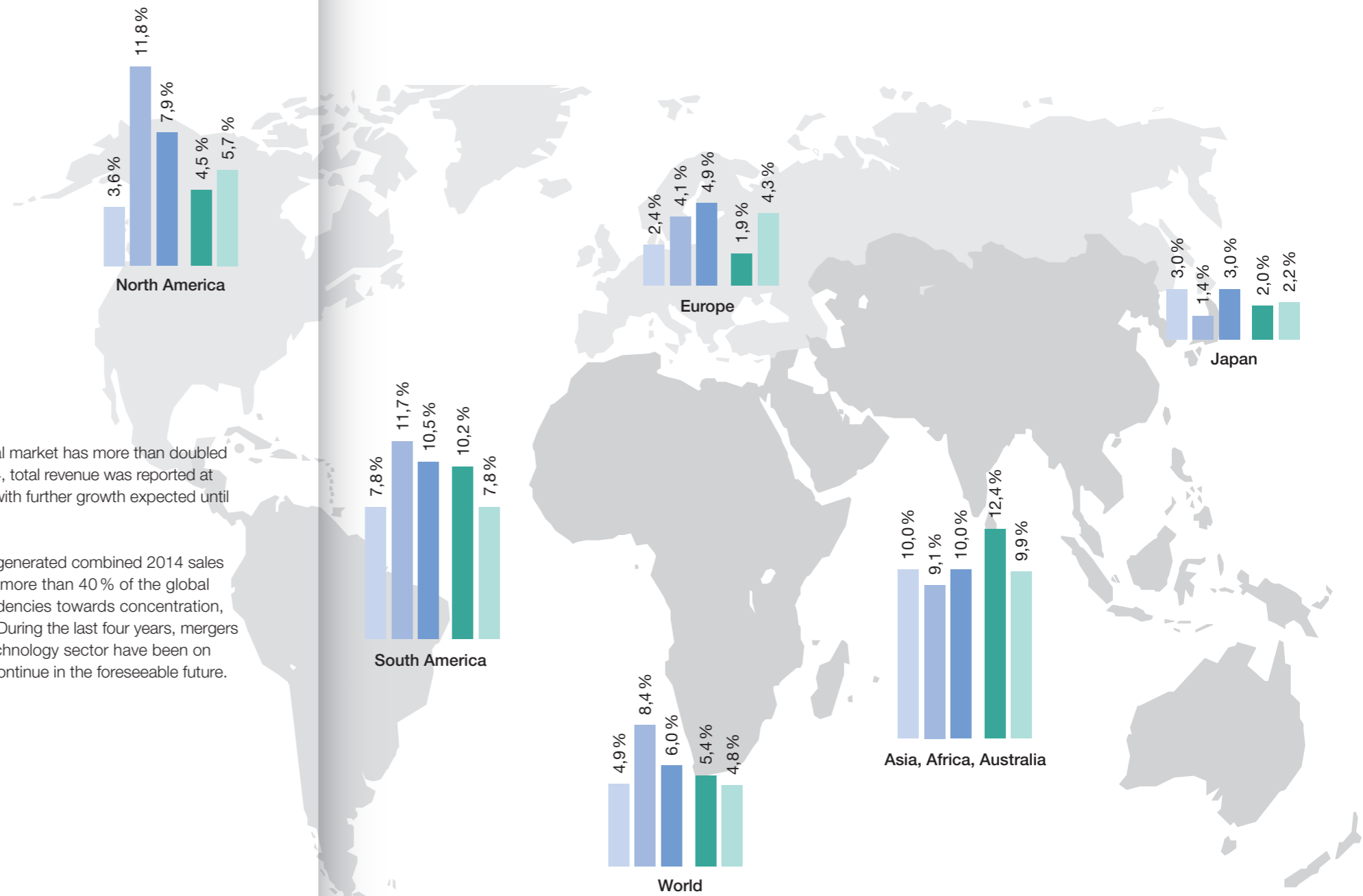


Fig. 1  
Annual growth of the pharmaceutical market

Source: IMS Health – May 2015 – www.imshealth.com

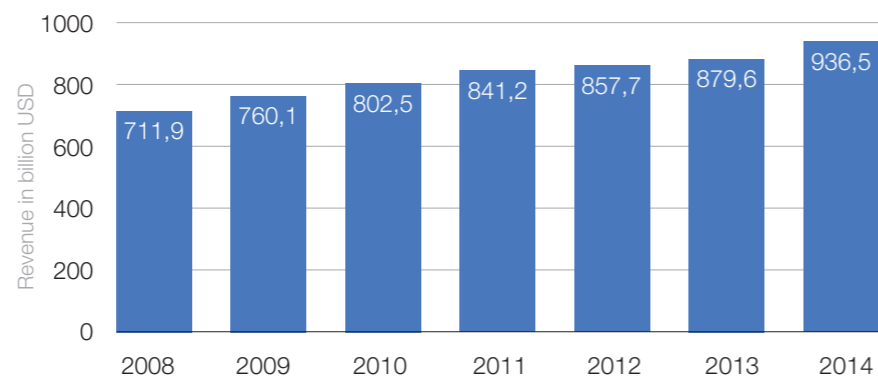
- 2013
- 2014
- 2015
- 2009–2014
- 2014–2019

# The Global Market for Pharmaceuticals

*A growing global market for pharmaceuticals will lead to further logistics challenges.*

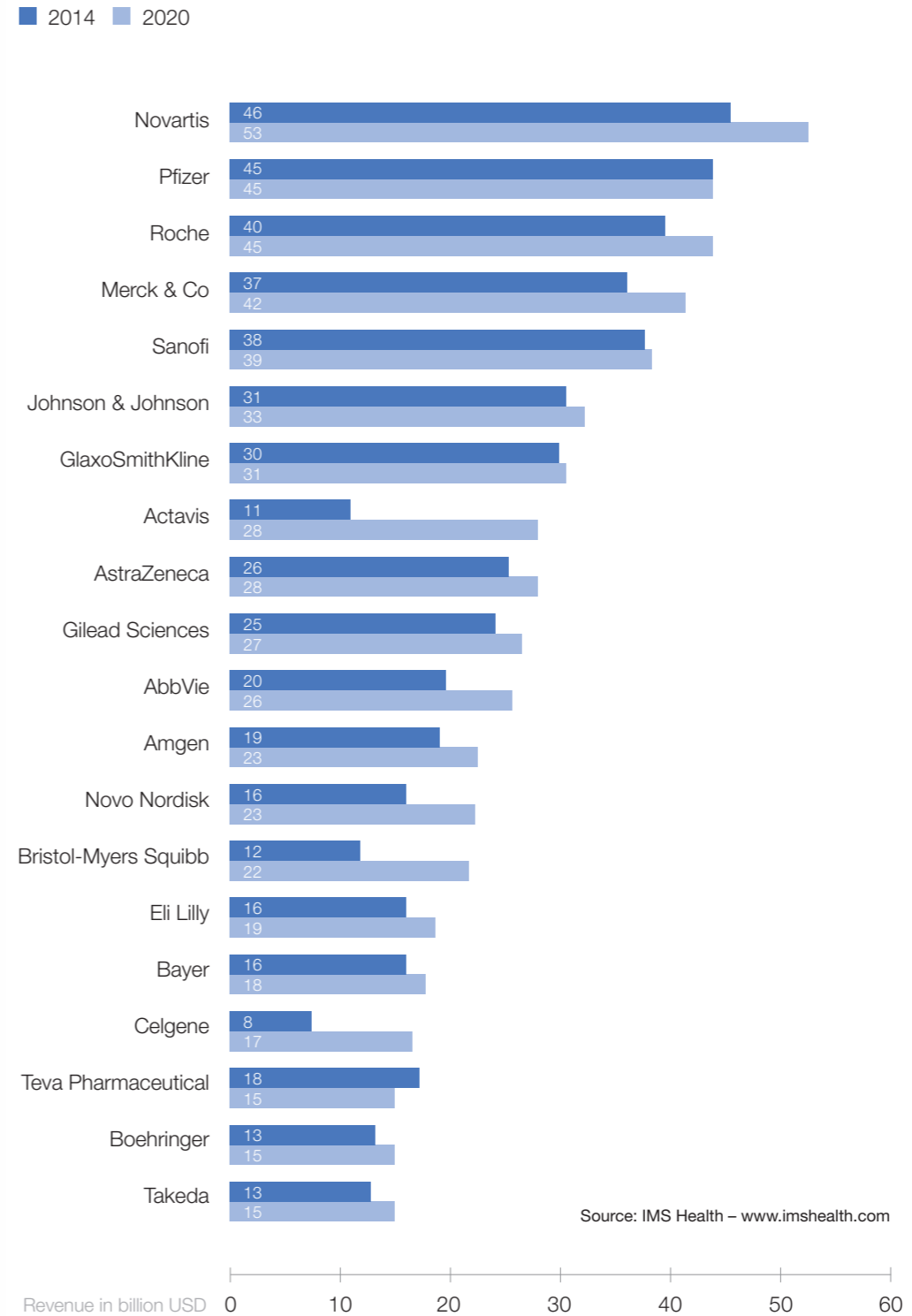
From 2008 to 2014 the revenue of the worldwide pharmaceutical market has increased by almost one third. This trend is expected to continue through 2020. A trend which can be observed in developed as well as developing countries. Especially in the European Union, an aging population will drive demand for more medication. Developing countries face a raise of wages and life standards and a growing middle class will boost pharma revenues over the long term.

Fig. 2  
Revenue development in worldwide pharmaceutical market from 2008 to 2014

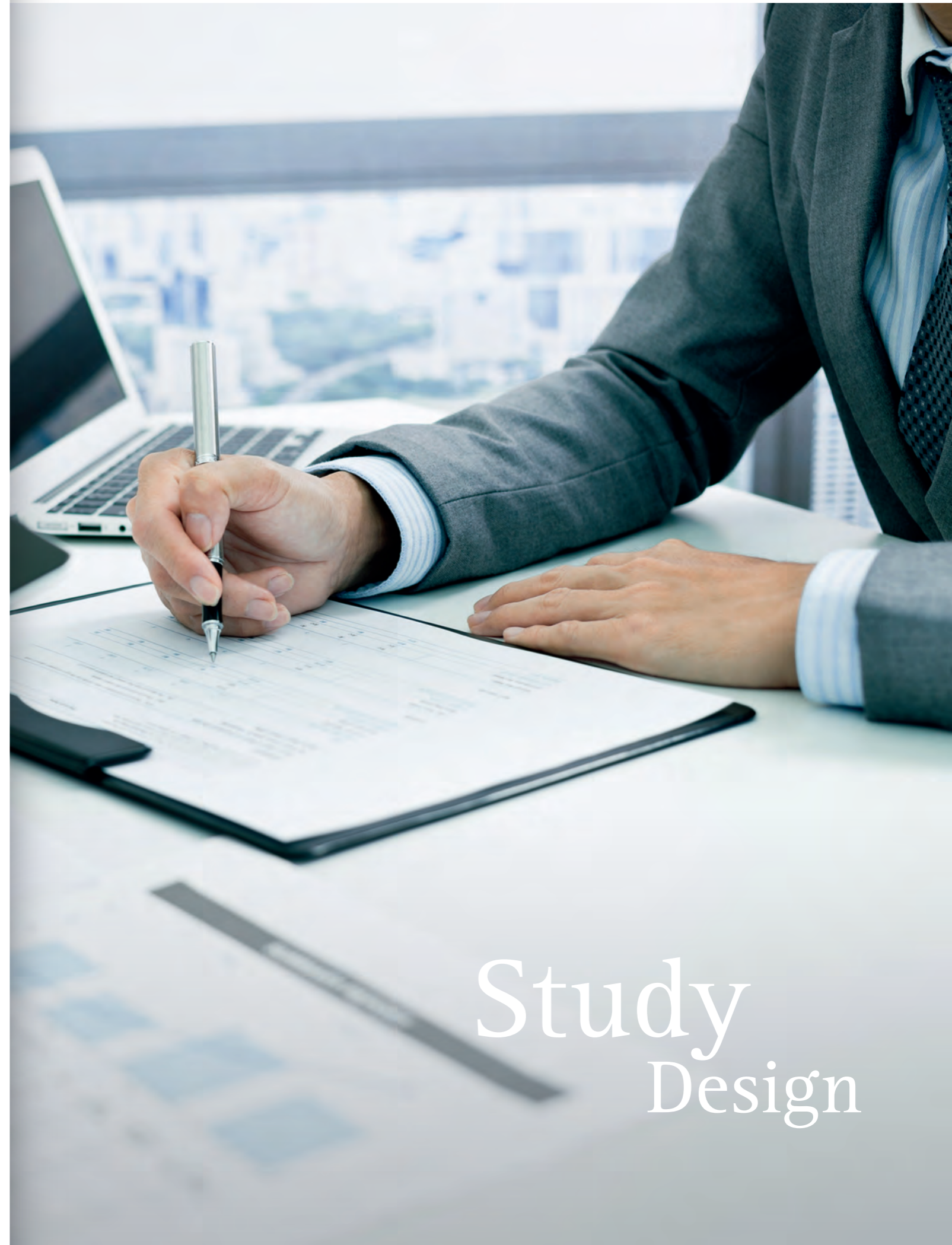


Source: IMS Health – December 2014 – www.imshealth.com

Fig. 3  
Top 20 pharmaceutical companies worldwide



Source: IMS Health – www.imshealth.com



# Study Design

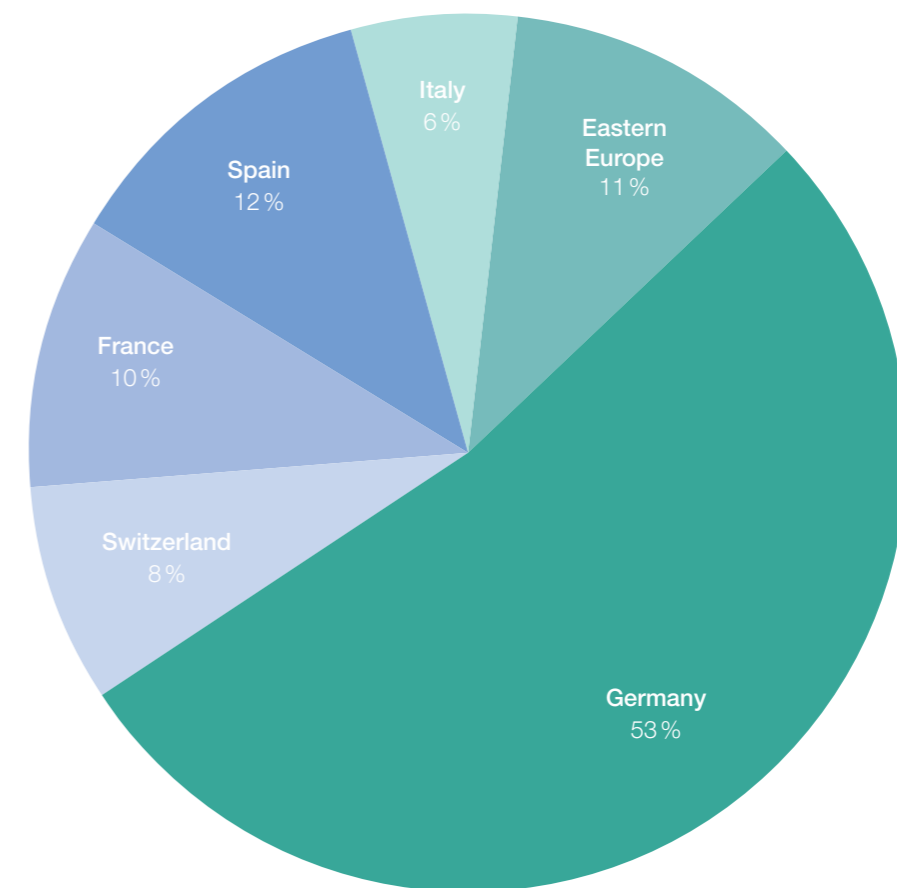


# Study Design

*The study is part of a worldwide online survey with 256 participants.*

The study is part of a worldwide online survey focusing on procurement-production, warehousing-cold-chain and distribution structures. In all, 256 persons participated in the study. The origin of the European participants: 53% Germany, 12% Spain, 6% Italy, 8% Switzerland, 10% France and 11% Eastern Europe.

Fig. 4  
Origin of European participants





# Study Results

# Study Results

*The top subjects in the pharmaceutical logistics are end-to-end supply chain visibility and optimizing the distribution networks. Pharma supply chain responsables face plenty of challenges!*

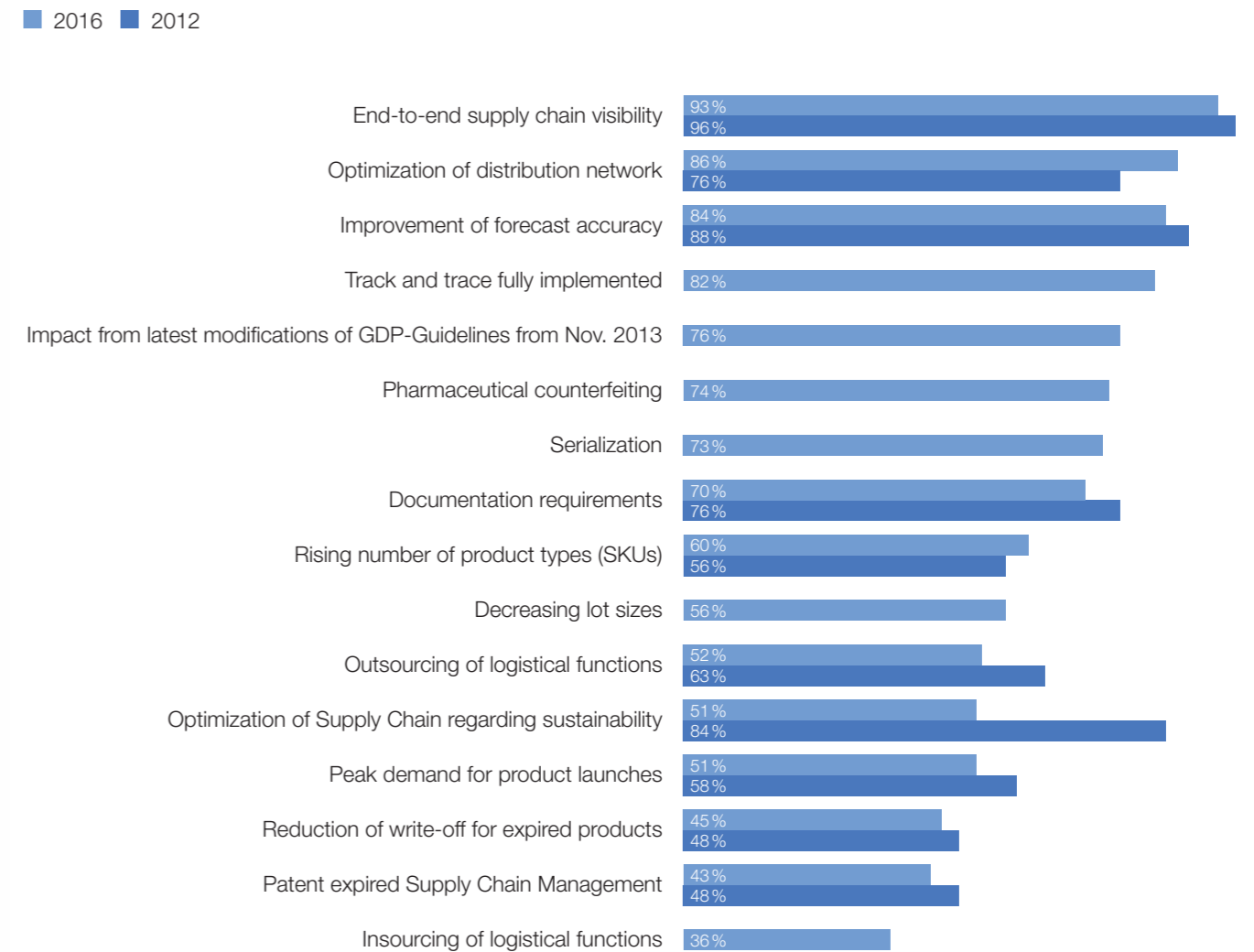
It has not been such a big surprise to find topics like end-to-end supply chain visibility (93 %), improving forecasting accuracy (84 %) and track & trace (82 %) as some of the most significant issues for the management, very much in line with our previous study.

Optimization of the distribution network has grown very much in importance (from 76 % to 86 %). The initiatives are aiming to transform many national networks into one more efficient and transparent European network, alongside with other many issues.

New challenges, and also very high in the ranking, are the impact of the change in GDP guidelines (76 %), counterfeiting (74 %) and serialization of product codes (73 %). These issues involve much more than the supply chain department. The entire company and even the pharmaceutical community need to find answers to these challenges. Counterfeiting, grey markets and illegal import-export of pharmaceutical products have already for decades been seen as a serious risk for the supply chain. Serialization might be the answer to some of the concerns and problems, but at first it puts a considerable amount of workload on all involved parties. From manufacturing-packaging to the departments of QA, IT, Marketing, Sales, Legal and of course Supply Chain – everybody is challenged.

Other mentioned subjects are ranked similar as in our previous pharma study. Issues such as increasing of SKUs, smaller batch sizes, demand peaks during product launches and others show more of mid-long term tendency to where the pharma industry is heading: globalization of the markets but at the same time personalization of the products.

Fig. 5  
The most important challenges in pharmaceutical logistics



Not in the ranking, but mentioned by several participants:

• **Temperature controlled supply chains**

It is very clear that the volume of products requiring different temperature conditions is increasing significantly: Not only biotech products but also vaccines for example need to be compliant with much stricter regulations. Please also have a look at our specific chapter about warehousing and cold chain on the following pages.

• **Reducing costs in the supply chain network**

This topic is very much in line with other industries, and has not been so much in focus during past surveys.



*Supply chain management in the pharmaceutical industry has become much more professional. We are talking about the European market in this study and it involves all steps from supplier to the final distribution. Plenty of challenges but also plenty of opportunities to improve lie ahead!*



Martin Eckert, Global Pharma Expert & Director, Miebach Consulting

# Procurement and Production Logistics

*Companies expect great challenges in supplier management, forecasting and lean approaches in manufacturing.*

The surveyed pharmaceutical companies see important potential benefits in improving supplier management (86%) and improving forecasting by optimization of the SCM processes (84%). Both subjects are closely connected and have been probably neglected in the past.

There are surely some lessons to be learned from other industry sectors like Fast Moving Consumer Goods or Automotive.

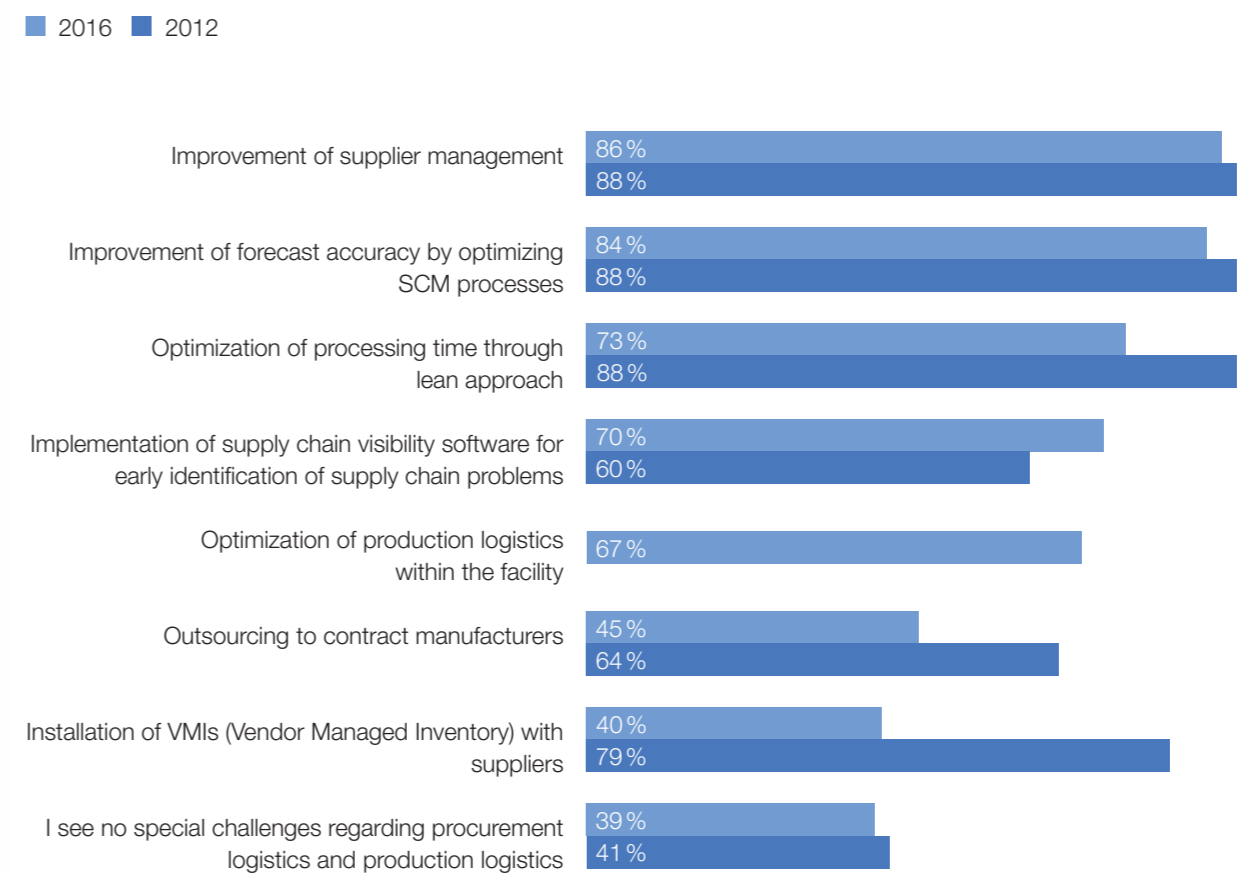
An important tool to facilitate both objectives will be the introduction of SCM software, which could connect all parties and in particular suppliers along the supply chain in real time (70%).

Ranked in second place are potential optimizations in manufacturing reducing throughput times (73%) by lean approach, and a general optimization of logistics in the manufacturing and packaging process (67%). Miebach Consulting can confirm these results from practical experience – in many pharmaceutical plants there is still a disconnect between logistics and manufacturing. Production lines are often running only 40–50% of the time and a real 24/7 operation is still far away.

Much less importance than in prior studies is given to outsourcing to contract manufacturers (45%) and the installation of Vendor Managed Inventory (40%).

The new requirements for serialization do not directly affect the logistics in production, but the production facility itself. Due to the 2D-codes (Data-Matrix), new printing and verification equipment is necessary to be implemented by 2019, as well as the data exchange and storage of the unique identifier-code.

Fig. 6  
Challenges in procurement and production logistics



# Warehousing and Cold Chain

*Expansion, optimization and outsourcing (external warehouses) have become routine tasks of the pharmaceutical industry! The strong focus is now on refrigerated and frozen products – which are growing and have quite different requirements.*

The results show that developing current warehousing structures is a major task for most participants of the study (64%). Optimization through automation (64%), outsourcing (62%) and constructing new warehouses compliant with GxP guidelines (54%) are in the same range.

Interestingly these answers are very similar to our prior pharmaceutical study. We tend to think, that these are routine tasks of a logistics and supply chain manager.

What is growing very fast year after year is the proportion of refrigerated and even frozen or deep frozen products (18 %/5 % expected in 3 years). Biotech and vaccines, but also other components and products require specific temperature conditions.

But still many of the pharmaceutical companies do not follow a complete cold chain, which for example is mandatory when distributing fresh food since many years. This is even more interesting, since the GDP guidelines (2013/C 343/01) are in place for over two years.

A major change in temperature controlling is, that the Mean Kinetic Temperature (MKT) is no longer allowed to be used as compensation for insufficient temperature control – but can only be used as a tool to decide if (well monitored) temperature deviation is critical or not. The impact depends very much on the stability of the API, which can be influenced by peak deviation as well as by plateau deviation.

Fig. 7  
Challenges in warehouse logistics

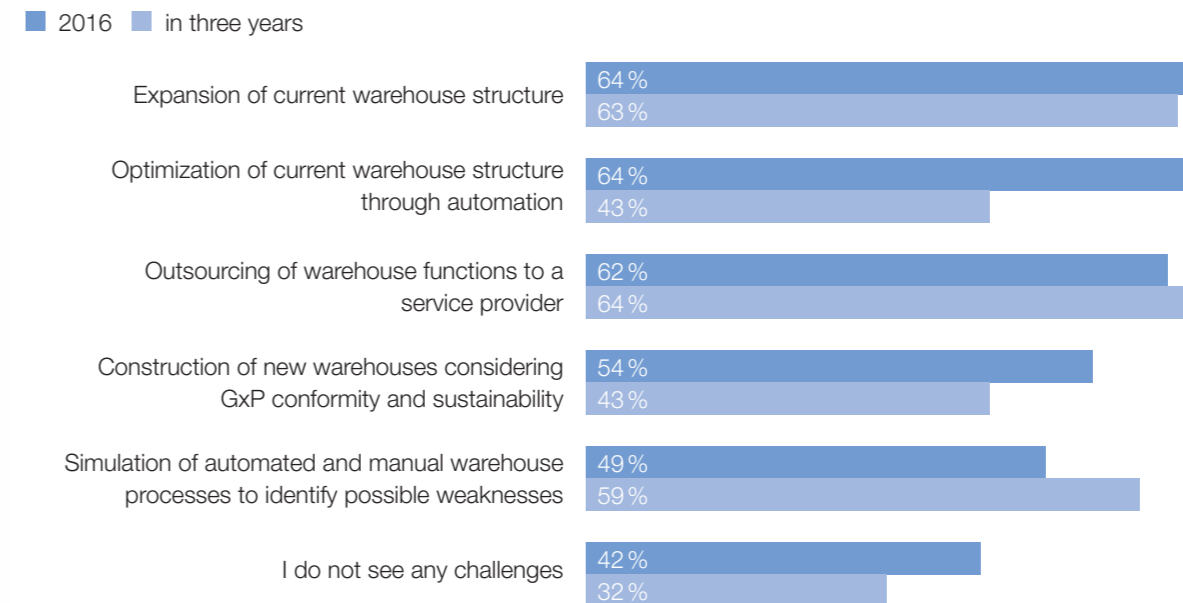
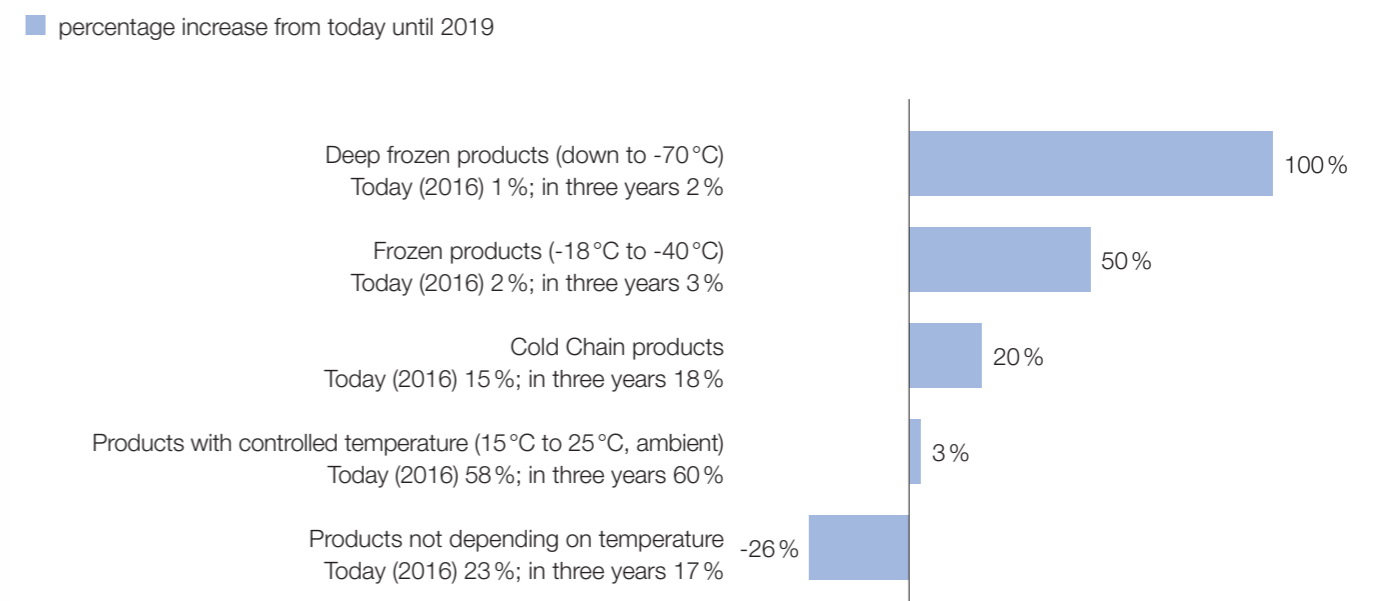


Fig. 8  
Growing percentage of products requiring specific temperature conditions



# Distribution

*The pharmaceutical industry is increasingly moving from national to European supply chain structures.*

Europe is considered by most pharmaceutical companies as a slowly but steadily growing market, as a result of the aging population in most countries. IMS Health estimates that the five largest markets for pharmaceuticals (Germany, France, Italy, Spain and the UK) will achieve somewhere between 1,5 – 3,0% growth on average per year.

A significant shift from national to European distribution structures could be observed by comparing with results of our 2012 pharma study, the current situation of 2016, and the outlook for the next 3 years.

National central warehouses will still be important, but are clearly in decline. Even a much more significant decline can be observed with national regional warehouses. There is little reason to maintain a costly regional structure when every client in the European countries can be served out of a national central warehouse within 24–48 hours.

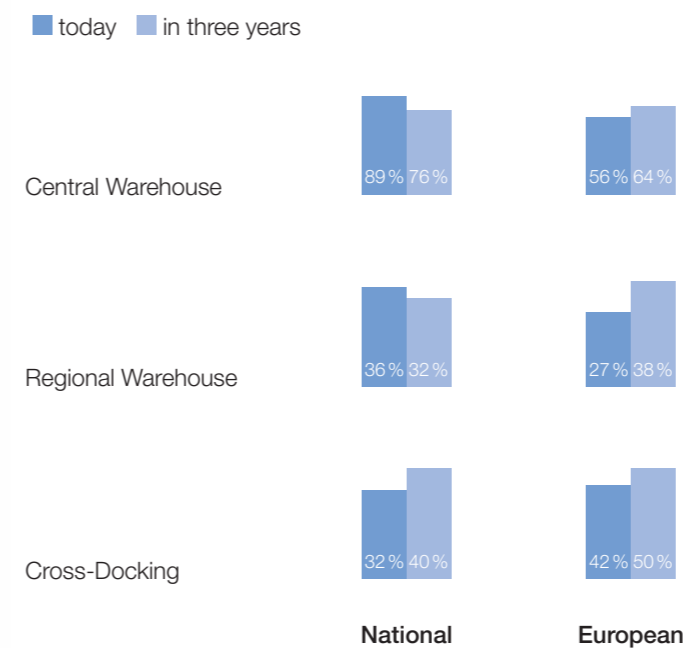
On the other hand, cross-docking operations (mostly run by 3PLs) are becoming a potential substitute to regional warehouses. They are more flexible and less costly.

European distribution structures are becoming increasingly important, as the result of this study shows: European Central warehouses are expected to grow from 56% to 64%, Regional warehouses from 27% to 38% and European Cross-docks from 42% to 50%.

Overall it can be stated that national supply chain structures are being substituted by European supply chain structures.

There might be several reasons for this development: Cost reduction, simplified management and control, less complexity and ease of regulatory compliance on an European level.

Fig. 9  
Development of European and National distribution structures



# Challenges in Distribution Logistics

*Optimization of the current distribution network and transportation are key for developing an efficient European supply chain structure.*

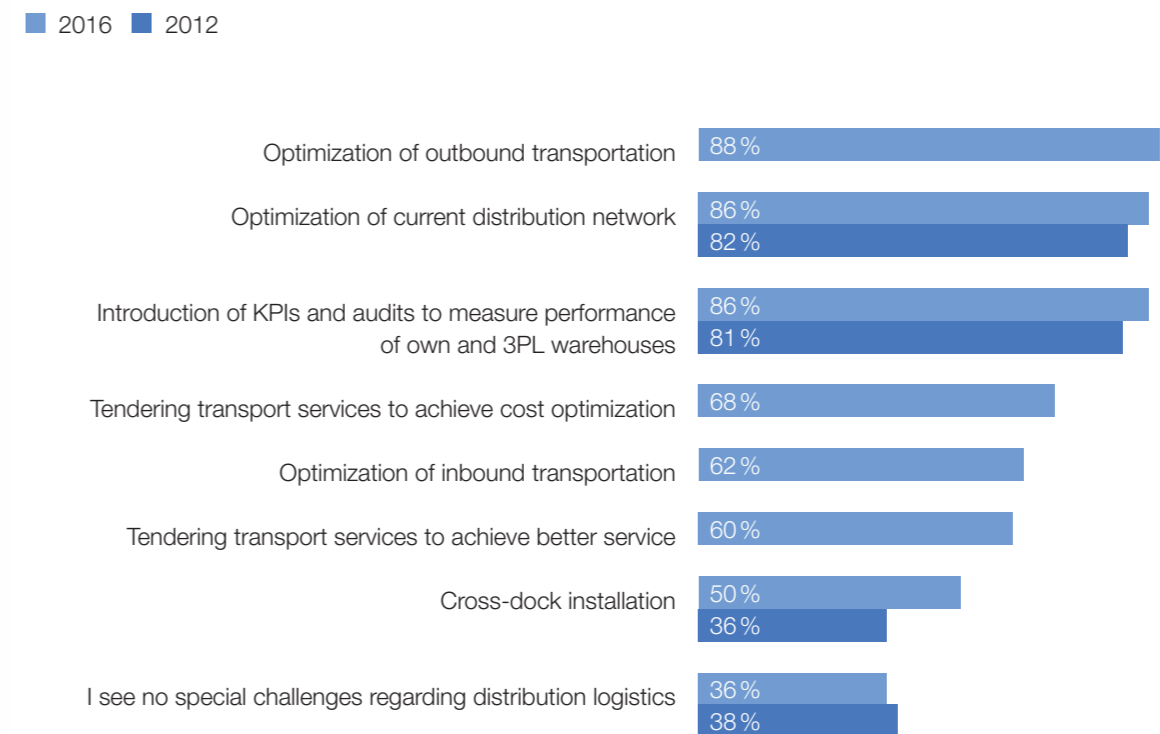
Optimizing outbound transportation (88%) and inbound transportation (62%) are very highly ranked as challenges. From our experience main concerns are compliance, control, responsibility and management of the different service providers rather than cost savings.

Optimizing the current distribution network (86%) and installation of cross-dock solutions (50%) are major tasks when changing from a national to a European distribution and supply chain structure – see previous pages about trends in distribution structures.

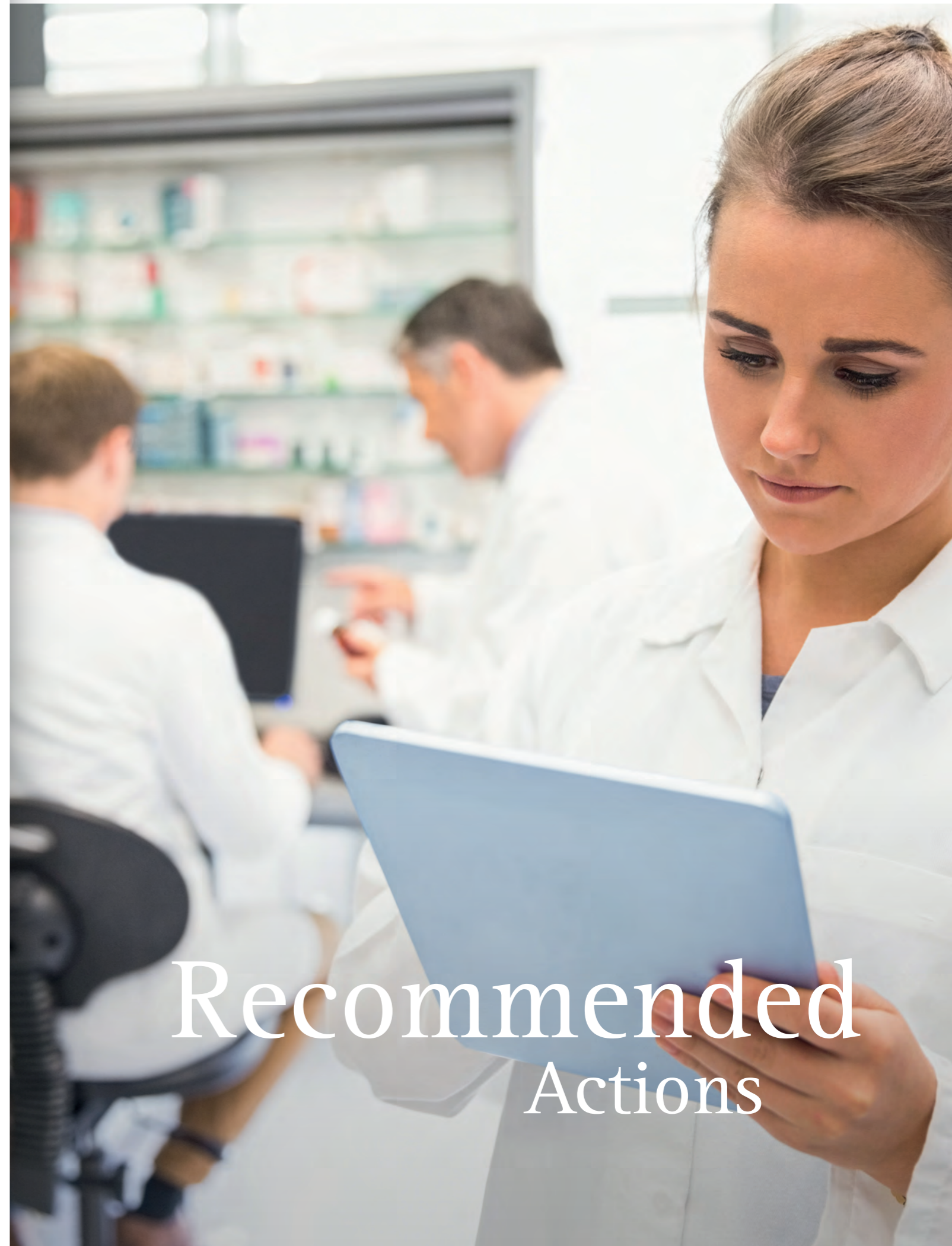
Other challenges involve the management of logistics third party service providers. Pharmaceutical companies use outsourcing mainly to manage transport and external warehousing and to a lesser degree also contract manufacturing and other minor logistics functions. Issues are the introduction of KPIs and audits to measure performance and compliance of external partners (86%).

Further tasks include tendering logistics services (typically every 2–3 years) to reduce costs (68%) and/or to improve service (60%).

Fig. 10  
Important challenges regarding distribution logistics







# Recommended Actions

## Supply Chain Transformation Projects

Most of pharmaceutical companies have already started or even completed the transition from national to European supply chains and distribution networks. These initiatives are aiming to simplify the network (besides a better control and compliance), to improve service and reduce costs.

Depending on the European footprint and size of the pharma company, we believe that such a major project should be undertaken every 5–7 years.

On a smaller scale, warehouse and distribution audits – still mostly on a country by country basis –, should probably be performed on a more regular base. Same for outsourcing and tendering of transport, warehousing and other logistics activities. Good experience has been made by performing these activities every 2–3 years.

### Efficient management of suppliers and service providers

Activities such as transport, external warehouses, contract manufacturing and others are often outsourced. Given the complexity of the European region, some pharmaceutical companies have 20, 30 or even more service providers to cover all of Europe.

To manage all these partners, efficient tools are very high in demand. Essential is the ease of gathering all relevant data (only possible with IT-systems support), so that most time could be dedicated to analysis and improvement.

If not already in place, we think the adequate KPIs should be gathered on a regular base. Audits also need to be performed on a regular basis.

*Most of pharmaceutical companies have already started or even completed the transition from national to European supply chains and distribution networks.*



## Lean Approaches and Optimization of Logistics in Manufacturing and Packaging

When working more than one shift in manufacturing and packaging – some plants today run 24/5 or even 24/7 per week – automation of all material flows and material handling is becoming very attractive. Even buffers, small warehouses and transport of material can be easily automated. The key to all of this automation is to connect the logistics with all the other work areas, such as sampling, kitting, dispensing, transport, palletizing, etc.

There are already plenty of pharmaceutical plants in Europe having successfully implemented such automation. Others have still some room for improvement.

To evaluate the potential to automate logistics and to improve the manufacturing process, a feasibility study is a good approach. Resulting projects for optimizing logistics in manufacturing and packaging are quite complex and require a certain CAPEX, often justified by improvements.

*Successfully implemented automation of all material handling in manufacturing and packaging show a remarkable improvement in velocity, safety and efficiency of the operation.*



# Cold Chain, Serialization, etc.

*Serialization and compliance with increasing cold chain regulations present a huge challenge!*



Initiatives and projects all along the pharmaceutical operation mean plenty of complex work for management and staff members.

Serialization should be well underway by now, according to the official timelines (e.g. securPharm in Germany). The “anti-counterfeiting” regulations ((EU) 2016/161 and 2011/62/EU) are finally released with due date February 9th, 2019. Implications on logistics are not driven by the regulations itself. The regulations demand an “end-to-end” verification system, which involves directly only production and retail. But considering the increasing interest in supply chain visibility, (e.g. tracking of single packages, handling of returns and random sampling), the tracking of the unique identifier might be a future challenge, especially for logistics IT systems.

Regarding cold chain – there is only limited experience available in many pharmaceutical companies. Why not apply some learnings from other industries such as the food or semi-conductor business.

To implement a cold store and then monitor the time out of refrigeration (TOR) is not a solution of the future. The effort to monitor, record and store all temperature data is significant.

We have seen in many aspects ever stricter regulations and we are completely convinced that in some near future a complete cold chain (very much as in frozen or refrigerated food) will be mandatory.

**With so many challenges ahead, it is probably wise to enhance the internal expertise with external experts, as required in each case.**



Miebach Consulting

# Miebach Consulting: The Supply Chain Engineers

## 1973

*Company founded by  
Dr. Joachim Miebach*

*With twenty offices in  
seventeen countries, we are  
one of the leading supply  
chain consultants.*

### Miebach Group

The Miebach Consulting Group was founded in 1973 in Frankfurt, Germany by Dr. Joachim Miebach to provide supply chain consulting as well as engineering services in logistics and production for large and medium-sized companies on a global scale.

The experience we have gained over the last forty years and by implementing countless projects has helped us to develop a methodical approach to supply chain engineering. We design and develop network structures, processes, and intralogistics along the supply chain. Strategy and technology are fully and equally taken into consideration as only integrating both elements will help develop an optimum result.

As consultancy partners, we deliver our services worldwide across twenty offices from Bangalore to Santiago de Chile. With approx. 320 employees Miebach is one of the leading global consultants for logistics and supply chain design.

Our global network of offices in key regions of Europe, North and South America, and Asia ensures we can provide optimum and effective support to our international customers based on local background knowledge.

### Client focus

Our main objective is to design and implement best in class solutions for our customers to achieve supply chain excellence and sustainable competitive advantage. We focus on cost and service efficiency, as well as flexible and reliable processes supported by an adequate level of automation to achieve maximum customer benefit.

Our mission is to add value and we are proud that our customers have won numerous logistics awards around the world.

### Expert knowledge

Over the last four decades, we have developed innovative logistics solutions, integrating the following competences which are key to an efficient and functional supply chain.

Miebach Consulting's strength is the ability to integrate these competences providing comprehensive solutions which exceed our customers' expectations. We design strategies, develop cost-effective feasible concepts, and determine IT solutions and technical equipment right down to the last detail. We take over responsibility and implement the solution we have developed. We also support customers during startup and fine-tune live operation. We believe that going the extra mile is the best way to make our customers' vision work. Our continuous efforts in Research and Development often generate ground-breaking innovations.

### Industry specialization

Miebach Consulting provides consultancy services to a broad range of industries. We believe that specialization is a must, in order to gain an exact understanding of our customers' specific requirements and processes. The exchange of expertise between industries also provides the perfect means to develop innovative and best in class solutions for our customers.

### Implementation driven

The primary focus of our strategy developments and designs is the implementation within budget, on time and providing full performance, including trained personnel.

More than 1000 logistics installations, designed and implemented by the Miebach Group, are operated successfully worldwide.

## 2014

- *Turnover of € 38.6 million*
- *320 employees*

# Miebach Consulting – global: directly available to you.



We would like to take this opportunity to thank all of the study participants. It is only thanks to their willingness to participate that studies, particularly in view of their strategic importance, can be realized.

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