



KALMS OPERATIONS
MEDICAL SUPPLY CHAIN SOLUTIONS

We support your **growth in Europe**

WHITEPAPER



Successful Device Operation in Europe

Launching operations in Germany and Europe for your medical device or pharmaceutical company can be a daunting task. It can be difficult to navigate the process without expert knowledge of the system and all the necessary steps you must take. With this list of **7 steps** from Kalms Operations, your company can start on the path to establishing successful operations in Germany and Europe.



The 7 Steps to Success

1

Fulfill necessary pre-requirements before entering Europe

Before beginning the process of establishing your operational business in Germany, there are several conditions you must fulfill. First, you must obtain a CE mark for any product you wish to sell and distribute in Germany and Europe. This step is of the utmost importance since no product can be sold in the EU without a CE mark, with only a few exceptions, e.g. for research. In many cases, you will also need to register your company at the DIMDI, the German Institute for Medical Documentation and Information. Additionally, all pertinent documents to your operational business in Germany must be translated into German.

Meanwhile, the process to begin operations in Germany can be lengthy, as there are many steps you must take within your company and with the German authorities. Therefore, all necessary forms should be prepared ahead of time to accelerate the process, helping ensure the process is as efficient as possible. Similar regulations apply in all other European countries with some small and bigger variations between those regulations.

To help companies expedite and simplify the process, Kalms Operations has created a thorough pre-requirement checklist of forms to complete. You can use this checklist to ensure your company and products are ready to begin operations in Germany and Europe. Kalms Operations is here to ensure the process is as quick and straightforward as possible.



2

Ensure your device logistics meet all necessary quality standards

Establishing EU-based device logistics helps you offer shorter delivery times, which is essential in the healthcare industry. You can save time and money by locating your warehouse in Europe, where the processing of shipments and customs can be handled locally. Opening an overseas division can be an expensive option for small and mid-size companies; therefore, a third-party logistics provider (3PL) can be the solution. Providing warehousing is not only about offering storage in Europe, but also entails upholding strict quality standards.

To sell your medical devices and pharma in Europe, you need a 3PL service that upholds Quality Management standards by being ISO 13485:2016 certified and can meet all your fulfillment needs. Additional key attributes to look for in a successful device operation include proper and secure storing measures, management of expiration dates, warehousing software with LOT-Management, worldwide shipping of goods, invoicing of goods and customs regulations and applications for shipments around the world.

Along with a warehouse that is ISO 13485:2016 compliant, the warehouse should uphold your SOP (Standard Operating Procedure) and any other quality standards. This includes a warehouse that will quickly report all feedback, especially any feedback from customers. Moreover, in the case of a product recall, your warehouse must support you with communication and return shipping and strictly follow your instructions and SOP. Kalms Operations' Berlin-based warehouse meets all quality standards and can reliably fulfill your requirements from a single delivery of goods to frequent shipments. We follow your SOP and quality requirements regarding service, warehousing, risk analysis, product handling and compliance/code of conduct (regulatory). Moreover, we help you to develop new and more effective new SOP in cooperation with your operations and quality teams.

3

Find a fulfillment partner with flexible and scalable services to fit your logistical needs

As your operational business in Europe expands, you need a fulfillment partner with extensive experience in healthcare logistics, who can tailor their services to you as you continue to grow. When choosing your fulfillment provider you should look for a provider who can increase your competitiveness. Things to look for include a flexible fee structure and fulfillment costs that mainly depend on the product shipping volume, as well as replenishment of consignment stock at clinical sites (if applicable), support with product recalls and customer mailings (marketing, customer information), invoicing including VAT handling and collection of bad debts. Furthermore, your fulfillment partner should be able to answer all your questions regarding bookkeeping and tax declarations and provide these services if necessary.

With Kalms Operations as your fulfillment partner, not only will our services be flexible and tailor-made to you, but we will be actively involved in creating your success. Our services can be flexibly added or canceled and are personalized to your needs and the size of your business in Europe. We constantly monitor our services and procedures to improve communication and efficiency.

4

Establish a multilingual, locally-based customer service team

European clients prefer local customer service in their time zone and who speak their language. However, employing a customer service team in Europe is costly and time-consuming to find the right, skilled staff for your company.

What services does a customer service team need to provide in the European environment? Customer Service is not only responsible for taking orders but must deliver effective complaint management and handle all the needs of your clients. A locally based, multilingual team must handle all problems, provide the delivery status and manage payment methods. They should also issue monthly reports on the number of shipments, customers shipped to with shipping data, issued invoices, warehouse stock and the shelf lives of stored goods. These services must be provided in a way that creates a positive customer service experience.

Kalms Operations customer service will inform clients of packing sizes and prices & shipping conditions, proceed with the packing of orders and provide service at the agreed upon times, per when and where your product is used. Our team will answer the phone in your name using dedicated phone numbers and fax lines that are available for orders and services. Furthermore, they will answer requests and provide offers, use a customer-branded email address and keep all customer-related documents and files as well as provide monthly statistics.

To further your presence in Germany, your company may also want to establish a virtual office with your locally based customer service team. This can be highly beneficial as your company can cultivate a presence in Germany without having to establish a formal entity, which would include renting an office and hiring staff. At Kalms Operations your company can have a virtual office in our Berlin office and take the first steps to establish yourself in Germany.

From our effective complaint management to our handling of your products, our multilingual customer service team will always go above and beyond for your company and your clients. Plus, establishing a virtual office can increase your presence and the effectiveness of your company in Germany.

5

Marketing material logistics

When you begin selling your medical device in Europe, your top priority will be to find a locally based 3PL service for your medical device, however, another priority should be finding a provider for marketing material warehousing and logistics. This may even be applicable before commercial rollout, e.g. when promoting the new product at a conference. Without a marketing material warehouse located in Europe, your company must ship material, and possibly heavy equipment internationally to clients or venues as needed, which is costly and time inefficient.

By utilizing a 3PL for your marketing material, you can save time and money by sending your material in bulk and allowing an experienced operation to handle the logistics of shipments to clients. Likewise, if your company exhibits at an international trade fair or

congress, the logistics of delivering and taking down your booth are time-consuming and costly. Instead, you can employ the marketing material logistic services of a warehouse to coordinate the delivery and safe return of your booth supplies.

Kalms Operations is here to solve all your marketing material logistical needs. With our fast-reach marketing warehouse in Central-Europe, your customers and your team are promptly provided with product information, conventional marketing material and product samples/equipment, with reasonable costs and significantly reduced risk of damage. Kalms Operations' support considerably reduces the need for extensive shipments to Europe. We monitor the stock of your marketing materials as well as shipments to events or clients, as well as managing the delivery and safe return of all marketing material and other booth materials from congresses or trade fairs.

6

Increase sales and improve Business Development plan

Does your product reach its goals? In the complex structure of the European Healthcare systems, it's easy to lose overview of your product's success. Sometimes small improvements can make a big difference, especially by utilizing professional contacts in the health care sector. Business development may not be top of mind as you expand your company in Europe, however, it is an essential component as it helps create long-lasting value for your company.

Kalms Consulting develops your business' overall game plan for reaching prospective customers and helps turn them into clients of the product or service you provide. We support you in communicating your products' attributes to the target customers based on their needs, competitive pressures and communication channels.

When building your pricing strategy, we consider segments, ability to pay, market conditions, competitive moves, margins and cost. The strategy will be targeted at the defined customers and against competitors. We evaluate the impact of approaching your customers directly, online, by phone or by using a combination of these channels; contracting a distributor or sales agent may also be part of this consideration. We propose a sales and distribution structure enabling your business to execute on this strategy successfully.

Kalms Group offers tailor-made solutions for your needs. In addition to the services of Kalms Operations, Kalms Consulting helps create market success by determining the best way to reimburse your product.

7

Find a local service partner

The road to operational success in Germany and Europe is not an easy one. That is why you need an experienced logistical partner whom you can trust to help guide you through the process and provide you with all necessary services.

Kalms Operations supports your company from the first stages; we are there to support you when you begin reaching out to start clinical trials and may only have a few shipments and only need support with a few other activities. We will be there to answer all your questions regarding topics like how a hospital can purchase your device, rules surrounding giving away free samples of your product, what needs to be invoiced, VAT and customs. Kalms Operations excels at clarifying the process of initiating operations in Germany.

When launching a successful medical device distribution business and going forward, you will be faced with a wide range of registration requirements in Europe. These can be for all of Europe or just for a few national states (eg. WEEE). Often you are going to need more than one partner.

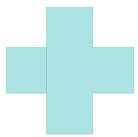
Kalms Operations can help you to coordinate and will review the necessary registrations with you. Kalms Operations helps to coordinate the various partners in your interest and thus relieves your company of additional, tedious coordination work.

Kalms Operations is, therefore, your ideal choice; we offer practical logistical solutions to help ensure your operational success in Germany and Europe. We provide central logistical and administrative services worldwide for companies who require a distribution center abroad.

Our mission is to be your smart one-stop solution for all your logistical and warehousing needs and who is actively involved in creating your success. This mission is supported by offering personal and multilingual customer service, flexible and scalable service modules and same-day response to your customers and your inquiries.

Whether your European business is about to start or already in place, a reliable partner is essential for your success, as well as to comply with regulations. We are your best option to grow your business in Europe and build a successful distribution operation.

Your European One-Stop-Shop Benefits



Bundling all necessary services for a successful device operation efficiently in one European Service Center and providing them modularly on your specific need is crucial to your European appearance.



We are a very experienced and dedicated, ISO-13485 certified, small team of experts with strong dedication to tech-based small and medium sized businesses.



Having only one point of access and communication for all administrative and operational requirements in Europe, it will save time and avoid extensive and redundant communicational effort.



Kalms Operations Services



3rd Party Logistics



Customer Service



Marketing Support



Product Registration



MDR & IVDR Importer of Record



Regulatory & Compliance



Corresponding Services

About us

Your Team Expert

Gerald Schröder

Head of Kalms Operations

Areas of Expertise

- Operation of 3PL services
- Regulatory Affairs
- Quality Management
- Compliance

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