KALMS
CONSULTING

Supporting your healthcare business from market entry to market success

Our Services:

Market Access

Companies face increasingly regulated markets in regard to pricing and reimbursement. Market access strategies are becoming crucial for commercial success.

Business Development

We support medical device, diagnostics, healthcare IT and biotech companies who are looking to enter the European marketplace.

Reimbursement

We focus on implementing reimbursement applications in all key European healthcare markets. Our local partners ensure professional knowledge and well established networks with important stakeholders.

Medical Aid / PZN Registration

The registration of your medical device for homecare purposes is crucial for a successful sale in the German healthcare system.

Public Affairs & Relations

In order to achieve a favorable reimbursement or regulatory framework, public affairs strategies should be an integral part of every market access strategy.

Operational Support

We offer healthcare logistics services that meet your requirements; from single deliveries to large scale shipping projects.

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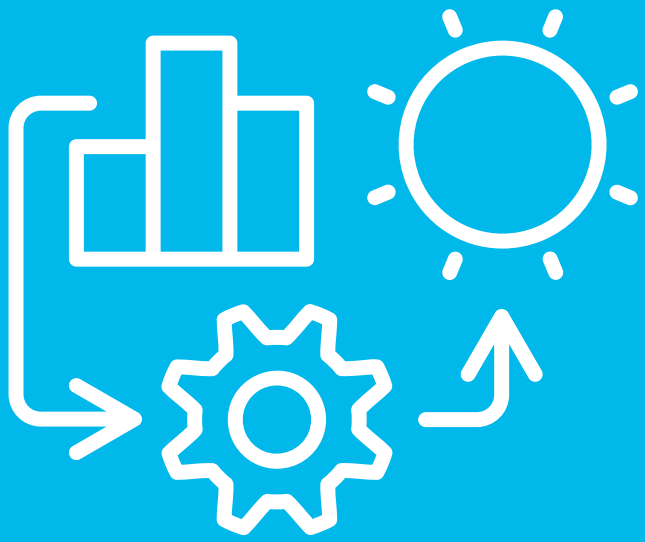
Market Access



Our Services:

- Market Potential Analysis
- Voice of Customer
- Identification of Key Markets
- Analysis of Evidence for Reimbursement
- Health Economics
- Consulting on Operational Structure and Fiscal Representation
- Business Development

Your Gateway to Europe

We are your gateway to one of the most lucrative healthcare and life science markets in the world.

Marco Kalms and his team have over 200 years of accumulated operational and strategic business experience in Europe; including sales and country management in various European leadership roles.

We offer strategic and operational support in the fields of market access, health economics, reimbursement and business development.

Our network of associated consultants in various countries enables us to manage and coordinate market access not only in Germany, but throughout the world. We know the healthcare markets and we understand the needs of international companies.

In-depth Strategic Planning

With your success in mind, we develop tailor-made pathways that match your individual needs. We'll keep you up to date about relevant changes in the market.

We do not work with standardized concepts. Instead, we'll analyze your projects in minute detail; because of our thoroughness, we'll find feasible, practical solutions for all your problems. Our experts will take care of your entrepreneurial issues and develop your projects from strategy to execution.

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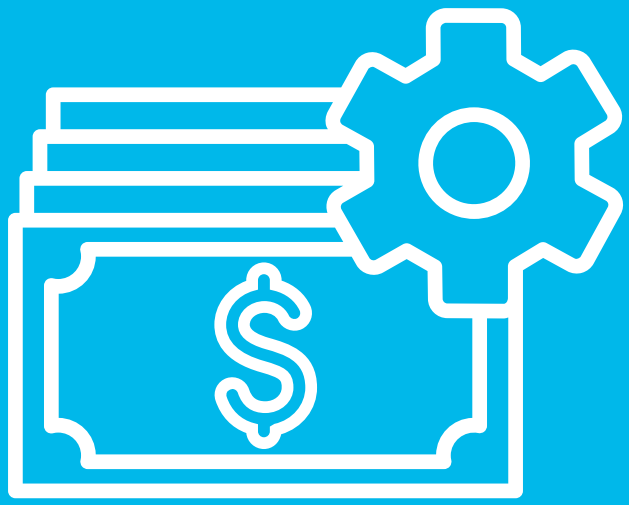
Reimbursement



Our Services:

- Development of Reimbursement Strategies
- Preparation of Reimbursement Applications
- Risk Assessments
- Key Opinion Leader Contacts
- Alignment with Medical Societies
- Selective Contracting with Statutory Health Funds
- Integrated Care
- Single Case Authorizations
- All Follow-Up Activities

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Regulatory Services

Our Services:

- Development of Regulatory Strategies/Solutions
- MDR/IVDR Classi ication
- Gap Analysis
- MDR/IVDR Compliant Documentation
- Setting up and Evaluting Quality Management Systems
- Audit Support
- Post-Market Surveillance
- Noti ied Body Selection and Coordination

Regulatory Solutions

In 2017 the MDR-Medical Device Regulation and IVDR-In vitro Diagnostic Medical Device Regulation replaced the former directives.

Through this fundamental change, a new European wide legislation is in force that will have a significant influence on the entire medical device market due to its central regulation, organization, changed procedures and standards that are aiming for advanced transparency, traceability and patient safety.

Kalms Regulatory team combines profound market knowledge and strong analytical capabilities to understand the value of your product and create and implement a streamlined regulatory strategy.

We believe that early assessment, preparation and constant product and process improvements are key to face the new MDR and IVDR requirements and challenges and will make your product, the healthcare market and in conclusion the patient's life safer and better.

Our Services

We support you in top regulatory compliance in a modular format:

- IVDD/R and MDD/R Gap Analyses
- QMS Setup (e.g. EN ISO 13485, 9001, 15189, etc.)
- Risk Analysis and Risk Management
- Clinical Evaluation Report Compilation
- TD Compilation and Update
- Audit Training and Readiness
- Post Market Surveillance Plans
- Compliance Training
- UDI and EUDAMED Registration

Support and management of Notified Body selection and application, as well as CRO selection from our network.

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Reimbursement

We specialize in developing and executing reimbursement strategies.

Obtaining reimbursement can quite often be a long-term project; and success depends on various factors, terms and regulations. Our experts will not only inform you about the opportunities and potential risks, but also support you with all the details of implementation. Our services include preparation, submission and support of all reimbursement applications in Germany.

With our strong global network of qualified partners, in all relevant healthcare markets, you are guaranteed to have full coverage in the areas of consulting we provide; ensuring that experts all over the world will be working to achieve your success.

Our Services

The reimbursement application services we provide in Germany include:

- NUB (Innovation Payment)
- OPS (Procedure Codes)
- DRG / ZE
- Medical Aid Catalogue
- PNZ (Pharmacies)
- BVL (Consumer Protection and Food Safety)
- Selective Contracting with Statutory Health Funds
- Integrated Care
- Single Case Authorizations

and much more. Similar services are provided in other countries by our local partners.

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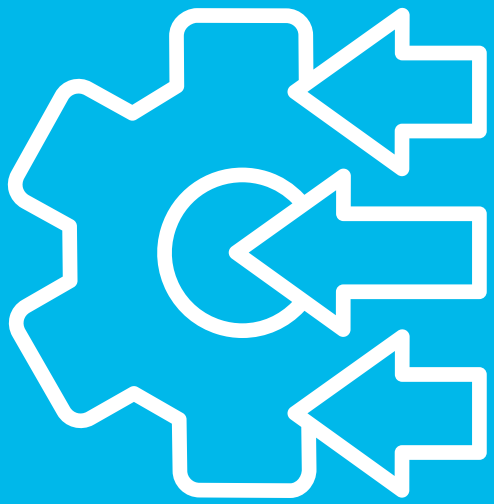
Operational Management



Our Experience:

- Market Access
- Reimbursement
- Strategy Development & Execution
- Public Affairs & Public Relations
- Interim Sales Models
- Company Representation
- Interim Management

Marco Kalms

- Built a sales & marketing organization and company structure / GmbH in Germany.
- Country Manager Germany / Geschäftsführer GmbH for 6 years - 25 employees, € 20M revenue, AMS Deutschland GmbH, double digit growth every year.
- Managing Director Europe for 3 years, 150 employees, € 100M revenue, American Medical Systems Inc. (NASDAQ), double digit growth every year and full P&L responsibility.
- M&A: due diligence and EU-wide integration of a major acquisition.
- Senior Director Strategy & Health Economics EMEA for 4 years - Built up an EMEA - wide structure: strategic leadership, HE, reimbursement & public affairs and major HE / reimbursement initiatives in EU Big 5 countries.

Visit kalmsconsulting.com to see the profiles of all our experts and associated partners.

Dr.-Ing. Holger Schaffrath

- 3 years managing a start-up (Inspire Health) in Germany, including FDA approval study, all market access activities from reimbursement to KOL and health insurance communication, marketing, market entry strategy and execution.
- Manager of another start-up (Trivascular) during ramp-up phase.
- More than 10 Years of Business responsibility within Medtronic, Head of Vascular Germany, Revenue responsibility € 30- 55M and a Team size of 30 heads.
- Start-up representation for Arterial Vascular, Manager and market access responsibility, Revenue up to € 20M, 2 country teams, 40 employees. Served 3 years in different positions and Marketing Manager to Managing Director Germany and Benelux.
- Marketing Manager Europe & product specialist at Boston Scientific for 5 years.

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Outpatient Care - Medical Aid Catalogue & PZN Registration

Our Services:

- Hilfsmittelantrag: Application for the Medical Aid Catalogue
- Allocation of Pharmaceutical Registration Numbers (PZN / Pharmacode Registration)
- Analysis of All Relevant Codes & Catalogues
- Application Writing
- Communication with Stakeholders
- Submission of Applications and All Follow-Up

Medical Aid Catalogue of SHI in Germany

In principle, the costs for medical aids can only be covered by statutory health insurances when they are listed in the medical aid catalogue (HMV).

Thus, the HMV is a positive list, which also specifies the essential quality criteria of all products. In the HMV, products are assigned to different product groups; according to their application areas. Products are listed at the request of the manufacturer, if all predefined features and quality characteristics are met, via a formal application.

Kalms Consulting offers a two-step approach: Firstly, an assessment of the proper medical aid category and the relevant application requirements, and secondly, with our assessment in mind, we'll submit your application; ensuring a successful and well-prepared market access.

Pharmaceutic Wholesalers Catalogues (PZN & Pharmacode)

Once prescribed, your medical aid for outpatient use needs to be easily accessible in every wholesalers catalogue. Kalms Consulting provides comprehensive services to register your device in the PZN and Pharmacode System of Germany, Austria and Switzerland. To avoid product substituton, make sure your product can be easily found in those catalogues.

We'll help you with all the necessary registration work.

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Public Affairs

Our Services:

- Public Affairs Strategies
- Awareness Initiatives
- Representation in Industry Associations
- Initiating Dialogues with Political Experts
- Establishing Relations with High Level Stakeholders
- High Level Contacts to Public and Private Health Funds

Public Affairs

In order to achieve a favorable reimbursement or regulatory framework, public affairs strategies should be an integral part of every market access strategy. Additionally, the reimbursement potential of direct contracts with public health funds require a high-level dialogue. We develop public affairs strategies and initiate contact with stakeholders. And we translate your message into a language that the stakeholder understands.

There are various reasons to establish contact with the public: such as increasing brand awareness, informing patient representatives on new therapies, seeking support for your regulatory proposals, improving your reputation and preventing any future communication risks.

Increasing Credibility

Our advantage in comparison to the large public affairs agencies is this:

With our clear focus on medical devices and pharmaceuticals, we have a thorough understanding of health economics and the medical background that is important for your product.

This increases your credibility.

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KALMS
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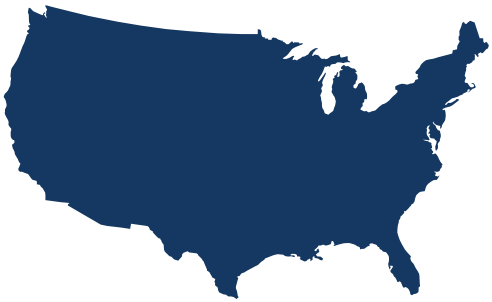
Your Gateway to the US

Our Services:

- FDA Approval
- Regulatory Support
- Market Access
- Reimbursement Strategy
- Code Analysis & Applications
- Coverage Advocacy
- Health Economics Analysis
- Business Development
- Logistical Support
- Accounting Services

The Biggest Healthcare Market in the World

American and international companies face the same challenges in bringing medical technologies into the U.S. market – the biggest healthcare market in the world. Answering the legal questions, figuring out market access and reimbursement, as well as stakeholder management and operational tasks (clinical and post marketing studies, sales structures, plans for product launch, etc.) are major topics to address in order to successfully introduce a product.
Kalms Consulting has established a network of reliable, experienced partners throughout the U.S. This puts us in a position to provide the best possible service for all stages of the market access process. Our long-term experience in American inbound and outbound services enables us to expertly coordinate your projects in the USA. Furthermore, if requested by the client, we are able to represent companies in the USA in a way that reduces the burden on their own personnel to a minimum.



New Opportunities

Introducing a new product into the American healthcare market requires specific skills, experiences and an exceptional understanding of the reimbursement system.

Together with our US based partners, Kalms Consulting supports international companies entering the U.S. market.

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About Us

Kalms Consulting offers a complete consultancy service for medical device manufacturers and selected services for pharmaceutical companies. Based in Berlin, we support your business success in Europe by applying our expertise of the medical device market in Germany.

We are your gateway to one of the largest medical technology markets in the world. Marco Kalms and his team have over 200 years of accumulated operational and strategic business experience in Europe, including sales and country management in various European leadership roles. We offer strategic and operational support in the fields of market access, health economics, reimbursement and business development.

Locations

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