

## Analysis

*“When we perform our assessments, we gather high quality information by interviewing local end users, distributors and industry or product specialists. We also access both proprietary and public databases from available resources. We can provide both country level and industrial level analysis services.”*

## Value Proposition

We support Medical Device manufacturers with local representation, transparency and access to information, professional management, and other leadership services. We help Medical Device manufacturers access the market and improve performance at a lower cost and lower risk than doing so independently. We also offer a trusted network of distributors who understand and conform to international standards of performance.

## Multifunctional Provider

The healthcare business is regulated in multiple layers. Regulatory changes may impact your decision-making, time-to-market and the competitive landscape. Expertise in a discipline is not enough to succeed in the healthcare business. You need an interdisciplinary partner like Servi-Star who can provide you with holistic business solutions to overcome business challenges.

## Client Profile

We work with Medical Device manufacturers along a continuum of growth. Some of our clients are already engaged in selling their products, but believe their sales potential is greater than their current performance. Many of our clients are frustrated by the lack of information and transparency of operations and are finding it challenging to make sound decisions without accurate information.

Some clients are experiencing issues with their partners in some countries and looking for help changing and implementing their business strategies. Some have made the decision to move forward within the opportunities in their respective markets and are engaged in country specific product registration. A number have recently received approval to sell products and are searching for the optimal execution strategy. Others are contemplating the opportunity to enter the market, but uncertain about the size of the markets and best path forward.

## Engaging our Services

We work with our clients to identify the desired scope of services to be performed and the best approach. Once business is in progress, we provide regular updates progress reports of all deliverables and specific milestones achieved.

We typically perform services on a retained services agreement or on a project based consulting agreement. If you decide to choose a market entry via our company pool and distributor network platform, we charge a membership fee as well as a nominal percentage of products sold through our network. We also act as regional agents.



**SERVI-STAR**  
CONSULTING

**30 years of experience and knowledge in the International healthcare industry**



SERVI-STAR



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**Your partner in the  
HEALTHCARE  
INDUSTRY**





## Introduction

Servi-Star Consulting is a regulatory consulting and advisory company with subsidiaries in Singapore (Implantex Pte. Ltd.), Indonesia (PT TF Consulting Business Solutions) and Malaysia (Implantex (M) Sdn. Bhd.) as well as partner offices in China, India, Japan, Korea, Thailand and Vietnam. We help medical device manufacturers understand and succeed in a very complex and dynamic marketplace. We are a team of professionals with extensive working expertise dedicated to the medical devices industry. We are singularly focused on helping our clients achieve their maximum potential with business operations in foreign markets.

We offer a comprehensive set of services designed to help medical device manufacturers at all stages of growth. We perform in-depth market analysis, competitive and opportunity assessments, market entry planning and execution, expansion and partnering strategies, OEM partnering as well as interfacing with our network of high quality medical device distributors. If our current distributor network isn't suitable, we can investigate to find appropriate distributors and adapt distributor management services as required. We provide education, training and other services for existing and new distributors to enhance their professionalism and level of client service.

[www.servi-star.com](http://www.servi-star.com)

## Experience Counts

Our staff have more than 27 years management experience in Asia Pacific, utilizing over 30 years of experience and knowledge in the International healthcare industry covering Asia, Oceania, Europe and Southern Africa. We have intimate knowledge of local markets and cultures with multilingual capabilities. We have assisted start-up companies in China, Indonesia, Malaysia Singapore and South Africa. We are experienced in set up of distribution networks, Key Account and Relationship Management, and have actively managed and supervised Human Resources for several large corporations.

## Business Development

- Business development plans, contracts and other commercial arrangements.
- Distribution agreements with Business Partners, strategic alliances.
- Service agreements and standard terms & conditions for your business.
- Sales forecasting and budgeting.

## Market Analysis

- Feasibility Studies/Market Analysis/Due Diligence.
- Distributor profiling.
- Convenient Market Entry via our company pool.
- Development and Implementation of Sales and Marketing Strategies.
- Customized Benchmarking and Customer feedback analysis.

## Partner Management

- Evaluation of existing Distribution partners.
- Research, selection and evaluation of suppliers and partners.
- Distributor screening process (Search, Qualification, Selection, follow-up).
- Training and Education of existing or new distributors for Medical Device Compliance and Regulatory.

## Quality Management

- Quality Management System (ISO 13485, GDPMDs) implementation for Medical Device Manufacturers.
- Audits, Due Diligence for 13485, 21CFR820, ANVISA, CDMCAS
- Support, Preparation of Audits & Inspections

## Regulatory Affairs

- Product Registration for Medical Devices.
- Licence Holder Management.
- Regulatory Consulting and Document service.
- Reimbursement.
- Adverse Event Reporting and Product recalls.
- Medical Device Regulatory Compliance training.
- Quality Management System (ISO 13485, GDPMDs) Implementation for Medical Device Manufacturers.

## Strategic Consulting

- Establish Country HQ Subsidiary or Representative office.
- Manufacturing process and pre-delivery inspections prior to shipment of your products.
- Outsourcing support for clinical studies.
- Supply Chain Management, Logistics and Warehouse location support.
- OEM Outsourcing consultancy.

