



International Resource Guide

Prepared for Participants of the VEDP Program

Virginia Leaders in Export Trade (VALET)

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Research Topic: International Medical Device Markets

Research Objective: Provide information on foreign medical device markets including market size, trade data, resources, events, and contacts.

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Division of International Trade

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Introduction

This international resource guide was developed for manufacturers, wholesalers, suppliers and service providers of various products and services used in the healthcare market. Information provided in this ample medical industry guide is organized for quick access to pertinent resources worldwide. Please browse through the sections and you will find hundreds of resources to get started in your international sales efforts in the complicated field of medical equipment, devices, supplies, and services. If you are looking for a more detailed analysis of the myriad healthcare markets, there are specialized reports available for purchase from major consulting firms.

For the purpose of this guide, medical devices are defined as: instruments, apparatus, implements, machines, contrivances, implants, in-vitro reagents, or other similar articles that are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. This definition was derived from the United States Food and Drug Administration (FDA) www.fda.gov/cdrh/devadvice/312.html . Other categories mentioned within, such as “healthcare equipment and supplies” may include medical devices or be a sub-category of the same, i.e., orthopedics, surgical. No attempt to reconcile the sales or trade numbers should be made. Ultimately, these labels merely provide a snapshot of the potential market for products within the group.

U.S. manufactures are required to register their facility and list their exported medical devices with the FDA. U.S.-based operations may import medical device parts, components, subassemblies, etc. for further processing or incorporation into unapproved devices which are to be subsequently exported. Companies cannot import a finished unapproved device without prior FDA marketing clearance, even if the device is to be imported solely for subsequent export. Medical devices that are in the U.S. legally can be exported virtually worldwide without prior FDA notification or approval. If the device has not been approved, it must follow the export provisions of the U.S. Food, Drug, and Cosmetics Act. Some countries require written certification that a firm or its devices are in compliance with U.S. law. The FDA or VEDP can accommodate Virginia exporters by providing a Certificate of Free Sale (for a fee) which will meet foreign regulations.

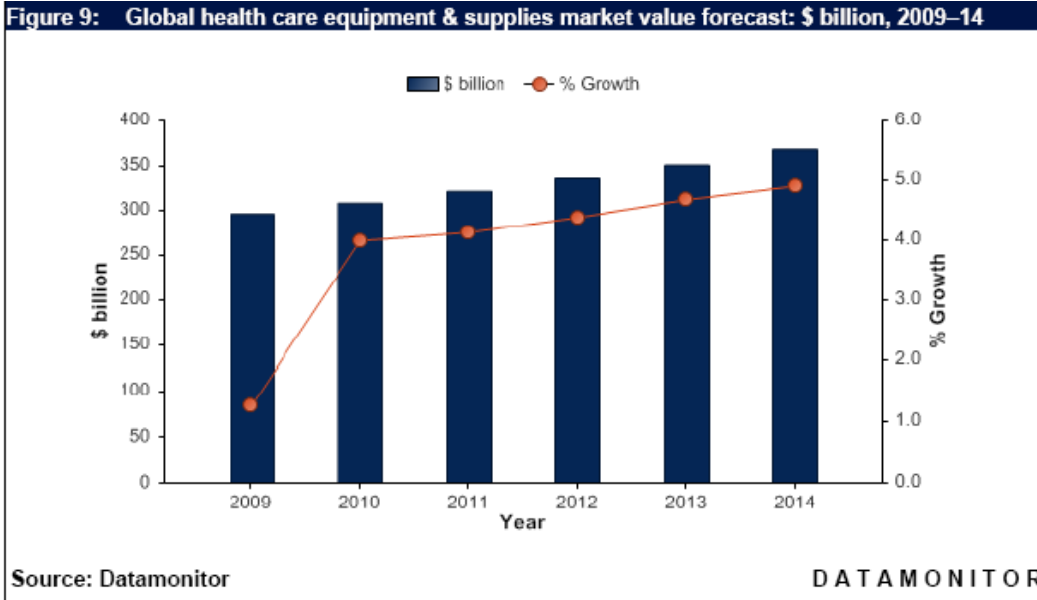
The U.S. medical device industry has long been one of the most successful exporting sectors. Virginia manufacturers are encouraged to capture their share of the worldwide market with the help of this international resource guide.

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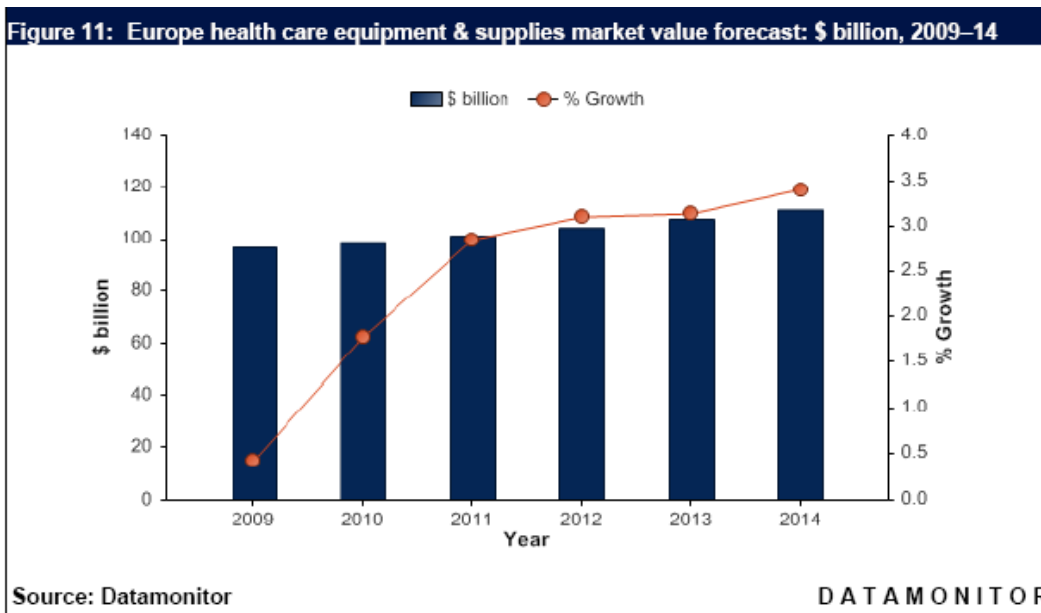
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Industry Overview

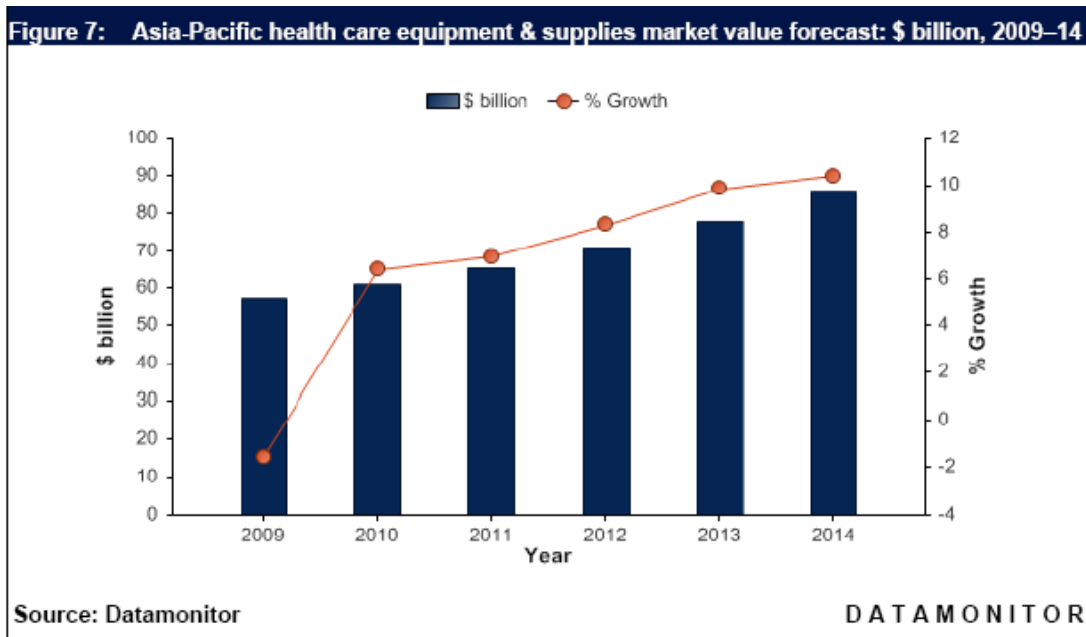
The **global health care equipment and supplies market** grew by 1.3% in 2009 to reach a value of \$296.7 billion. In 2014, the worldwide market is forecast to have a value of \$368.5 billion, an increase of 24.2% since 2009. Disposable equipment and supplies is the largest segment of the total market, accounting for 40% of the market's total value. The Americas account for 48% of the global market value.



The **European health care equipment & supplies market** grew by 0.4% in 2009 to reach a value of \$96.8 billion. In 2014, the European market is forecast to have a value of \$111.4 billion, an increase of 15.1% since 2009. Disposable equipment and supplies is the largest segment of the European market, accounting for 41.9% of the total value. Germany accounts for 31.3% of the European market value. The European market is characterized by large international incumbents which increases rivalry somewhat. Large sales forces and sustained marketing efforts raise the stakes in the market which makes it harder for small companies to compete. Leading companies are Abbott Laboratories, Johnson & Johnson, Medtronic, Inc., and Siemens Healthcare.



The **Asia-Pacific health care equipment and supplies market** shrank by 1.5% in 2009 to reach a value of \$57.6 billion. In 2014, the Asia-Pacific market is forecast to have a value of \$86.1 billion, an increase of 49.6% since 2009. Disposable equipment and supplies is the largest segment of the market, accounting for 37.6% of the total value. Japan accounts for 39.5% of the Asia-Pacific market value. Similar to the European market, the Asia-Pacific health care equipment and supplies market is characterized by large international incumbents which increases rivalry somewhat. Leading companies are Abbott Laboratories, GE Healthcare, Siemens Healthcare, and Toshiba Medical Systems Corporation.



The global orthopedics market grew by 7.2% in 2008 to reach a value of \$19.2 billion. In 2013, the worldwide market is forecast to have a value of \$27.4 billion, an increase of 42.9% since 2008. The spine implants segment generated 30.7% of the market's overall revenues. Americas leads the global orthopedics market accounting for 71% of revenue.

Excerpts and graphs above from Datamonitor Industry Profiles: Healthcare Equipment & Supplies – April 2010

The **U.S. medical supplies and devices manufacturing industry** includes about 11,000 companies with combined sales of \$75 billion annually. Major companies include Baxter International, Boston Scientific, Johnson & Johnson, and Medtronic. This industry is very concentrated as the 50 largest companies earn about 75 percent of total revenues.

The **U.S. medical equipment and supplies distribution industry** consists of more than 7,600 companies with revenue around \$135 billion annually. Major companies include Henry Schein, Owens & Minor, Patterson Dental, and PSS World Medical. This industry is concentrated as the top 50 companies earn more than 70 percent of revenue.

In terms of U.S. exports, it is highly probable that major manufacturers and distributors are responsible for even more than their share of revenue from foreign markets as noted above. Foreign regulations and market risks are very costly and small companies generally struggle to compete.

U.S. Exports of Select Equipment and Products for Medical/Hospital Use

Despite the worldwide recession over the past two years, the data below shows that U.S. exports of many medical and hospital goods continue to grow, or at least rebounded from 2008 volumes. The medical industry has not been as hard hit as other industries, but there can be a lag in market contractions as upgrades and new construction are delayed or people simply delay treatment. For many products, the U.S. may be one of the few sources which stabilize demand.

HTS	Product Description	Millions of U.S. Dollars			△09/08
		2007	2008	2009	
9018-90	Other Med/Surg/Den/Vet	\$ 3,561.46	\$ 3,667.59	\$ 3,951.40	7.7%
9018-39	Other Med Needle/Catheters	\$ 1,656.56	\$ 1,773.69	\$ 1,892.93	6.7%
9018-19	Other Elec-Diagnostic Appliances	\$ 1,361.20	\$ 1,410.75	\$ 1,448.56	2.7%
9021-39	Artificial Joints & Parts & Access	\$ 981.62	\$ 909.96	\$ 1,204.61	32.4%
9021-90	Other Device Worn/Carried/Etc	\$ 641.25	\$ 789.16	\$ 687.49	-12.9%
9021-31	Artificial Joints and Parts An	\$ 418.95	\$ 523.07	\$ 566.64	8.3%
9021-10	Orthopedic or Fracture Appliance	\$ 523.19	\$ 565.77	\$ 551.75	-2.5%
9001-90	Lenses, Prisms, Mirrors	\$ 473.52	\$ 287.58	\$ 527.60	83.5%
9022-90	X-Ray/Hi Tnsn C Panel	\$ 448.99	\$ 402.64	\$ 460.39	14.3%
9019-20	Ozone/Oxygen/Etc Therapeutic	\$ 350.52	\$ 334.98	\$ 412.77	23.2%
9022-12	Computed Tomography	\$ 218.59	\$ 212.97	\$ 338.66	59.0%
9018-12	U-Sonic Scanning Appliance	\$ 335.27	\$ 284.20	\$ 321.33	13.1%
9022-14	Other X-Ray/Med/Surg/Etc	\$ 271.56	\$ 306.02	\$ 315.58	3.1%
9018-31	Syringes, Parts + Access	\$ 354.83	\$ 255.22	\$ 271.66	6.4%
9021-50	Pacemakers	\$ 245.84	\$ 345.88	\$ 270.90	-21.7%
9018-50	Other Ophthalmic; Parts	\$ 222.63	\$ 221.91	\$ 260.87	17.6%
9018-13	Magnetic Res Imaging Appliance	\$ 149.95	\$ 177.81	\$ 244.92	37.8%
3006-10	Surgical Catgut/Etc	\$ 172.18	\$ 203.84	\$ 218.42	7.2%
9022-30	X-Ray Tubes	\$ 177.58	\$ 196.01	\$ 212.87	8.6%
9402-90	Furniture/N Dental /Barber Chair	\$ 158.65	\$ 169.05	\$ 178.81	5.8%
9022-19	X-Ray Base/Nt F Med	\$ 174.02	\$ 154.00	\$ 175.24	13.8%
9018-49	Other Dental Science	\$ 206.07	\$ 176.86	\$ 172.16	-2.7%
9021-29	Dental Fitting, Parts + Accessories	\$ 121.39	\$ 132.26	\$ 162.73	23.0%
9019-10	Mech-Therapeutic /Massag/Psyc	\$ 141.11	\$ 107.33	\$ 138.10	28.7%
3006-40	Dental Cement/Filling	\$ 97.60	\$ 93.94	\$ 116.12	23.6%
9018-32	Tubular Metal Needle	\$ 68.43	\$ 94.45	\$ 115.40	22.2%
9021-40	Hearing Aids	\$ 139.97	\$ 77.00	\$ 71.08	-7.7%
9018-11	Electrocardiograph/P/Ac	\$ 99.64	\$ 81.27	\$ 70.77	-12.9%
3006-91	Appliances Identifiable For Os	\$ 53.03	\$ 52.65	\$ 70.25	33.4%
3006-20	Blood-Grouping Reagents	\$ 54.94	\$ 60.63	\$ 60.54	-0.2%
9021-21	Artificial Teeth, Parts + Access	\$ 68.72	\$ 63.15	\$ 56.20	-11.0%
9012-90	N-Opt Microscope Parts	\$ 34.87	\$ 36.76	\$ 42.19	14.8%
9012-10	Microscope/N Optical	\$ 36.35	\$ 38.64	\$ 41.45	7.3%
9022-13	Other X-Ray Base for Dental	\$ 46.04	\$ 32.29	\$ 39.86	23.5%
9018-14	Scintigraphic Apparatus	\$ 47.31	\$ 49.55	\$ 36.76	-25.8%
9001-20	Sheet + Plate of Polarized Mater	\$ 27.31	\$ 13.20	\$ 36.02	172.9%
9018-20	U-Violet, Infrared Ray	\$ 23.94	\$ 23.61	\$ 34.46	46.0%
3006-30	Opacifying For X-ray	\$ 25.99	\$ 28.42	\$ 32.40	14.0%
9022-21	Alpha/Beta/Etc Base	\$ 21.24	\$ 14.72	\$ 28.68	94.8%
9402-10	Dental, Barber Chairs & Parts	\$ 23.71	\$ 20.61	\$ 24.81	20.4%
9022-29	Alpha/Beta/Gamma/N Med	\$ 27.25	\$ 17.84	\$ 16.82	-5.8%
9018-41	Dental Drill Engine	\$ 11.47	\$ 12.64	\$ 13.39	6.0%
3006-70	Gel Preps For Medical Use/ Lube	\$ 8.06	\$ 7.86	\$ 11.63	47.9%
3006-50	First-Aid Box/Kits	\$ 5.20	\$ 4.89	\$ 5.09	4.0%
	Group Total	\$ 14,888	\$ 15,013	\$ 16,568	10.4%

Source: World Trade Atlas

U.S. Export Destinations of Select Medical/Hospital Goods

Rank	Destination	Millions of U.S. Dollars			△09/08
		2007	2008	2009	
Total to All Destinations of Select Medical Products (as listed above)		\$ 61,105.68	\$ 70,166.73	\$ 76,769.08	9.4%
1	Germany	\$ 6,276.17	\$ 7,632.57	\$ 8,881.61	16.4%
2	Netherlands	\$ 6,656.07	\$ 8,159.09	\$ 8,769.05	7.5%
3	Canada	\$ 6,168.40	\$ 6,252.54	\$ 7,532.11	20.5%
4	Japan	\$ 5,259.47	\$ 6,003.81	\$ 6,386.93	6.4%
5	United Kingdom	\$ 5,237.98	\$ 5,629.43	\$ 5,611.01	-0.3%
6	Belgium	\$ 3,526.90	\$ 4,563.40	\$ 4,449.83	-2.5%
7	Switzerland	\$ 3,098.73	\$ 3,362.76	\$ 3,388.47	0.8%
8	Mexico	\$ 2,181.65	\$ 2,743.87	\$ 3,063.86	11.7%
9	France	\$ 2,551.29	\$ 2,836.31	\$ 2,785.21	-1.8%
10	Spain	\$ 1,508.04	\$ 2,618.99	\$ 2,784.18	6.3%
11	Australia	\$ 1,792.59	\$ 1,987.81	\$ 2,390.45	20.3%
12	China	\$ 1,522.59	\$ 1,740.38	\$ 2,170.00	24.7%
13	Ireland	\$ 1,962.34	\$ 1,796.11	\$ 1,900.93	5.8%
14	Italy	\$ 1,663.07	\$ 1,849.04	\$ 1,882.84	1.8%
15	Brazil	\$ 1,188.36	\$ 1,479.99	\$ 1,498.76	1.3%
16	Korean Republic	\$ 1,268.69	\$ 1,150.82	\$ 1,338.44	16.3%
17	Sweden	\$ 626.97	\$ 698.91	\$ 1,223.30	75.0%
18	Hong Kong	\$ 531.83	\$ 584.97	\$ 687.22	17.5%
19	Singapore	\$ 555.43	\$ 550.40	\$ 635.32	15.4%
20	Taiwan	\$ 683.38	\$ 549.12	\$ 620.47	13.0%
21	Austria	\$ 436.85	\$ 488.80	\$ 564.41	15.5%
22	India	\$ 402.82	\$ 474.32	\$ 545.70	15.1%
23	Luxembourg	\$ 17.98	\$ 19.07	\$ 464.66	2336.3%
24	Saudi Arabia	\$ 230.36	\$ 336.12	\$ 434.24	29.2%
25	Venezuela	\$ 325.71	\$ 541.70	\$ 431.97	-20.3%
26	Colombia	\$ 305.58	\$ 388.84	\$ 415.89	7.0%
27	Denmark	\$ 312.58	\$ 374.52	\$ 410.63	9.6%
28	Israel	\$ 410.19	\$ 434.25	\$ 389.95	-10.2%
29	Argentina	\$ 268.41	\$ 327.88	\$ 361.81	10.4%
30	Turkey	\$ 268.26	\$ 301.25	\$ 298.72	-0.8%
31	Thailand	\$ 214.34	\$ 246.49	\$ 259.00	5.1%
32	South Africa	\$ 223.18	\$ 262.02	\$ 251.78	-3.9%
33	Costa Rica	\$ 174.76	\$ 201.58	\$ 222.90	10.6%
34	United Arab Emirates	\$ 142.31	\$ 168.33	\$ 220.15	30.8%
35	Chile	\$ 164.50	\$ 194.07	\$ 198.98	2.5%
36	Dominican Republic	\$ 234.17	\$ 220.24	\$ 188.07	-14.6%
37	Russia	\$ 195.54	\$ 260.48	\$ 187.15	-28.2%
38	Malaysia	\$ 147.73	\$ 155.38	\$ 161.12	3.7%
39	Poland	\$ 155.51	\$ 226.19	\$ 150.20	-33.6%
40	Greece	\$ 139.61	\$ 145.87	\$ 144.02	-1.3%
41	Finland	\$ 104.97	\$ 99.69	\$ 136.32	36.7%
42	Philippines	\$ 106.09	\$ 116.87	\$ 134.07	14.7%
43	New Zealand	\$ 109.22	\$ 134.69	\$ 131.54	-2.3%
44	Peru	\$ 76.99	\$ 99.46	\$ 127.45	28.1%
45	Panama	\$ 258.74	\$ 118.85	\$ 118.20	-0.6%
46	Czech Republic	\$ 86.96	\$ 106.97	\$ 106.11	-0.8%
47	Egypt	\$ 90.68	\$ 93.54	\$ 93.42	-0.1%
48	Pakistan	\$ 35.18	\$ 47.09	\$ 80.47	70.9%
49	Iran	\$ 44.14	\$ 47.25	\$ 74.34	57.3%
50	Ecuador	\$ 43.27	\$ 65.20	\$ 73.19	12.3%

Source: World Trade Atlas

Top 30 Medical Device Manufacturers – Fiscal 2009

It helps to know your competitors and how their products compare to yours. Knowing where they are located gains an insight of market demand and existing distribution channels. Large companies in major markets are very competitive having vast financial resources, dedicated sales forces and the need to generate high revenue. Depending on the market dynamics, it may be prudent to enter second tier markets which are not as well served and have good growth potential. The following companies are the top 30 medical device manufacturers worldwide. Notice they were all over \$2 billion in revenues. Some of these companies have supplier procurement websites where you should register your company. If you are already selling to these major companies stateside, some of your product may be going overseas already. Many companies have been successful by following their customers supply chain to foreign markets. If your customers are selling in certain markets, your target markets have been identified (as long as you don't squash existing sales).

(Company profiles are web-linked by clicking on the name.)

Johnson & Johnson	\$23.6 B	Zimmer	\$4.1 B
Siemens Healthcare	\$17.4 B	Olympus Medical	\$4 B
GE	\$16 B	Hospira	\$3.9 B
Medtronic	\$14.6 B	Smith & Nephew	\$3.8 B
Baxter International	\$12.6 B	Toshiba	\$3.7 B
Philips Healthcare	\$11.2 B	Synthes	\$3.4 B
Abbott Laboratories	\$8.4 B	Beckman Coulter	\$3.3 B
Boston Scientific	\$8.2 B	Terumo	\$3.1 B
Covidien	\$7.8 B	Danaher	\$3.1 B
Becton Dickinson	\$7.2 B	Alcon	\$3 B
Stryker	\$6.7 B	Fresenius Medical	\$2.9 B
B. Braun	\$5.8 B	Biomet	\$2.5 B
St. Jude Medical	\$4.7 B	CR Bard	\$2.5 B
Cardinal Health	\$4.6 B	Varian Medical	\$2.2 B
3M Healthcare	\$4.3 B	Dentsply International	\$2.2 B

Source: <http://www.mpo-mag.com/articles/2010/07/the-top-30>

Hospital Directories

These directories provide search features to identify thousands of medical facilities worldwide. Use these directories to identify specific facilities and/or regions and begin a targeted marketing campaign.

Allianz Worldwide Care: <http://www.allianzworldwidecare.com/hospital-doctor-and-health-practitioner-finder>

MediLexicon: <http://www.medilexicon.com/hospitalsdirectory.php>

Hospitals Worldwide: <http://www.hospitalsworldwide.com/>

Hospital World Ranking: http://hospitals.webometrics.info/hospital_by_country_select.asp

Hospital Scout: <http://www.hospitalscout.com/en/page/hospital.html>

Hospital Soup: <http://www.hospitalsoup.com/listing/medical-search/>

World Hospital Directory: <http://www.hospital-directory.info/> or <http://www.worldhospitaldirectory.com/>

Medical Device Associations

Below are links to medical device and IVD industry associations in various countries. Unfortunately, while some websites are in multiple languages, some are NOT offered in English.

European Committee of the Radiological, Electro-medical & Healthcare IT Industry (COCIR):

<http://www.cocir.org/index.php?mode=0>

European Disposables & Nonwovens Association (EDANA): <http://www.edana.org/content/default.asp?PageID=91>

European Diagnostic Manufacturers Association (EDMA): <http://www.edma-ivd.be/>

European Confederation of Medical Devices Associations (EUcomed): <http://www.eucomed.org/>

European Federation of the Contact Lens Industry (EFCLIN): <http://www.efclin.com/>

European Association for Bio-industries (EuropaBio): <http://www.europa-bio.be/>

European Health Industry Business Communications Council (EHIBCC): <http://www.ehibcc.com/>

Health First Europe: <http://www.healthfirsteurope.org/>

AUSTRALIA – AusBiotech: <http://www.ausbiotech.org/>

AUSTRALIA - Australian Medical Association (AMA): <http://www.ama.com.au/>

AUSTRALIA - Medical Technology Association of Australia (MTAA): <http://www.mtaa.org.au/pages/index.asp>

AUSTRALIA - Science Industry Australia (SIA): <http://scienceindustry.com.au/>

AUSTRIA - Austromed: <http://www.austromed.org/>

BELGIUM - Agoria-Hospibel:

www.agoria.be/s/p.exe/WService=WWW/webextra/prg/izContentWeb?vWebSessionID=9322&vUserID=999999&TopicID=2334&FActionSource=olTopics&FAction=SearchTopic

BELGIUM - Assoc for Bio-Industries, BioBio.be: <http://www.bio.be/index.cfm?lang=en>

BELGIUM – Pharma Diagnostics: <http://www.pharma.be/>

BELGIUM - Assoc of disposable medical products (UNAMEC): <http://www.unamec.be/fr/index.awp>

BRAZIL - Associação Brasileira dos Importadores de Equipamentos, Produtos e Suprimentos Médico-Hospitalares (ABIMED): <http://www.abimed.org.br/>

BRAZIL - Sociedade Brasileira de Biotecnologia (SBBiotech): <http://www.sbbiotech.org.br/>

BRAZIL - Association of Medical Devices Manufacturers (ABIMO) & Union of the Industry of Dental, Medical and Hospital Articles and Equipment (SINAEMO): <http://www.abimo.org.br/novo/index.php?lang=en>

CANADA - BioAlberta: <http://www.bioalberta.com/>

CANADA - LifeSciences British Columbia: <http://www.lifesciencesbc.ca/Sub-Sectors/Medical-Devices/Default.asp>

CANADA - Medical Devices Canada (MEDEC): <http://www.medec.org/>

CHINA - Association for Medical Device Industry (CAMDI): <http://www.camdi.org/en/>

CHINA - Medical Device Information Network (CMDI): <http://www.cmdi.gov.cn/cmdi/lmewen.nsf>

DENMARK - Association of Drug & Biotechnology Industries: <http://www.danskbiotek.dk/uk>

DENMARK - Diagnostic & Laboratory Association (DADIF): <http://www.dadif.dk/>

DENMARK - Dental Branchen: <http://www.dentalbranchen.dk/>

DENMARK – Medicoindustrien Medevice assoc: <http://www.medicoindustrien.dk/Default.aspx?ID=3755>

FRANCE – Appamed: <http://www.appamed.org/>

FRANCE – Comident Dentist assoc: <http://www.comident.asso.fr/>

FRANCE – Comité Interprofessionnel des Fournisseurs du Laboratoire (CIFL): www.cifl.com/cifl/anglais/index.htm

FRANCE – French National Association for Medical Technology Industries (SNITEM): www.snitem.fr/index.php?glang=EN

FRANCE – Syndicate of large manufacturers of contact lenses (SYFFOC): <http://www.syffoc.org>

GERMANY – Med Tech Assoc - Bundesverband (BVMed): <http://www.bvmed.de/Start/?language=2>

GERMANY –Dental Assoc - Bundeszahnärztekammer Arbeitsgemeinschaft der Deutschen Zahnärztekammern eV: <http://www.bzaek.de/english.html>

GERMANY – High-tech Med assoc - Spectaris eV: <http://www.spectaris.de/english.html>

GERMANY – Diagnostic Industry assoc - VDGH Verband der Diagnostica-Industrie eV: www.vdgh.de

GREECE - Hellenic Dental Association: <http://www.eoo.gr/>

GREECE - Institute of Biomedical Technology (INBIT): <http://www.inbit.gr/home/index.html>

IRELAND - Irish Medical Device Association (IMDA): <http://www.ibec.ie/imda>

ITALY - Assobiomedica: <http://www.assobiomedica.it>

JAPAN - Association for the Advancement of Medical Equipment (JAAME): <http://www.jaame.or.jp/>

JAPAN - Federation of Medical Devices Associations (JFMDA): <http://www.jfmda.gr.jp/e/>

JAPAN - Industries Association of Radiological Systems (JIRA): <http://www.jira-net.or.jp/e/index.htm>

JAPAN – National Institute of Health Sciences: <http://www.nihs.go.jp/>

MALAYSIA - Association of Malaysian Medical Industries (AMMI): <http://www.ammi.com.my/>

NETHERLANDS - Diagnostica Associatie Nederland (DIAGNED): <http://www.diagned.nl>
NETHERLANDS – BENELUX dental assoc (INDENT): <http://www.indent.nl>
NETHERLANDS – Dutch assoc of medevice importers (NEFEMED): <http://www.nefemed.nl/>
NORWAY - Leverandørforeningen for Helsesektoren (LFH): <http://www.lfh.no/>
PORTUGAL – Medtech assoc – Apormed: <http://www.apormed.pt>
SPAIN – Healthcare Tech assoc - Federacion Española de Empresas de Tecnologia Sanitaria (FENIN): <http://www.fenin.es/en/index.php>
SPAIN – medical implants assoc - Sociedad Española de Implantes (SEI): www.sociedadsei.com/pg_home.aspx
SWEDEN - Swecare Healthcare Foundation: <http://www.swecare.com/default.asp>
SWEDEN – Swedish Medtech assoc: <http://www.swedishmedtech.se/sidor/about-swedish-medtech.aspx>
SWITZERLAND – Medtech assoc FASMED: <http://www.fasmed.ch/>
U.K. - Association for Clinical Biochemistry: <http://www.acb.org.uk/>
U.K. - Association of British Healthcare Industries Limited (ABHI): <http://www.abhi.org.uk/>
U.K. - Association of X-Ray Equipment Manufacturers (AXrEM): <http://www.axrem.org.uk/>
U.K. – Anesthetic & Respiratory Assoc (BAREMA): <http://www.barema.org.uk/visitors.htm>
U.K. - BioIndustry Association (BIA): <http://www.bioindustry.org/>
U.K. - British Healthcare Trades Association (BHTA): <http://www.bhta.net/>
U.K. - British In Vitro Diagnostics Association (BIVDA): <http://www.bivda.co.uk/>
U.K. - British Medical Association (BMA): <http://www.bma.org.uk/>
U.K. - Dental Laboratories Association: <http://www.dla.org.uk/>
U.K. – Instrumentation, Control, Automation, & Labs Technology (GAMBICA): <http://www.gambica.org.uk/>
U.K. - Health Technologies Knowledge Transfer Network: <https://ktn.innovateuk.org/web/healthktn/?mode=0>
U.K. - Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH): <http://www.match.ac.uk/>
U.K. - Surgical Dressings Manufacturers Association (SDMA): <http://www.sdma.org.uk/>
U.K. - The Association of Contact Lens Manufacturers (ACLM): <http://www.aclm.org.uk/>

Tradeshows / Conferences

Attending the following international tradeshows and conferences offers an opportunity to learn about the market and identify potential competitors or partners. If the show appears to be worthwhile, it may be profitable to exhibit there in the future. Many of these websites have lists of exhibitors which you can use to evaluate the attractiveness of the show. These lists also provide a pool of potential partners to research and contact even if you do not attend the show. U.S. companies might consider using an in-country proxy to walk the show, identify contacts, set-up meetings, and provide a summary on the show's potential usefulness.

Expo Medical, Buenos Aires, Argentina, October 13-15, 2010: <http://www.expomedical.com.ar/english/index.html>
Medica, Dusseldorf, Germany, November 17-20, 2010: <http://www.medica-tradefair.com/>
CompaMed, Dusseldorf, Germany, November 17-19, 2010 <http://www.compamed-tradefair.com/>
Medist, Istanbul, Turkey, December 2-5, 2010: http://www.cnr-medist.com/content/en_index.asp
Medtec (various locations), Shanghai, August 2011: http://www.canontradeshows.com/expo/shanghai10/index_en.html
Arab Health, Dubai, UAE, January 24-27, 2011: <http://www.arabhealthonline.com/>
Medizin, Stuttgart, Germany, January 28-30, 2011: http://cms.messe-stuttgart.de/cms/medizin2011_infosaussteller0.0.html
Yenisey Medica, Krasnoyarsk, Russia, March 15-18, 2011: <http://www.krasfair.ru/eng/info-2010/medica/info.pdf>
Hospimedica (various locations), Mumbai, India, March 25-27, 2011: <http://www.hospimedica-india.com/>
SalMed, Poznan, Poland, March 15-16, 2012: <http://www.salmed.pl/en/>

Sources for a Calendar of Events

Events Eye: www.EventsEye.com
The Medica: <http://www.themedica.com/trade-shows.html>
Biz Tradeshows: <http://www.biztradeshows.com/medical-pharma/>
Medical Events: <http://www.medical-events.com/>
The Medical Conference Website: <http://www.medical.theconferencewebsite.com/>

Federal Regulation Agencies

Below are links to many federal agencies or Ministries of Health (MOH) which like the FDA control medical devices. For a more complete list of Foreign Liaisons, see the FDA list for updates:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ucm050356.htm>

AUSTRALIA - Therapeutic Goods Administration: <http://www.tga.gov.au/devices/devices.htm>

AUSTRIA - Federal Ministry of Health Department: <http://www.bmsk.gv.at/cms/siteEN/>

BAHRAIN - Kingdom of Bahrain Ministry of Health: <http://www.moh.gov.bh/>

BELGIUM – Health, Food Chain Safety & Environment: <http://www.health.belgium.be/eportal>

BRAZIL - National Health Surveillance Agency (ANVISA): <http://www.anvisa.gov.br/eng/index.htm>

CANADA - Health Canada: <http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php>

CHILE- Ministry of Health: http://www.minsal.cl/portal/url/page/minsalcl/g_home/home.html

CHINA - State Food & Drug Administration (SFDA): <http://eng.sfda.gov.cn/eng/>

COLUMBIA – INVIMA: <http://web.invima.gov.co/portal/faces/index.jspx?id=3253>

CYPRUS - Ministry of Health: <http://www.moh.gov.cy/moh/moh.nsf/All/4842763027B99BB0C225732B0037D278?OpenDocument>

CZECH REPUBLIC - State Institute for Drug Control: <http://www.sukl.cz/medical-devices-1?lang=2>

DENMARK - Danish Medicines Agency: www.medicinskudstyr.dk/1024/forside.mu.asp?artikelID=509

ESTONIA - State Agency of Medicines: <http://www.ravimiamet.ee/213>

FINLAND - National Agency for Medicines: http://www.nam.fi/medical_devices

FRANCE - French Agency for the Safety of Health Products (AFSSAPS): <http://www.afssaps.fr/>

GERMANY - Federal Institute for Drugs & Medical Devices (BfArM): www.bfarm.de/clin_103/EN

GREECE - National Organization for Medicines: <http://www.eof.gr/>

HONG KONG - Medical Device Control Office: <http://www.mdco.gov.hk/eindex.html>

HUNGARY - Authority for Medical Devices:

http://www.eekh.hu/en/index.php?option=com_content&task=blogcategory&id=14&Itemid=28

ICELAND - Directorate of Health: <http://www.landlaeknir.is/>

INDIA - Ministry of Health & Family Welfare: <http://mohfw.nic.in/>

INDONESIA - General Directorate of Pharmacy & Medical Equipment: <http://www.binfar.depkes.go.id/>

IRAQ - Ministry of Health: www.moh.gov.iq/english/index.php or www.healthiraq.org/english/home.html

IRELAND - Irish Medicines Board: <http://www.imb.ie/>

ISRAEL - Ministry of Health: <http://www.health.gov.il/english/>

ITALY - Ministry of Labor, Health & Social Affairs, Department of Innovation: <http://www.salute.gov.it/>

JAMAICA - Ministry of Health: <http://www.moh.gov.jm/>

JAPAN - Pharmaceuticals & Medical Devices Agency (PMDA): www.pmda.go.jp/english/index.html

JORDAN - Ministry of Health: http://www.moh.gov.jo/MOH/En/rules_regulations.php

KOREA - Korea Food & Drug Administration (KFDA): <http://eng.kfda.go.kr/index.php>

LATVIA - Health Statistics & Medical Technologies State Agency:

LEBANON - Ministry of Public Health: <http://www.moph.gov.lb/Pages/Home.aspx>

LIECHTENSTEIN - Ministry of Health: <http://www.spmid.llv.li/>

LITHUANIA - State Health Care Accreditation Agency: <http://www.vaspvt.gov.lt/index.php?1874291980>

MALAYSIA - National Pharmaceutical Control Bureau: <http://www.mdb.gov.my/mdb/>

MEXICO - Secretaria de Salud: <http://www.salud.gob.mx/>

NETHERLANDS - Dutch Healthcare Inspectorate (IGZ): <http://www.igz.nl/>

NEW ZEALAND - Medicines & Medical Devices Safe Authority (MedSafe): www.medsafe.govt.nz/regulatory/wand.asp

NORWAY - Directorate of Health: <http://www.helseidirektoratet.no/>

PANAMA - Ministry of Health: <http://www.minsa.gob.pa/>

PERU - General Directorate of Medicines, Supplies & Drugs (DIGEMID): <http://www.digemid.minsa.gob.pe/>

PHILIPPINES - Department of Health: <http://www.doh.gov.ph/>

POLAND - Office for Registration of Medicinal Products, Medical Devices & Biocidal Products: www.urpl.gov.pl/

PORTUGAL – Infarmed: <http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH>

RUSSIAN FEDERATION - Federal service on surveillance in healthcare & social development of Russian Federation (Roszdravnadzor):

<http://www.roszdravnadzor.ru/>

SAUDI ARABIA - Ministry of Health: <http://www.moh.gov.sa/english/index.php>

SINGAPORE - Health Science Authority (HSA): <http://www.hsa.gov.sg/publish/hsaportal/en/home.html>

SLOVAKIA - State Institute for Drug Control (SIDC): <http://www.sukl.sk/en/about-us>

SLOVENIA - Agency for Medicinal Products & Medical Devices (JAZMP): <http://www.jazmp.si/index.php?id=115>

SOUTH AFRICA - Department of Health: <http://www.doh.gov.za/>

SPAIN - Ministerio de Sanidad y Política Social – Agencia Española de Medicamentos y Productos Sanitarios:

<http://www.aemps.es/en/home.htm>

SWEDEN - Medical Products Agency: <http://www.lakemedelsverket.se/english/>

SWITZERLAND – SwissMedic: <http://www.swissmedic.ch/produktbereiche/00450/index.html?lang=en>

TAIWAN - Department of Health, Executive Yuan, R.O.C. :

THAILAND - Food & Drug Administration: <http://www.fda.moph.go.th/eng/index.stm>

TURKEY - Ministry of Health:

<http://www.saglik.gov.tr/TR/Genel/Default.aspx?F6E10F8892433CFFAAF6AA849816B2EF4376734BED947CDE>

UKRAINE - Ministry of Public Health: <http://www.moz.gov.ua/en/portal/>

UNITED KINGDOM - Medicines & Healthcare Products Regulatory Agency (MHRA): <http://www.mhra.gov.uk/index.htm>

Countries Permitting the Importation of Used Medical Devices

Note: The countries below permit the importation of used medical devices on the same terms as new products.

Countries with public procurement policies barring or discouraging purchase of pre-owned equipment are in ***bold italics***

<i>Bahamas</i>	Iceland	<i>Paraguay</i>
Barbados	India	<i>Philippines</i>
Belize	<i>Indonesia</i>	Poland
Bolivia	Israel	<i>Romania</i>
Botswana	Jamaica	Russia
<i>Cameroon</i>	Jordan	<i>Saudi Arabia</i>
Chad	Kazakhstan	Serbia and Montenegro
<i>Chile</i>	Kyrgyzstan	<i>Senegal</i>
<i>Costa Rica</i>	Kenya	Singapore
Czech Republic	Liberia	Slovak Republic
Dominican Republic	Luxembourg	Slovenia
<i>Ecuador</i>	Malawi	<i>Sri Lanka</i>
<i>El Salvador</i>	Malaysia	Switzerland
Ethiopia	<i>Mexico *</i>	Taiwan
Finland	Morocco	<i>Tanzania</i>
Gabon	Mozambique	Trinidad & Tobago
<i>Ghana</i>	Nepal	Tunisia
Guatemala	Netherlands	Turkmenistan
<i>Guinea</i>	New Zealand	<i>Uganda</i>
Haiti	<i>Nicaragua</i>	Ukraine
<i>Honduras</i>	Niger	<i>United Arab Emirates</i>
Hong Kong	Nigeria	<i>Venezuela</i>
Hungary	<i>Oman</i>	Yemen
	<i>Panama</i>	Zambia

* Mexico permits unrestricted sales to end-users, but restricts cross-border transactions between brokers, refurbishers, etc.

Source: U.S. Department of Commerce

Consultants and Service Providers

The following companies provide a variety of services, resources, and worthy contacts to help your company bridge into foreign markets. It may be useful to contact them and explore their knowledge of your industry in a target market. Often, potential exporters learn a great deal just from preliminary conversations with in-country, industry specialists.

Health Level Seven International (HL7)

3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104

Tel: 734-677-7777 E-mail: hq@HL7.org

<http://www.hl7.org/>

HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's 2,300+ members include approximately 500 corporate members who represent more than 90% of the information systems vendors serving healthcare.

EMERGO GROUP INC. (HQ)

611 West 5th Street, Third Floor, Austin, Texas 78701 USA

Phone: 512.327.9997

<http://www.emergogroup.com/>

Description: Emergo Group is an ISO registered medical and IVD device consulting firm with offices in the United States, Canada, Mexico, France, UK, Netherlands, Russia, China, Japan, Brazil and Australia. By focusing on providing outstanding customer service and value for our clients, we have grown to become a leading medical device consultancy with expertise in regulatory affairs, quality system compliance, clinical trial consulting, in-country representation and medical distributor search.

Global Regulatory (online resource)

Tel: 403-770-1994

<http://www.globalregulatory.com/>

Description: Founded by a former US FDA Consumer Safety Officer, Global Regulatory has facilitated and centralized the Regulatory Outsourcing Process for over 5 years.

Medcore Consulting

8180 Bülach, Switzerland

Phone: +41 79 8631681 Email: eric@medcoreconsulting.com

Website: www.medcoreconsulting.com

Description: MedCore Co., Ltd. is an independent European and Asian based regulatory consultancy company for the medical devices industry, with its headquarters in Bangkok, Thailand. The solid knowledge and experience of MedCore Co., Ltd. covers the following EU directives: MDD (classes I to III), AIMDD, R&TTE, WEEE, RoHS, EMC, Package and Waste. MedCore Co., Ltd. works in accordance with the latest and up to date GHTF guidelines and keeps up to date with the harmonisation efforts of ASEAN and AHWP. As such Medcore can provide you the valid insight of the dynamic and quickly changing regulatory environment in the various South East Asian economies.

CanReg Inc.

4 Innovation Drive, Dundas, ON, Canada L9H 7P3

Phone: 905-689-3980 Email: info@canreginc.com

Website: www.canreginc.com

Description: CanReg is one of North America's largest consulting firms dedicated exclusively to regulatory affairs for life sciences companies. Our clients benefit from the extensive experience of more than 100 in-house consultants and staff. One of our teams specializes in Medical Devices and Quality Systems. Whether it's a regulatory assessment, strategy development, or application preparation, CanReg has the expertise to move your product forward.

Medical Device Safety Service

Schiffgraben 41, Hannover, Germany 30175

Tel: (+49) 511-6262 8630 Email: info@mdss.com

Website: <http://www.mdss.com/>

MDSS specializes in European Regulatory Affairs and provides customized solutions for compliance with European Medical Device requirements. MDSS acts as your Authorized European Address for your products, registers your products with the authorities and provides representation to the European Commission and National Competent Authorities.

Advanced Medicals Consortium

9907 Oakleaf Way , Suite #1, McCordsville, IN, 46055

Phone: 866-790-3727

Email: peter.ackerman@advancedmedicalconsortium.com

Website: <http://www.advancedmedicalconsortium.com/>

Description: Advanced Medicals Consortium's vertical integration allows our clients the benefit of industry expertise in the Medical Device, Pharmaceuticals and Biotechnology domains. Our qualified national associates have experience and expertise communicating directly with the FDA regarding regulatory guidance, medical device submissions and post-marketing surveillance. We assist our clients through all phases of the regulatory process. Our team provides timely, concise and valuable expertise to clients required to participate with FDA, EU (EMEA & GHTF), Canadian Health and Japanese Ministry of Health agencies for their regulatory submissions.

Medical Device Consultants, Inc.

49 Plain Street, North Attleboro, Massachusetts 02760

Tel: 508-643-0434

www.mdci.com

Description: MDCI is a full-service [contract research organization](#) and consulting firm that helps emerging and established firms commercialize novel and innovative medical devices, [in vitro diagnostics](#) and combination products. Our client engagements number in the thousands and represent almost every therapeutic area and medical device specialty area, for both [U.S.-based](#) and [international clients](#). By leveraging MDCI's comprehensive knowledge of FDA and international regulations, you can capture and grow market share, increase productivity, and stay competitive in an increasingly complex global marketplace.

Pacific Bridge Medical

7315 Wisconsin Ave., Suite 609E, Bethesda, MD 20814 USA

Tel: (301) 469-3400

<http://www.pacificbridgemedical.com/>

Description: PACIFIC BRIDGE MEDICAL (PBM) is a leading Asia medical consulting firm dedicated to assisting international medical companies in Asia. We have helped hundreds of medical companies with business development and regulatory affairs in Asia since our founding in 1988. We assist medical device, drug, IVD, OTC, and biotech companies in Asia.

Chindex International Inc.

4340 East West Highway, Suite 1100, Bethesda, MD 20814

Tel: 301-215-7777

<http://www.chindex.com/>

Description: The Company's distribution platform is managed by its wholly-owned subsidiary, Chindex Shanghai International Trading Co. which provides full-scale distribution, logistics, and supply chain management services, including planning, purchasing, importation, inventory management, and domestic sourcing, to both the MPD and UFH operations, as well as to third party manufacturers and hospitals on a consulting basis. As a purchaser of both domestic and imported medical products, a full-service logistics provider, and a seller of medical equipment and consumables to hospitals throughout China, Chindex has a rare understanding of the medical device industry in China from numerous perspectives, allowing it to provide uniquely specialized service to buyers and sellers, both within China and abroad, alike.

L.E.K. Consulting

28 State Street, 16th Floor, Boston, MA 02109

Carol Wingard c.wingard@lek.com

Tel: (617) 951-9500 www.LEK.com

LEK helps clients uncover and create new opportunities, and assess and mitigate potential risks, clients turn to L.E.K. for assistance in addressing the full spectrum of life sciences specialties, including: Biotechnology, Medtech , diagnostics, Genomics and proteomics, Imaging technologies, Pharmaceuticals, Specialty pharmaceuticals, Generic pharmaceuticals, Surgical products, and E-health.

Pan Globus

145-157 St. John Street, London EC1Y 4PY, United Kingdom

Tel: +44 (0)207 608 5797 Email: info@panglobus.com Web: <http://www.panglobus.com/>

Description: The Pan Globus Medical Device Business Consultancy Division is a multi service company providing Start Ups, Late Start Ups and Small to Mid Size Enterprises (SMEs) in the Medical Device Industry with effective international sales and marketing resources. Services include: Distributor Selection and ongoing distributor management by country or region; Establishment and development of KOLs and CofEs; Assessment or recommendation of partnering opportunities; Should there be a requirement for Partnering or Joint Venture opportunities; Finding the most reliable partner is found and business established; Sourcing of local contract manufacturing facilities; Regulatory/CE marking and national product approvals, including Pharma registrations; and Marketing services such as advertising, exhibitions and web design.

Kantar Health

1 Independence Way, Princeton, NJ 08540-6638 (609) 720-5480

New York Tel: (212) 647 – 7200 Email: info.usa@kantarhealth.com Web: <http://www.kantarhealth.com>

Kantar Health is a leading healthcare-focused global consultancy and marketing insights company. Kantar Health provides on-the-ground service and local guidance through more than 40 offices around the world—giving you the broadest global reach coupled with the deepest local knowledge.

Milliman

1301 Fifth Avenue, Suite 3800, Seattle, WA 98101-2605

Tel: (206) 624.7940 Web: www.milliman.com

Milliman is among the world's largest independent actuarial and consulting firms, with 52 offices worldwide. Our staff of 2,400 people includes more than 1,100 qualified consultants and actuaries. Through consulting practices in employee benefits, healthcare, investment, life insurance and financial services, and property and casualty insurance, Milliman serves the full spectrum of business, financial, government, union, education, and nonprofit organizations.

Logistics Service Providers Specializing in Healthcare Supply Chain Solutions

DHL Life Sciences & Healthcare Supply Chain Solutions:

http://www.dhl.com/en/logistics/industry_sector_solutions/life_sciences_and_healthcare_logistics.html

Exel Life Sciences Industry Solutions: http://www.exel.com/exel/exel_life_sciences.jsp

FedEx Healthcare Industry Solutions: <http://fedex.com/us/supplychain/industrysolutions/healthcare.html>

HealthLink Europe: <http://www.healthlinkeurope.com/logistics.php>

Hellmann Logistics Healthcare Industry Solutions:

http://www.hellmann.net/en_EN/unitedstates/industry_solutions/healthcare_logistics

UPS Healthcare Logistics Supply Chain Solutions: <http://www.ups-scs.com/solutions/healthcare.html> and

http://www.ups.com/bussol?loc=en_US&viewID=categoryView&contentID=ct1_solg_cat_healthcare

Owens & Minor Healthcare Logistics: <http://www.omhcl.com/Pages/default.aspx>

Research Publishers - Reports Available for a Fee

Euromonitor – Health and Wellness reports: http://www.euromonitor.com/Health_And_Wellness

Frost & Sullivan – Medical Device Research: <http://www.frost.com/prod/servlet/svcg.pag/HCMD>

International Business Strategies – Healthcare Reports:

<http://www.internationalbusinessstrategies.com/market-research-reports/healthcare.html>

Works Cited and Additional Resources

Authentication (Apostiles) - Virginia Secretary of the Commonwealth provides this documentation service for a fee:
<http://www.commonwealth.virginia.gov/Authentications/authentications.cfm>

European Union Medical Device Directive Guide: http://gsi.nist.gov/global/docs/EUGuide_MedicalDvceDirective.pdf

Healthcare Sales & Marketing Network: http://salesandmarketingnetwork.com/profiles_summary.php

Hospital International: <http://www.hospital-int.net/>

International Hospital Federation (country sector reports): <http://www.ihf-fih.org/jsp/index.jsp?lnk=800>

Medical Buyer: <http://www.medicalbuyer.co.in>

Medical Design Excellence Award Program: <http://www.canontradeshows.com/expo/awards/home/>

Medical Device and Diagnostics Industry Magazine Online: <http://www.mddionline.com/>

Medical Device Network: <http://www.medicaldevice-network.com>

Medical Product Outsourcing: <http://www.mpo-mag.com/>

Pharmaceutical & Medical Packaging News online: <http://www.pmpnews.com/>

QMed – Qualified Suppliers to the Medical Device Industry (online): <http://www.qmed.com/>

The Medica - Global healthcare marketplace online: <http://www.themedica.com/>

U.S. Commerce Department - Global Regulations for Pre-Owned Medical Devices 2008:
http://www.trade.gov/td/health/PreOwnedMedEquipment_FINAL_050608.pdf

U.S. Food and Drug Administration – Exporting and Importing Medical Devices:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/default.htm>

U.S. Food and Drug Administration -- Regulations on Medical Device Reporting (21 CFR Part 803):
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803>

U.S. Food, Drug, and Cosmetic Act:
<http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdact/default.htm>

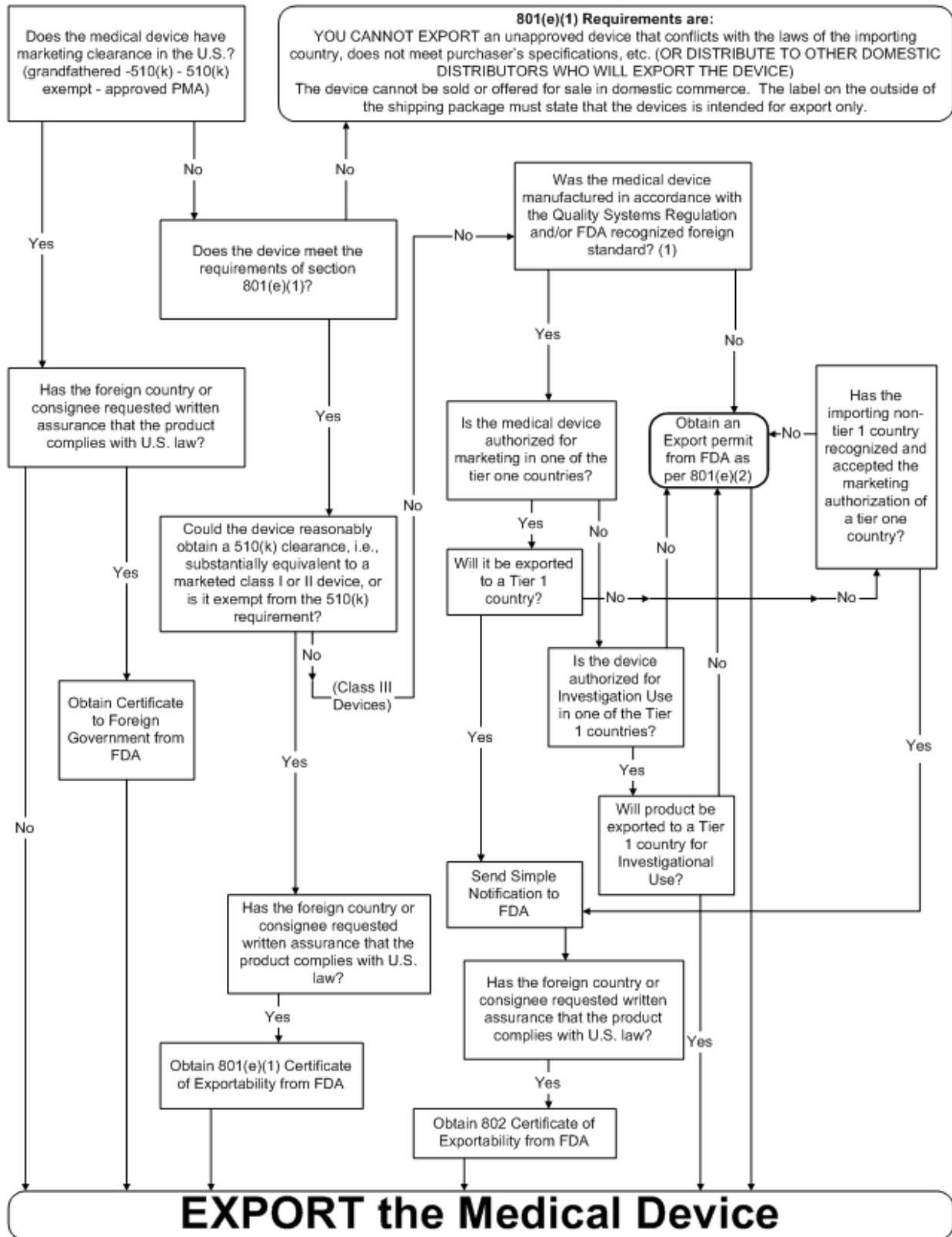
U.S. ITC Country Overviews: <http://www.trade.gov/td/health/regulations.html>

The Gray Sheet – medical publication online: <http://thegraysheet.com/>

WHO Medical Device Regulations Global Overview 2003:
http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf

Medical Device Export Decision Flowchart (DIAGRAM)

The Medical Device Export Decision Tree flow diagram below depicts a firm's options to export. This quick reference chart shows when to export under sections 801(1), 801(e)(2), and 802 of the FD&C Act.



(1) To date, FDA has not recognized any.

Source: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ucm050521.htm#flowchart>