



# **ARGOS COMPANY LTD.**

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## **Medical Device Market In Poland**

Commissioned by:



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## ***Medical Device Market in Poland***

ARGOS Company Ltd. ([www.argotranslations.com](http://www.argotranslations.com)) has been offering medical device translation/localization services since 1996. Over time, as our clients grew familiar with the translation services that Argos offered, they began to request additional assistance in the medical device market. This occurred largely due to the fact that we were based in their targeted local market and thus could offer additional business support. Many of our clients not only needed their devices localized and their documents translated, but also needed to understand the regulatory issues connected with entering Central and Eastern European markets. Argos understood that by being able to offer a turnkey solution that would include assisting in market entry as well as taking care of the translation/localization process, we would provide our clients with unique additional benefits. As a result, Argos joined forces with PMR Consulting ([www.pmrconsulting.com](http://www.pmrconsulting.com)), a local consultancy firm with the reliability and extensive experience that complemented Argos' service. The result of this collaboration is an offer of a complete solution for all medical device manufacturers interested in entering East European markets. This white paper has been commissioned by the Argos Company Ltd. and is intended to provide investors with information about the basic issues they will face when considering entrance to the Polish market with their medical devices. While some of the issues raised in this white paper may be common across other East European markets it is important to note that each country has its own regulatory requirements and thus it is important not to draw any far-reaching conclusions about the region without consulting a local expert for advice.

For more information about East European medical device market entry services or translation/localization services please send us an e-mail at: [info@argotranslations.com](mailto:info@argotranslations.com)

### ***1. Background to this study***

## **2. *About Argos***

Argos Company Ltd. is a translation and localization company offering high quality medical and pharmaceutical translation services for all the European languages with an emphasis on Eastern European support. Argos is ISO 9001:2000 certified, has an international staff of 50 in-house employees, 400 freelance translators, and a client list with numerous global 1000 companies. Argos has experience in translation of pharmaceuticals, medical devices & surgical instruments, biotechnology, in vitro diagnostics documents as well as medical software, articles for medical journals, and marketing documentation. The span of this experience covers areas such as translation projects that comply with the MDD (Medical Devices Directive), IVDD (In-Vitro Diagnostics Directive), and IFUs (Instruction for Use). Argos' clients include global companies such as Medtronic, Roche, GEMS, Biomet, and Siemens Medical. The company, now in operation since 1996, has grown in size, experience and the diversity of its services. Argos provides a unique one-stop business-to-business globalization solution for companies requiring translation, localization, desktop publishing, and consulting services.

## **3. *About PMR Consulting***

PMR Consulting is part of PMR Ltd founded in 1995. It is a British-American company based in Poland with a staff of 35 people, which provides consulting services in Central and Eastern European countries. In the pharmaceuticals sector it has recently reviewed life sciences research options for a Scandinavian company, researched Central European Pharma sector companies for clients from Japan, France and Germany, and profiled oncology reagent producers. PMR's Managing Director formerly ran a company in Poland that represented a division of a leading US specialist medical-device corporation. His company implemented IT systems in hospitals and for the Ministry of Health. PMR publishes a bi-monthly magazine titled Polish Pharmaceutical News; a report on the OTC healthcare market in Poland, and manages the [www.pharmapoland.com](http://www.pharmapoland.com) web site, as well as [www.polishmarket.com](http://www.polishmarket.com) and [www.ceemarket.com](http://www.ceemarket.com).

## ***Launching medical devices in Poland***

Since Poland joined the EU in May 2004 the level of interest in the market for medical devices has expanded considerably. There are two fundamental questions that any international medical device manufacturer should ask before attempting to enter into the Polish market:

1. Is there a market for their product in Poland, either in the state funded sector, where crumbling buildings and an atmosphere of financial crisis sometimes conceal surprisingly modern operating theatres and equipment, or in the small but growing private sector?
2. What has to be done to gain regulatory approval? The possibility of using existing European Union registrations to gain approvals in Poland is obviously of great interest. The additional good news is that Poland does recognize EU certification for two categories of medical devices. The less good news is that a number of hard to interpret forms (shown at the end of this white paper) may need to be completed (in Polish) and submitted to the relevant authorities in order to take advantage of the mutual recognition provisions. The status of each individual medical device (and whether documentation needs to be filed) should be carefully reviewed case-by-case. Furthermore, the situation with respect to enforcement of EU mutual recognition laws, is far from clear.

In 2002 there were 739 general hospitals in Poland of which 678 were state-owned and the remaining 61 were either privately owned or controlled by non-governmental entities. Additionally, the Ministry of National Defense operates 24 hospitals and the Ministry of Internal Affairs and Administration operates 29 such

institutions. There were only 3 more new hospitals added in comparison to 2001, but this was due to the fact that 16 new private hospitals started operations while

13 old state-owned hospitals folded. This seems to reflect a growing demand for higher quality medical services, as most state-owned hospitals are huge complexes, often with out-of-date and worn-out equipment and located in old, damaged buildings, some built more than a hundred years ago.

As far as the usage of medical devices goes, one recent study showed that 85% of medical devices available in 49 public hospitals in the Malopolskie region (area around Krakow) were in a "bad" or "unsatisfactory" condition, and there was not a single hospital whose overall medical devices were in a condition described as "very good". Simultaneously

### ***Is there a market?***

72% of all technical infrastructure was described as at least “worrying”. There is no reason to expect that the state of medical infrastructure of Polish hospitals is much better in the remaining 15 administrative regions across the country.

Other than hospitals there are also nearly 16,000 clinics where patients come to consult a doctor or have minor treatments. These medical units (of which 76% are privately owned) vary in size and most of them are staffed by just a few persons. The medical devices used in private clinics are often quite good while their state-run counterparts often use older equipment dating back to the 1960’s or 1970’s, which is highly damaged and even defective due to overuse and poor servicing. However, higher priced equipment is often only available in the state funded hospitals (being beyond the reach of most private clinics). Private clinics form an unofficial gateway to provide queue busting access to the most expensive medical kits offered sometimes only in the better funded hospitals, located in any given town or region. How does this occur? Simply put, a patient pays 50-100 zloty (5-10 Euros) to see a specialist in a private clinic. There he is told (if necessary) to show up in a state hospital when that same specialist is there on duty. The client then calls that same doctor/specialist on his mobile phone, who then fixes a second appointment on expensive hospital equipment that is not available in his private clinic.

Poland will have to upgrade its health care system as its population ages. This together with the relatively poor health of many of its inhabitants, creates a reasonable expectation of sustainable and increasing demand for many types of medical devices. In some cases European Union funds that Poland (and other new member states) are now entitled to, may be available to subsidize some of the costs.

Altogether, this means that Poland is likely to be a growing market for medical devices over the next few years because, investments in medical technology are a necessary part of the process of bringing the national health care system up to European standards.

## ***How is a medical device defined in Poland?***

Medical devices' legal regulations are found in "The Medical Devices Act of 20th April 2004", which contains definitions and laws concerning:

- marketing and implementation,
- clinical assessment,
- conditions of use,
- surveillance over manufacturing, marketing and implementation,
- procedure of reporting medical incidents,
- registering medical devices,
- authorities concerned with controlling medical devices,
- classification of medical devices,
- testing conformity of manufacturer or vendor registered medical devices,
- basic requirements for medical devices.

The above-mentioned Act was prepared shortly before Poland's accession to the European Union and adapted Polish regulations to the relevant EU directives.

The Act describes medical devices as: all tools, materials, apparatus, equipment and other devices which, solely or jointly, with other equipment or software have been designed by its producers to be used on (or in connection to) human beings during the following processes:

- diagnosing, prevention, monitoring, treating or easing the symptoms of illnesses,
- diagnosing, monitoring, treating or easing the symptoms of injuries and disabilities,
- conducting research, remodeling of human anatomy or physiological processes,
- contraception, where this is not achieved by using pharmaceutical, immunological or metabolic means (unless they are used as supplements).

## ***What is required to sell a medical device in Poland?***

The Act mentions three main groups of medical devices:

- active medical products for implantation – are defined as medical
- devices that depend on an external source of electricity or energy (not generated by the human body or by force of gravity) and which are
- permanently implanted into the body during surgery or via medical treatment,
- medical products that are used for in-vitro diagnosis including vacuum containers for samples and lab equipment for in-vitro research,
- multi-purpose medical devices – all other medical devices.

Polish law describes two different ways of bringing a medical device to market:

- “placing” – describes the first time a medical device is made available (whether for free or sold) for use or distribution, regardless of whether it is new or fully refurbished. This does not apply to medical devices intended for clinical investigations or in-vitro diagnostic medical devices for performance evaluation.
- “putting into service” – means the stage at which a medical device is available to the final user (patient or health care professional) as being ready for use.

The law designates a limited number of bodies that are allowed to register and sell medical devices. It is more important for manufacturers/distributors/sellers to have contracts or agreements confirming their registered status, than to repeatedly present health authorities with certificates demonstrating capability and experience in trading of medical devices. Proper documentation (as far as local law is concerned) is far more important than relevant experience.

Bodies mentioned in the Act are:

- medical device manufacturers,
- authorized representatives of medical device manufacturers,
- medical device importers,
- medical device distributors,
- specialized agencies and companies responsible for bringing medical devices to market.

Only medical devices that are compliant with Polish law i.e. both The Medical Devices Act and any other regulations in force that are relevant to a specific device, are permitted to be sold.

- 1) compliance with the so-called 'basic requirements' (mentioned in an ordinance issued by the Minister of Health), especially regarding design, manufacture, packaging and labeling of such products,
- 2) a 'declaration of conformity',
- 3) a 'CE' label (in cases of specific medical devices short transitional periods that may apply).

It is also very important that the CE marking used for medical devices must conform to the rules described in the ordinance published by the Minister of Health. There are rare exemptions to the above rules that primarily apply in very specific cases regarding single device units.

Prior to launching, medical devices should be tested by a notification body in order to evaluate their conformity with legal requirements. The notification body must be in possession of an ID number issued by the European Commission and be listed in the Official Journal of the European Communities. (note: A list of the Polish notification bodies is provided at the end of this White Paper). All stated local regulations are strictly followed and non-Polish notification bodies are also acceptable.

All medical devices should be accompanied by a (Polish language) user's manual and description (including all markings, labels, etc.). However, an exemption exists for some medical devices designed to be used by professionals who consent to non-Polish language instructions. Given the Polish population's limited knowledge of foreign languages, it is strongly recommended to always localize medical devices into the language of the market where they are to be sold. Even for products where risks associated with improper use are much lower, it is highly unusual for professional companies to offer goods without good quality local language documentation. In addition to controlling the risk of legal action in the event of a "health incident", local translation helps ensure that the device is properly used and maintained.

### ***The three major requirements for medical devices are:***

In Poland medical devices are classified into six groups (four groups of multipurpose medical devices and two groups of specific use medical devices) depending on the potential hazards to human health through their usage. The list of groups and their description can be found in relevant regulations issued by the Ministry of Health.

## ***Where can medical devices be sold?***

In Poland medical devices can be sold only in predefined types of retail and wholesale businesses. The Pharmaceutical Code (Act of 6 September 2001) lists the following types of outlets:

- pharmaceutical wholesalers,
- veterinarian pharmaceutical wholesalers,
- pharmaceutical retailers (pharmacies),
- small pharmacies,
- non-pharmacy retailer - some other retailers are allowed to sell pharmaceuticals, e.g. specialized retailers dealing in supplying hospitals and clinics only.

## ***How to register medical devices?***

Medical devices must be listed in the 'Register of medical devices and bodies responsible for their launch and usage' prior to marketing the device or its use by patients. This register is run by the Office for Registration of Medicinal Products, Medical Devices and Biocides. The first step to get the medical device registered is to fill out an application that is then supplied by the manufacturer directly or, by a company authorized to do business with the manufacturer (e.g. an authorized representative or distributor) that is registered in Poland. A special form should be used for this filing. A fee is payable (equivalent of €80 at the time of writing). Registry staff may require additional documents certifying and confirming statements made in the application. The application form and any attached documents should be prepared in Polish (despite the fact that the application form is bilingual), or translated by an approved Polish legal translator. Given the speed of local bureaucracy it is recommended to double-check the application before submission to avoid being rejected, or suffering lengthy delays after the two-month processing period. Consultants can help the process go smoothly.

The same Office is also responsible for registering: 'medical incidents' that are described as defects in a medical device's functioning, a change of specification, improper marking or user's manual descriptions that might cause hazards to the patient. In each case the manufacturer or their representative

is responsible for carrying out an investigation. Finding your medical device in the 'medical incidents' register may result in the product/company being deleted from the 'Register of medical devices and bodies responsible for their launch and usage', and in consequence, be effectively barred from doing business in Poland.

As Appendix II at the end of this paper presents, companies like Bayer Healthcare, Olympus Diagnostica and Abbott Japan, continue to register their devices even after CE approval (the table shows some of the devices registered in August 2004). It is possible to find government officials who claim that if you have CE marking you do not have to have the local approval. One such official was interviewed for this white paper. However the actual practice, confirmed by the regulatory affairs specialist of a major international healthcare group, indicated that most hospitals and doctors will not consider buying products without a Polish PL/DR number. Thus even if in theory it may be possible to launch a product in Poland without local approval, commercial success very often requires approval even if government officials may not. Application forms that allow one to take advantage of reciprocal CE recognition can be downloaded from the web site [www.bip.urpl.gov.pl](http://www.bip.urpl.gov.pl) shown in Appendix I.

According to current Polish regulations medical devices that comply with legal requirements should be tested to make sure that using them will cause no harmful side effects. Clinical evaluations are carried out by the manufacturer of a medical device or by an authorized representative. The evaluation process should be based on three sources:

- combined data from available medical literature describing the application area in which the device will be used,
- a written study containing a critical analysis of the above mentioned data,
- results of clinical research conducted according to current legal requirements.

***Do you have to register your medical device if it already has CE approval?***

Both multipurpose and active medical devices for implantation require clinical research. Data obtained from secondary sources (e.g. medical literature) is not sufficient to perform the clinical evaluation. Such clinical research should be performed in order to:

- check whether the medical device's specification described by the manufacturer comply with basic requirements of Polish law,
- identify any possible harmful side effects that may occur during normal usage of the medical device.

## ***Quality control procedures***

Before starting clinical research works the entity responsible for carrying it out must obtain specific permits issued by a bioethical commission and the Office for Registration of Medicinal Products, Medical Devices and Biocides. Permits are payable within a range of €220 to €1,100.

## ***Summary***

This White Paper shows that, as in other countries, the regulatory issues concerning the sale of medical devices in Poland are complex and have to be taken seriously. For companies with competitive products that meet a medical need, this is a challenge they are familiar with and are capable of grasping. Furthermore, the market in Poland is large enough (together with its potential for sustained growth) to make such challenges worth undertaking.

## ***Sources:***

1. Central Statistical Office
2. Ministry of Health of the Republic of Poland
3. Office for Registration of Medicinal Products, Medical Devices and Biocides
4. Act of 5 December 1996 on the profession of a doctor
5. Act of 27 July 2001 on the Office for Registration of Medicinal Products
6. Medical Devices and Biocides
7. The Medical Devices Act of 20th April 2004

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internet: www.eltest.com.pl

***Useful addresses:***

***Notification bodies:***

**Institute of the Medical Technology and Devices (ITAM)**

ul. Roosevelta 118, 41-800 Zabrze

tel.: +48 32 271 60 13

fax: +48 32 276 56 08

e-mail: [itam@itam.zabrze.pl](mailto:itam@itam.zabrze.pl)

internet: [www.itam.zabrze.pl](http://www.itam.zabrze.pl)

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internet: [www.predom.com.pl](http://www.predom.com.pl)

**Polish Centre of Research and Certification (PCBC)**

ul Kłobucka 23a, 02-699 Warszawa

tel. +48 22 857 99 16

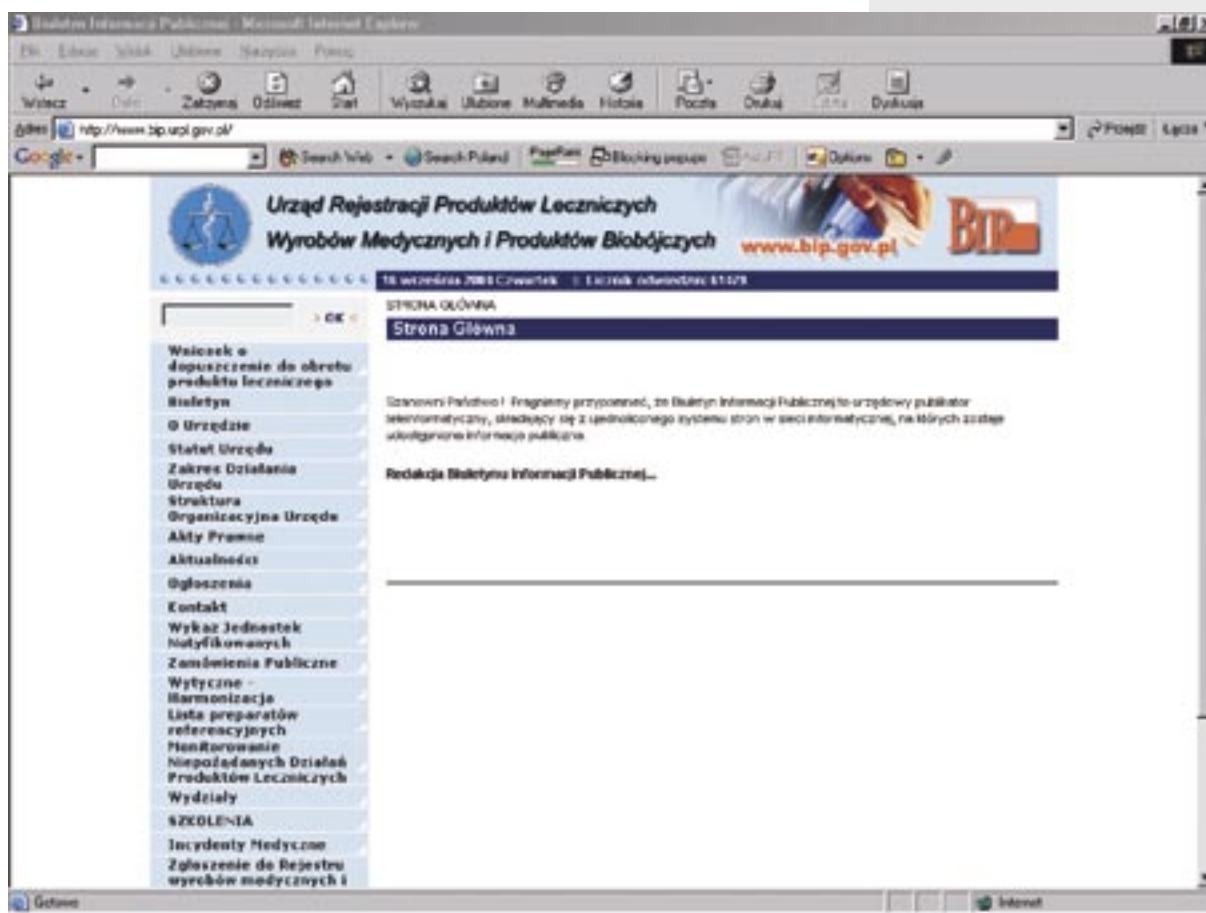
fax. +48 22 647 11 09

e-mail: [pcbc@pcbc.gov.pl](mailto:pcbc@pcbc.gov.pl)

internet: [www.pcbc.gov.pl](http://www.pcbc.gov.pl)

## Attachment I

### Web site of the Office for Registration of Medicinal Products, Medical Devices and Biocides



Source: <http://www.bip.urpl.gov.pl/>

## Attachment II

### **Bulletin of the Office for Registration of Medicinal Products, Medical Devices and Biocides, about newly registered medical devices**

Lp.	Nazwa (rodzaj, nazwa handlowa)	Nazwa i wpis do Rejestru wytwórcy	№ rejestru wyrobów medycznych (data ważności wpisu)
1	17-Hydroksykortykosteroidy cod.: 11006 - 40 testów - Chromatografi mikrokolonimowa	BioSystems S.A. HISZPANIA PLCA01 00079	PLDR 007712
2	Abbott Determine Syphilis TP Serum/Plasma Assay	Abbott Japan Co., Ltd. JAPONIA PLCA01 01361	PLDR 007789
3	Alkaline Phosphatase (ALP) OSR6103; Alkaline Phosphatase OSR6204, OSR6204 - Chemia kliniczna	Olympus Diagnostica GmbH (Irish Branch) IRLANDIA PLCA01 00549	PLDR 007807
4	ANAER 53638 - Podłoże dla beztlenowców	Bio-Rad Laboratories FRANCJA PLCA01 00494	PLDR 007724
5	Analizator Clinitek Status	Bayer Healthcare LLC, a subsidiary of Bayer Corporation USA PLCA01 01459	PLDR 007846
6	Analizator DCA 2000+ wraz z wyposażeniem - system zamknięty,	Bayer Corporation:	PLDR 007791

Source: [http://62.233.142.15/rej\\_lek/uploadedDocuments/08\\_SIERPIEN\\_2004.xls](http://62.233.142.15/rej_lek/uploadedDocuments/08_SIERPIEN_2004.xls)

## Attachment III

**Application form from the Office for Registration of Medicinal Products, Medical Devices and Biocides for permission to conduct a medical device clinical research, pages 1-2 of 11 (must be submitted in Polish)**

The image shows a Microsoft Word document with two pages. The left page is the title page, and the right page contains the main form fields. The title is 'WNIOSK O WYDANIE POZWOLENIA NA BADANIE KLINICZNE WYKONANE WYKONANE WYKONANE'. The form includes sections for 'Opis produktu', 'Opis badania', and 'Opis procedury'. There is a table with 4 columns and 8 rows, and several text input fields.

№	Wskazanie	Wzrost	Waga	Ciężar ciała
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

Source: [http://62.233.142.15/rej\\_lek/uploadedDocuments/zal\\_badania\\_kliniczne\\_30042004.rtf](http://62.233.142.15/rej_lek/uploadedDocuments/zal_badania_kliniczne_30042004.rtf)

## ***Argos Company Ltd.***

Argos is a privately held American-British owned translation company offering services for all the European languages with an emphasis on Eastern European support. Having a decade of professional translation, localization and desktop publishing experience, Argos has come to be associated with service excellence, high quality translations and outstanding value. Argos is ISO 9001:2000 certified, has an international staff of 50 in-house employees, 400 freelance translators, and a client list with numerous global 1000 companies. All of these aspects combined have helped to distinguish Argos as the expert language provider with an Eastern European locale and a decidedly Western business approach.

### ***Argos' services include:***

- Document Translations
- Software Localization
- Website/Multimedia Localization
- Desktop Publishing Services
- Voice-over services
- Localization engineering and consulting services

The company, now in operation since 1996, has grown in size to become one of the largest translation companies in Central and Eastern Europe. Argos has also grown in experience, industry positioning and the diversity of its services.

Currently, Argos provides a unique one-stop business-to-business globalization solution for

companies requiring translation, localization, DTP, and consulting services in advanced translation technologies.

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## Localization in Poland: A Market Primer

The Polish market is tough to break into but great opportunities exist for those wanting to stretch their business across the Polish borders. Read about the difficulties with the Polish market and opportunities that await. The success of companies competing with each other will ultimately depend on how well they are able to sell to local consumers or end clients, and this in turn will depend on how well their content or in the case of software companies, their systems, are localized.

## The Culture of Translation in Poland

This white paper describes an accurate first-hand account of the translation and localization business in Poland. Find out what kind of needs Polish end clients have when it comes to localizing their products. Discover what Polish translation/localization companies can offer. Learn about the Polish translation business.

## Localization Challenges

If you are an IT manager responsible for localizing a product or if you're just starting out as a localization manager, we recommend this white paper. You will learn about the basic steps of localizing a project and find out how the translation process differs from the localization one. This paper will help you prepare for the typical problems that you might encounter and look into the localization tools.

## ERP Localization Opportunities in Poland

In Poland, the ERP market is fairly saturated, but the CRM market seems to hold great potential for the future. This white paper analyzes the market for corporate class software in Poland and presents areas for growth opportunity. A brief case study shows what went wrong when one ERP producer attempted to localize into Polish. If you are a localization company interested in competing for a piece of this attractive market or if you are a producer of corporate class software and you want to better understand the market and avoid the pitfalls, then this white paper is a must read.

## Strategic Localization Decisions: To outsource or not to outsource?

The time has come to localize your software application or your website. Basically you have three routes to choose from.

- 1) You can choose to localize in-house if you have the personnel, resources and experience.
- 2) You can localize key components such as the user interface in-house and outsource the documentation and the online help.
- 3) You can choose to outsource the entire project to a localization company.

The choice is yours. There are advantages and disadvantages to all three solutions. This white paper outlines the pros and cons for each.

To Receive One of the Following Argos White Papers Visit our Website at [www.argostranslations.com](http://www.argostranslations.com) and Sign Up Today!

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- ISO 9001: 2000 certified (BVQI)



- LISA (Localization Industry Standards Association)



- GALA (Globalization and Localization Association)



The American Translators Association

- ATA (American Translators Association)



- Argos is an approved EU translation vendor



- The Association of Language Companies

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