

Dana Pharma Company for Medicines, Medical Supplies and Equipment Ltd.

DanaFarma 2012

Company History

DANAFARMA Company has been working in this field since 2000, **DANAPHARMA** is a company registered in the Ministry Of Health, Chamber Of Commerce and KMCACenter (Kurdistan Medical Control Agency) under License Number (64883-02) issued on (23/06/2008), and it is represented in the middle and southern of Iraq under the name of “Al-Shafaq Scientific bureau”.

Our Goals

The main purpose of our company is to actively contribute to the safe and high-level health service operation through providing high-level medicines products, medical devices and lab agents in our country.

We intend to maintain our position achieved through the past years and wish to be an important and reliable participant of the market in the long run.

Services Overview

DANAFARMA is pleased to offer any kind of service in many different fields of laboratories, medical, and pharmaceutical for its customers, suppliers and international partners wishing to carry out business activities in Iraq.

Marketing and representation services

Through its well established network of relations and its experience in Iraq, **DANAFARMA** is the ideal partner for an efficient penetration of the Iraqi market. The marketing services organization provides principals with an extensive range of expertise ensuring the implementation of dedicated marketing and sales strategies.

Executing projects

DANAFARMA gathers the tenders and requests from the market and organizes the bidding with its partners and suppliers. **DANAFARMA** is able to offer a very rich scale of products. **DANAFARMA** leads negotiations of prices and follows up the offer bidding, to award to contract to supply, and finally to after sales services.

Product Management

DANAFARMA can offer product management to the manufacturer. Our product management includes a wide range of management activities, ranging from the time that there is a new idea for a product to eventually providing ongoing support by means of sales and distribution. Within our distribution network we are able to launch and promote products on your behalf in the Iraqi markets without the hassle of distribution costs and storage charges. Our managed products consist of drugs, lab reagent, medical equipment, surgical products and OTC (over the counter), existing and new innovations. Our module provides a wide overview of considerations in developing and managing a product. How a product is developed or managed depends very much on the nature of the organization and its foresight, creating a demand could be the solution for the manufacturer. We are interested in hearing from companies that are seeking to rationalize their portfolio and are looking to outsource their sales and distribution for Iraqi market.

Basic Figures

Turnover:	3 million US\$	2008
	5 million US\$	2009
	8 million US\$	2010
	9 million US\$	2011

Headcount: 40 peoples

Warehousing: 2000 pallet places

Companies that we are representing now in Iraq

DanaFarma Company in Kurdistan region with it is another bureau in Baghdad under the name (Al-Shafaq Scientific bureau), are representing for the bellow international companies:

Pharmaceutical Companies

Sterop Overseas: www.sterop.be



STEROP GROUP is a Belgian based group with the ambition to be a global leading player in the field of essential drugs and to innovate in the development of products.

Innovative thinking, customized solutions, quality raw materials, highly automated production methods, end to end customer support, competitive pricing and a dedicated workforce all contribute to a privileged relationship with our customers worldwide.

STEROP GROUP for more than 75 years, STEROP has used its experience, know-how and state of the art technologies to develop and manufacture a substantial range of products. Sterop offers a portfolio of essential drugs injectable or on dried forms, manufacturing facilities and support services for pharmaceutical development.

DESMA PHARMA Group: www.desmapharma.com

DESMA PHARMA Group culminates the vision of establishing a profitable business through the acquisition of manufacturing, sales and distribution rights to branded, off-patent, pharmaceutical products from major pharmaceutical companies. Most of these products have become non-core business to their originator's portfolio or too small for big pharma companies. Intense merger and acquisition activity often leaves fragmented portfolios which big pharma rationalizes.

**Labatec Pharma: www.labatecpharma.com****LABATEC-PHARMA SA**

Labatec Pharma is a Swiss pharmaceuticals company based in Geneva, Switzerland, backed by more than 50 years experience in producing high-quality products. Labatec's breadth of orals and injectable products, help patients worldwide improve their quality of life every day. We aim to provide very high Swiss quality products.

**Jordanian Pharmaceutical Manufacturing Co. PLC: www.jpm.com.jo**

JPM is one of the leading developers, manufacturers and distributors of generic pharmaceuticals in the region and has been in business for over 27 years. Today we offer over 100 prescriptions and OTC products in a wide range of formulation and dosage strengths. We aim to continue our significant business growth, which we maintained over the past years.

Medical Devices Companies

Laboratorios KIN: www.kin.es



Laboratorios KIN was founded in 1964 with the purpose of researching and developing oral care products aimed at oral healthcare professionals and consumers. A clear innovative and vanguard talent, our consistent collaboration with the most prestigious universities, and our significant and managerial efforts, have created a favorable environment for our company. Today, our products deserve the interest and confidence of both the medical-pharmaceutical professionals and patients.

aap Implantate AG : www.aap.de



aap is a medical technology company that develops, manufactures and markets biomaterials and implants for the areas Ortho/Trauma/Spine. Its product portfolio includes bone cements, bone graft substitutes, antibiotic carriers, and implants for fracture healing and joint replacement.

In addition to its headquarters the company has sites in Dieburg near Frankfurt am Main and Nijmegen in the Netherlands.

aap Implantate AG stock has been listed in the Prime Standard segment of the Frankfurt Stock Exchange since May 16, 2003.

Implantech : www.implantech.com**Implantech®**
Superior Patient Aesthetics
CIMEOSIL | ALLIED BIOMEDICAL | GELZONE

Since 1989 Implantech has manufactured a complete line of sterile silicone facial implants designed by some of today's leading aesthetic surgeons. We are also your source for composite implants consisting of flexible silicone fully encased in ePTFE material.

We proudly maintain FDA, ISO-9001, EN-46001 and CE certifications — your assurance that each and every one of our implants is manufactured to the highest quality standards.

Implantech offers almost 200 sizes and shapes, in stock and ready to ship. We also provide custom implants for ideal facial and soft-tissue contouring solutions. Ancillary products include ePTFE sheeting, smoke aspiration tips, anti-clog suction tubes, periosteal elevators and free technique videos.

XiantaoSanda industrial co.,Ltd. : www.xtsd888.com

Established in 2001, Xiantao Sanda industrial co.,Ltd. is one of the leading manufacturers of disposable nonwoven and plastic products in china. Our 2 factories are located in Xiantao Hubei which is the production base of nonwoven products in Asia. Our word shop and warehouse cover a total area of 70,000 square meters. We have 2,000 highly skilled staff, including 1,850 skillful workers and 150 management personnel. Usually we can supply 15*40' HQ products each week, which are mainly exported to American and European and Asian markets.

POLYGANICS

Bioresorbable Medical Device Solutions

Polyganics : www.polyganics.com

Polyganics is a privately held biomedical company founded in 1998 with more than 25 years of successful research experience in close collaboration with the Groningen University, the Groningen University Medical Centre and the Martiniziekenhuis, the general hospital in the city of Groningen, on bioresorbable medical implants.

Polyganics harbors all the commercial, chemical, medical, biological and clinical knowledge and expertise needed for the development, manufacturing and marketing of innovative biomedical products based on bioresorbable polymers.

Polyganics possesses a well-equipped laboratory, nearby the University Medical Center Groningen and collaborates with a total of 15 academic/clinical research groups. Polyganics has a certified quality system according to international regulations (ISO 13485) and is an FDA-registered facility.

Instantina: www.instantina.at

Our company is specialized in the development and production of instant products.

Renowned branded companies, trade organizations, and the processing industry trust in our company's performance with respect to quality and know-how.

Registration Regulations for both of Companies and Products – Iraqi MOH and KMCA, MOH-Kurdistan Region

General:

According to the pharmaceutical regulations in Iraq, a pharmaceutical product cannot be marketed unless it is registered. The product should be approved by national committee for selection of drug and national board for selection of herbal and food supplement.

Registration is the filling of certain information about the safety, efficacy, quality and origin of products to be marketed in Iraq.

Registration should be done by **manufacturers, marketing authorization holder, and contract manufacturers.**

Companies required to be registered are:

- ❖ Pharmaceutical companies that have one or more of a pharmaceutical factory.
- ❖ Companies producing General products and food supplement producing companies, and the therapeutic milk and neonate nutrition production companies.
- ❖ Medical appliances and disposable producing companies.
- ❖ Laboratory diagnostic kit manufacturers.

Products that are required to be registered are any pharmaceutical products with A therapeutic effect, vaccines and sera and food supplement products:

- ❖ Prescription only drugs (full documentation is required).
- ❖ OTC drugs (reduced documentation* is required).

***Reduced documentation: - no bioavailability or bioequivalence study is required, however dissolution profile to be submitted.**

Requirements for the registration of pharmaceutical companies:

- 1) Company registration form to be filled in one copy signed and stamped by the person responsible on the establishment.
- 2) GMP certificate Legalized from responsible authority and it should be valid.
- 3) **ML** Manufacturing license certificate legalized from responsible authority and that mention all the pharmaceutical production lines.
- 4) Copy of the CPP for at least two of its products released from one of the following authorities:
 - a) **FDA** (USA), Food and Drug Administration.
 - b) **HPFB** (Canada), Health products and Food Branch, therapeutic products directorate.
 - c) **EMA** (EU or any of its countries), European Union, European Agency for the Evaluation of Medical products.
 - d) **MHLW** (Health authority of Japan), Ministry of Health, Labor, and Welfare, pharmaceutical and Medical Safety Bureau.
 - e) **TGA** (Australian certificate).
 - f) **MHRA** (UK certificate).
 - g) Swiss Medic.
 - h) **GCC** (central registration in gulf countries).

Otherwise the company should be inspected by Registration Department.

Requirements for the registration of companies producing general products, companies producing therapeutic milk and nutrition, companies producing food supplements:

- ❖ Company registration form to be filled in one copy Signed and stamped by the person responsible on the establishment.
- ❖ GMP certificate or any other certificate approved by responsible authority (the country of origin officially legalized).
- ❖ ML manufacturing certificate or any other Quality assurance certificate such as ISO 9001, 9002 or equivalent.

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