SARCK SOLUTION

QMS System Construction Proposal

Submitted To:

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Submitted By:

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1. General

ISO 13485 Quality management System is harmonized standard for regulatory approvals. It is mandatory for a company seeking CE approval for its products. ISO 13485 is a system to ensure theperformance and safety of the product and provides a road map for regulatory approvals.

Poor QMS Systems alienates customers, European Authorized Representative, notifiedbodies or competent authorities.

In contrast, good documentation has tangible benefits. Clear reference materials can preventproduction errors and make business processes more reliable. Example includes;

- Improved sales that result from the availability of easily referenced product information whichmeet the customer, notified bodies and competent authority requirements.
- Training is more effective because of high quality written materials.

2. Sarck Solutions

Sarck Solutions is a technical consulting company providing certification and technical solutions for various sectors and mainly for medical device manufacturers. Laying off manufacturers' regulatory matters enables them to focus on expending their sales volume by exploring new markets. Sarck Solutions is providing solutions to many industries such as Active Medical Devices and non-active medical devices. Following is the list of successful projects done by Sarck Solutions.

a. Needle Cannulas
b. Electrosurgical Accessories (Bipolar/Monopole Forceps, ES Pencils, Electrodes)
c. Gauzes, bandages and Abdominal Sponges
d. Medicated Tulle Bandages (Antibacterial and Antiseptic)

e. Hydrogel Dressings
f. Surgical Instruments (Scissors, Forceps, Retractors, Needle Holders, Speculums, Suction Tubesand curettes)
g. IV Cannulas
h. Tracheotomy Tubes

Team Members

Sarck Solutions has a dedicated team comprising of Engineers and Doctors (for clinical and risk assessments) with extensive industrial and medical knowledge of the field. This hand on industrial andmedical experience enables Sarck Solutions to complete work professionally in a timely frame.

3. Scope of services

Scope of Assignment

To build you're QMS Manual, Mandatory procedures required by Standard and ISO 13485 Certificate

Scope of QMS Certification

" Manufacture and Sales of Medical Instruments disinfectants, Medical Surface disinfectants , Liquid Acid concentrate , Nasal Spray. "

Note: Certificate will provided by IAF Accredited certification Body

SARCK Solutions will conduct work in compliance with ISO 13485 for the Products mentioned above which includes the following:

Following will done as part of QMS System preparation

- Preparation of Quality manual as per ISO 13485
- Preparation of Mandatory Procedures as per ISO 1385
- Preparation of process Instruction, activities flow, required forms.
- Performing process Risk Management format

Note: These all activities will be performed offsite and a 5 days visit can be performed if it is required during the audit or for training purpose, requiring that the travel cost to be paid by the APF.

4. Client Responsibilities

Client shall appoint a Management Representative (MR) having the following responsibilities & authorities:

- Reporting directly to management
- Responsible for the Regulatory affairs about the medical devices
- Client shall be responsible to provide the following
  - Description of the product along with intended Use
  - Product Variants
  - Complete Manufacturing and quality Process of the devices
  - Technical Drawings each category (if applicable)
  - Details of Product and raw material Specifications and any applicable testing
  - Area qualification and process validations
- Client shall be committed to the direction of the consultant and provide full cooperation

5. Project Duration

Sarck Solution will complete the project for ISO 13485 Implementation in **25 to 30** Days please note that lead-time may change depending on late replies from client, testing labs and global pandemic situation.

6. Pricing

Services	Qty	Charges (SAR)	Total Amount (SAR)
ISO 13485 Documentation Preparation Cost	01	**7500/-**	**7500/-**
ISO 13485 Certification audit + Audit report + certificate Cost (3 years)	01	**18000/-**	**18000/-**
Complete Project Cost			**25500 /-**
Not: Travel and accommodation charges will be additional in case of audit and visit.			

7. Payment Term

a. In Case of ISO 13485 and ISO 9001 System , 100% payment is to be provided in Advance
b. Bank Details :
    i. Bank: United Bank limited
    ii. Bank Swift Code : UNILPKKA
    iii. Branch code : 0136
    iv. ACCOUNT TITTLE: SARCK SOLUTION
    v. ACCOUNT NO:290495791
    vi. IBAN: PK44UNIL0109000290495791

8. Confidentiality

Consultant not, at any time, during or after the engagement, disclose or allow to be disclosed to any person any information relating to the business affairs of the client without their prior approval.

9. Authorization

If any portion of this letter is held invalid, it is agreed that such invalidity shall not affect any of the remaining portions.
Please confirm the Company's acceptance of this letter by signing below and returning one copy to us.We appreciate the opportunity to continue to work with the Company and assure you that this engagement will be given our closest attention.

Yours truly,
Agreed and *Accepted* by: