

# Implementing a Medical Device Manufacturing QMS

There are key steps that every company implementing a Quality Management System will need to consider:

## **Purchase the Standard**

Before you can begin preparing for your application, you will require a copy of the appropriate standard. The selection of the appropriate standard will be influenced by the devices you manufacturer (classification), the markets where you wish to sell your devices and the relevant regulatory requirements (e.g. FDA, CE marking, CMDCAS).

You should read the standard and make yourself familiar with it.

## **Consider Training**

There are training courses available to help you implement and assess your Quality Management Systems.

## **Assemble a team and agree your strategy**

You should begin the entire implementation process by preparing your organisational strategy with top management. At this stage you should determine the Scope of your Registration - whether the system will be adopted company wide or by one or more departments.

## **Review Consultancy Options**

You can receive advice from independent consultants on how best to implement your quality management system.

## **Undertake a Gap Analysis**

Assess the gaps between your current documented quality management system and the requirements of the standard you have selected to meet.

## **Develop a Quality Manual**

This will demonstrate management, policy, support and commitment to the Quality Management System.

## **Develop Supporting Procedures**

Develop and document procedures to support your quality manual. This will cover all relevant areas of your Quality Management System with appropriate documentation control, personnel, physical and environmental facilities.

## **Choose a Registrar**

The registrar is the 3rd party, like BSI, who come and assess the effectiveness of your quality management system, and issue a certificate if it meets the requirements of the standard. Choosing a registrar can be a complex issue as there are so many operating in the market. Factors to consider include industry experience, geographic coverage, price, service level offered and accreditation for the QMS standard. The key is to find the registrar who can best meet your requirements. A great place to start is by contacting us.

## **Implement your Quality Management System**

The key to implementation is communication and training. During the implementation phase everyone begins operating to the procedures of the management system.

## **Conduct a Pre-assessment**

Most registrars offer a pre-assessment service to determine the readiness of your Quality Management System for the formal audit. Registrars cannot offer consultancy services but they can provide valuable feed back on the effectiveness of the implementation your Quality Management System and opportunities for improvement.

## **Gain Registration**

You should arrange your initial assessment with your registrar. At this point the registrar will assess your Quality Management System and determine whether you should be recommended for registration.

## **Continual Assessment**

Once you have received registration and been awarded your certificate, you can begin to advertise your success and promote your business. Your Quality Management System will be periodically assessed by your registrar to ensure that it continues to meet the requirements of the standard.

For more information on implementing a medical device manufacturing QMS, please contact us on + 44 (0) 1442 278607 or alternatively email [product.service@bsi-global.com](mailto:product.service@bsi-global.com).