Quality Manual

SAS COMPANY

ISO 13485:2016

QUALITY MANUAL SIGNATURES

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Introduction about QM

- This manual describes the quality systems applicable to the products manufactured by **SAS** co

- **SAS** developed its quality system to better satisfy the needs of its customers.

- **SAS** upgraded its management system to comply with the international quality standard ISO 13485:2016.

- This Quality Manual is the key to SAS documentation system. It is divided into 5 parts comprising the ISO 13485:2016 quality system requirements. In each part a “Company Policy” statement is introduced and followed by a general and brief outlining of the activities of that section. Also each part refers to the “Operating Procedures” related to that section.

- **SAS** quality system is to instruct and guide employees whose actions affect product quality, and to inform SAS’s customers what controls are implemented to assure product quality.

- The Quality Manual is proposed and received by the quality Manager and approved by the Chairman, it's effective since 1/10/2008

Introduction about SAS co.

Scope : SAS Co manufacture Safe Approved Sterile Medical Syringes with needle
sizes : 1 ml , 3 ml , 5 ml , 10 ml syringes. for single use

1- General Information

- Company Name : SAS CO For Syringe Manufacture.
- Starting Date in 2003

2- Site Head Office

- Address: Elsagha square . Tanta Egypt
- Email: sas_ medical_co@hotmail.com
- Web : www. Sasmedical.com
- Fax : 0020403409632
- Tel:0023354627

3- Company Product

- sterile medical syringe 1ml , 3ml (Adult) ,3 ml (child), 5ml , 10 ml

Quality Policy

The top management, executive management and employees of SAS offers all efforts to obtain the international situation in the field of manufacturing and distribution for surgical instruments by:-

- ensuring the organisation's personnel understand and implement the quality policy.

- not accepting deviations from quality policy or wasted resources in any part or aspect of the organisation.

- providing adequate resources and training to support quality system development and implementation.

- Focus on our customer to realize their requirements, satisfaction, expectations and all new developed products.

- Commitment to continual improvement in work system, products and employees Performance and we are Strive for zero defects and Produce the best product at the lowest cost.

- Manufacturing surgical instruments comply with international standards for quality and safety and we do preventive actions to eliminate any problems .

- Adding new market either local or international.

- Commitment to comply with legal and regulatory requirements.

To realize above objectives, SAS implement QMS ISO 13485 and continually maintain its effectiveness.

THE MODELS OF A PROCESS BASED QUALITYMANAGEMENT SYSTEM

Figure 1 below illustrates that customers play a significant role in defining requirements as "inputs". Monitoring of customers satisfaction requires the evaluation of information relating to customers perception as to whether the organization has met the customer requirements as "output

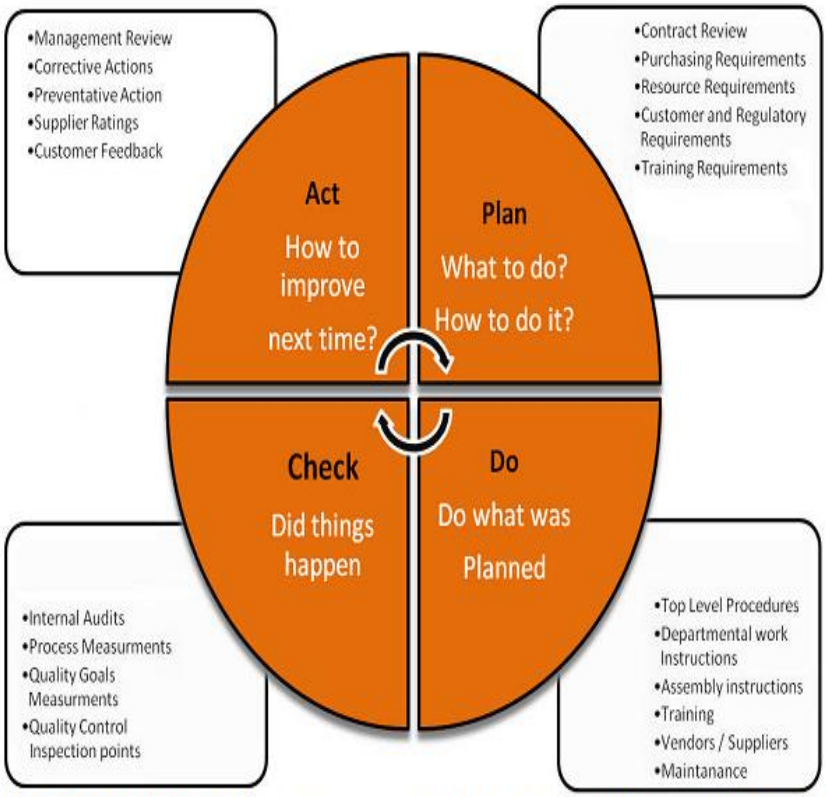
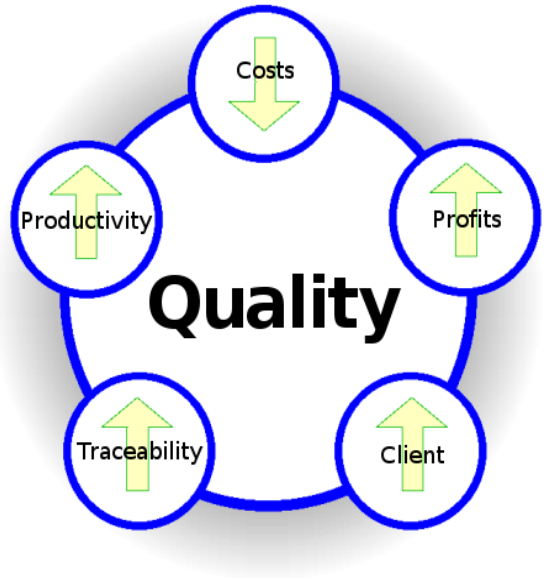


Figure 1 - ISO 9001 / ISO 13485 process models for Quality Management vs. ISO Standards.

4.2.4 Control of records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. A documented procedure (QA-OP-04-02) is established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.



8.5 Improvement

8.5.1 Continual improvement

SAS continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

SAS takes action to eliminate the cause of nonconformities in order to prevent recurrence.
Corrective actions is appropriate to the effects of the nonconformities encountered.
A documented procedure is established as shown in procedure QA-OP-08-06.

8.5.3 Preventive action

SAS determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions is appropriate to the effects of the potential problems.A documented procedure as shown in Q-OP-08-06 established