

About Allanta

Allanta consists of a team of consultants, specialized in the field of quality, lean, six sigma, safety, environment, sustainability, personal skills and management.

Our mission is to support companies and organizations in the development, implementation and improvement of their business processes, by providing **training, consultancy, interim management and coaching**.

Allanta focuses on five key management elements : **Quality, Safety, Environment, Human Resource Management and Sustainability**.

Our experience in these different areas makes us one of the few companies able to offer you a global solution with regard to integrated management systems.

Allanta offers services to multinationals, but also to small and medium enterprises; to manufacturers as well as to service companies **in the automotive, medical and food industry**. Allanta combines knowledge with practical experience. You will continuously get a "pool of **knowledge**" at your disposal.

As a result your business processes will run smoother, leading to a higher degree of safety, quality, efficiency, transparency and finally to the achievement of your objectives.



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MEDICAL DEVICES



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Implementation of MDD and/or FDA regulations
Quality Management System ISO 13485
Quality System Regulation FDA 21 CFR PART 820
Risk analysis and evaluation
Technical File and CE marking
Product Safety – Process Safety
Good Manufacturing Practices GMP
Good Distribution Practices GDP
Product, process and system audits
Complaint analysis and improvement / CAPA

MEDICAL DEVICES TRAINING PROGRAMS AND/OR WORKSHOPS (OPEN FORMULA AND IN COMPANY)

GENERAL

1 Awareness Training Medical Devices for Board of Directors and Management Team

Introduction to European regulatory and quality assurance requirements for medical devices compared with the requirements of the US and other countries.

2 Training : ISO 13485

Specific insight into the requirements of a medical device quality management system.

3 Workshop : Advanced Medical Product and Process Quality Planning

Developing skills for establishing a quality planning for product and process development, preparing and documenting a Technical File and CE marking / FDA compliance.

4 Workshop : Risk Management for Medical Devices: Medical Failure Mode & Effect Analysis / FMEA

Developing skills for the implementation of a risk analysis according to ISO 14971.

5 Workshop : Internal audits ISO 13485 according to ISO 19011

Developing skills for performing internal audits of medical device quality management .

6 Training : Good Distribution Practices (GDP)

Handling, storage and distribution are important activities in the integrated supply-chain management of medical devices. To maintain the safety and performance of medical devices and the quality of the service offered by distributors, guidelines have been developed to provide distributors with recommendations on Good Distribution Practice. General reference is made to the content of the relevant provisions outlined in the Medical Device Directives including amending Directive 2007/47/EC, Decision 768/2008/EC and Regulation EC 765/2008 (the latter two insofar as reasonably applicable to medical devices).

7 Training : Comparison between ISO 13485 and FDA 21 CFR PART 820

The ISO13485 standard and the 21 CFR PART 820 regulation have several differences, what have kept them from harmonizing. ISO 13485 is a standard specific to medical devices, based on ISO 9001. The FDA does not adopt this standard but participated in writing ISO 13485:2003 to make sure their requirements and ISO 13485:2003 are aligned. The FDA quality system regulation has more stringent complaint handling & reporting requirements.

8 Training and workshop: Root-cause investigation / CAPA

One of the most important quality system elements for the FDA and MEDDEV 2.12-1 (MDD) is the corrective and preventive action subsystem.

The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence. Verifying or validating corrective and preventive actions, communicating corrective and preventive action activities to responsible people, providing relevant information for management review, and documenting these activities are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures.

EUROPEAN MARKET

1 Training : Medical Legal and Statutory Requirements: Medical Device Directives

Specific insight into Medical Devices Directive 93/42/EC or In Vitro Diagnostic Devices Directive 98/79/EC and consequences for the organization / processes / product quality control.

2 Workshop : Medical Devices Vigilance System and CAPA

Skills for analyzing incidents and complaints. Skills for the initialisation of corrective and preventive actions (CAPA) according to MEDDEV 2.12-1.

OTHER RELEVANT TRAINING PROGRAMS:

Manufacturing / GMP

Process improvement / Lean
Six sigma
VSM
5S
SMED
KAIZEN
TPM

Personal skills

Coaching
Train the trainer
Leadership skills
Management skills
Communication with results
MBTI

US MARKET

A. Training program: Quality System Regulation 21 CFR PART 820 / Medical Device Good Manufacturing Practices (GMP)

Manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products are known as current good manufacturing practices (cGMP's). cGMP requirements for devices are listed in part 820 (21 CFR part 820).

B. Training program: FDA Medical Device Regulatory requirements for US Market distribution

B1. Premarket notification process – 510(k) Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k). This allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories.

B2. Premarket Approval (PMA)

Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

B3. Device establishment registration & listing

Owners or operators of establishments that are involved in the production and distribution of medical devices intended for use in the United States are required to register annually with the FDA. This process is known as establishment registration.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices.

B4. Medical Device Reporting (MDR)

Medical Device Reporting is the mechanism for the FDA to receive significant medical device adverse events from manufacturers, importers and user facilities, so they can be detected and corrected quickly.

B5. Electronic records; electronic signatures

This guidance is intended to describe the FDA's current thinking regarding the scope and application of part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11).

C. Managing FDA inspections at your company

From planning for an inspection through post inspections.

*Origin of FDA inspections/FDA today

*FDA inspectional process:

- Planning by FDA
- FDA inspectors
- Inspection approach
- GxP inspection process
- Tools used during inspections
- Enforcement actions (483, warning letter, etc.)
- Establishment Inspection Report (EIR)

*Planning for an FDA inspection at your company

*During the inspection

*After the inspection

Are you developing, manufacturing, handling and/or distributing devices for medical and in vitro diagnostic purposes?

Then this leaflet is important to you!

At Global, European and national level various quality and product safety regulations are applicable for medical and in vitro diagnostic devices. It is extremely important that medical devices:

- when used, do not compromise the safety of patients, users or other persons;
- comply with international and national laws and regulations;
- achieve the performances intended by the designer and manufacturer.

Europe - EU Legal and Regulatory Framework

Medical Device Directives (MDD) are obligatory within the European Economic Area (EEA) and Switzerland. These directives comprise quality and safety requirements for medical devices. Manufacturers shall use harmonized standards to demonstrate that medical devices comply with EU legislation. With the CE marking on a product the manufacturer ensures that the product conforms with the essential requirements of the applicable EC directives.

United States of America - FDA - Regulations for Medical Devices - FDA Compliance

FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States.

Some of the basic regulatory requirements that medical device manufacturers must comply with are:

Premarket Notification 510(k), Premarket Approval (PMA), Labeling regulations, Establishment registration, Medical Device Listing, Quality System (QS) regulation, Medical Device Reporting (MDR), Electronic records and electronic signatures.

Before a medical device can be marketed in the USA a marketing application must be submitted to the FDA and clearance obtained.

Risk Management - according to ISO 14971

Medical Devices must be designed and manufactured in such a way that, when used under the conditions and for the intended purposes, they will not compromise the clinical condition, safety or health of patients, users or other persons. Risk Management provides a way of identifying, evaluating and controlling potential risks associated with medical devices. Preventive, detective and protective measures will be defined to monitor the effectiveness of these controls.

CE marking and Technical File (or Design Dossier)

Before a device can be placed on the European market, the manufacturer must demonstrate that the device is developed and manufactured meeting essential requirements and harmonized standards. The EC declaration of conformity is a part of the procedure whereby the manufacturer declares that the product meets the provisions of the directive on medical devices. This declaration is supported with a documented technical file or design dossier.

Medical Devices Vigilance System and CAPA

The principal purpose of the Medical Device Vigilance System is to improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence of an incident elsewhere. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such incidents.

ISO 13485 and auditing according to ISO 19011

The international standard ISO 13485 represents the quality management system requirements for the design and manufacture of medical devices, including design and development, production, installation and servicing of medical devices.

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Interested ?
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