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IMPLEMENTATION OF ISO 13485:2016 IN MEDICAL PRODUCTS HANDLING MULTINATIONAL CORPORATION

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Abstract

The report is focusing on quality management system implementation in a transnational company. This organization, which we refer to as Corporation X (hereinafter referred to as CX), is a large multinational, multi-branch organization. It operates over 250 subsidiary companies in what is termed "the CX family of companies". The corporation operates in three broad divisions; CX is operating in 60 countries and is selling products in more than 170 countries now - in 2019.The quality system, which is under implementation is ISO 13 485: 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes.

Keywords: *Quality management system (QMS), Large multinational, multi-branch organization, Medical Products Handling, ISO 13 485: 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes.*

JEL Codes: *L15-Information and Product Quality • Standardization and Compatibility*

1. Introduction

Quality management is an extremely important area of organizational management that includes strategic, tactical, operational and linear aspects of the organization's functioning. The main goal in the material is the revealing of the implementation of ISO 13 485: 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes in large multinational, multi-branch organization. The multinational company, as a complex system with its special characteristics, possesses a number of both universal and specific aspects in quality management.

The goal is achieved by the following tasks, which are structured in the main chapters of the report, namely:

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1.Short overview of the multinational company, where the QMS was implemented;

2.Basic parameters of ISO 13 485: 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes, which standard represents the implemented QMS;

3.ISO 13485:2016 –Implementation in TSD as a part of the multinational corporation CX.

The main methodological approaches used in the dissertation are the following:

1. A System approach that sees organizational and managerial phenomena as complex systems, i.e. as sets of interrelated factors, resources and elements acting as one whole.

2. Structural-functional approach considering the organization, in the case as a structural complex, in which each structural unit fulfills a certain functional role;

3.The Design approach, which is an extremely important quality management approach for complex systems, insofar as this approach integrates the various components of the system in the most appropriate way, as well as forms a focus of effort.

2. Short overview of the multinational company, where the QMS was implemented

Corporation X (further mentioned as CX) is big multinational, multi-branch organization. It operates over 250 subsidiary companies in what is termed "the CX family of companies". The corporation operates in three broad divisions; Consumer Healthcare, Medical Devices and Pharmaceuticals. CX is operating in 60 countries and is selling products in more than 170 countries now – in 2019. Every day, our more than 115,000 employees of CS across the world are blending heart, science and ingenuity to profoundly change the trajectory of health for humanity.

CX is founded in 1901. The Corporation produced its first products in 1902 and incorporated in 1911. Those products already featured a logo resembling the signature of the founder - Peter Smith, very similar to the logo used today. It is one of the longest-used company logos in the world.

Corporation X in today’s form is created by many efforts, which included:

- Expanding existing capacities and markets;
- Merger and acquisition of various business companies.

The Corporation is headquartered in New York, DC. Its common stock is a component of the Dow Jones Industrial Average and the company is listed among the Fortune 500.

The company has made the 7th largest pharmaceutical settlement with the U.S. Department of Justice. CH's brands include numerous household names of medications and first aid supplies.

- The CX Family of Consumer Companies offers the world's largest range of consumer healthcare products. The baby care, skin care, oral care, wound care, over-the-counter and women's health products feature brands trusted by consumers and healthcare professionals worldwide. By anticipating needs and creating solutions and experiences, CX help people live healthy, vibrant lives.

Medical Devices - Having made significant contributions to surgery for more than a century, the CX Medical Devices Companies are in the business of reaching more patients and restoring more lives. The CX group represents the most comprehensive surgical technology and specialty solutions business in the world, offering an unparalleled breadth of products, services, programs and research and development capabilities directed at advancing patient care while delivering clinical and economic value to health care systems worldwide.

Pharmaceutical Products - The Pharmaceutical Companies of CX address some of the most devastating and complex diseases faced in our time. With advanced biologic and other treatments, CX is investing in a transformative future, changing the way diseases are prevented, intercepted, treated and cured.

The key attention in the work is put on the Technical Service Department /TSD/, which is one of the unit in World Wide Engineering (WWE), which is part (unit) of Corporation X. The Technical Services Department's is accountable for the worldwide technical services of World Wide Engineering (WWE) products. This includes regions directly serviced by the departments and regions that manage their own local service with support from the WWE-TS. To enable effective control over TS activities, the department has three major service regions:

- USA
- EMEA (Europe, Middle East, Africa);
- APAC (Asia Pacific).

A regional Technical Service Managers/Directors head each region. The Managers/Directors directly report to the World Wide Engineering TS Director.

The type of products, which serviced by TSD include durable active medical devices, which are marketed by WWE. These devices are non-disposable, non-sterile, not shelf life limited and not implantable. These devices are referred to in the TSD environment as "Products".

The types of services provided by the TSD are:

- Installation and de-installation of products;
- Maintenance and repair of products;
- Product upgrades;
- Support in the performance of Field Corrective Actions.

All Technical Services Department members are involved in providing technical services to customers. These processes are covering all the services executing by TSD.

The technical service processes, which have an impact on the quality of the WWE products, are so-called after sale technical service provided to customers.

The Regional TS Manager is accountable for technical service in all the countries in the region, the management of the TS team of Field Service Engineers, local suppliers, local depot repair centers, call center support and the regional Back Office support team.

There are two types of countries serviced by TSD:

• Direct Serviced Countries (DSC);

• Non- Direct Service Countries (NDSCs).

In the case of Direct Serviced Countries (DSC), specific Field Service Engineer (FSE) is responsible for service of accounts in each geographical area. In the case, there is the model of the Primary FSE assignment in the Technical Services Application database. According to the workload, tasks may be assigned to other engineers from different areas. In many DS countries, WWE TS staff or their Suppliers directly provide the Field Service.

Within the EMEA and APAC regions, some countries have their own Non-Direct Services., i.e. there are so-called NDSCs. These NDSCs are in written agreement with WWE TS regarding the guidelines of product servicing. In that case, the Field Service staff provides on-site servicing. FSEs are trained and certified to maintain WWE products at field level. The model of NDSCs includes:

• Global controlled technical documents;

• Product traceability is recorded and maintained;

• Complaint and Service Records are recorded through applicable CX channels and local authorities;

• Copies must be provided to WWE upon request or available in the flobal service and repair data base;

• Spare Parts for NDSCs repairs must originate from the Original Equipment Manufacturer (OEM);

• The Regional WWE TS supports the NDSCs with depot maintenance.

• Non-Repairable spare parts are normally sourced by the NDSC directly from the CX Medical Devices Distribution Center.

3. Basic parameters of ISO 13 485: 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes, which standard represents the implemented QMS

ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a

medical device and design and development or provision of associated activities (e.g. technical support).

ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of ISO 13485:2016 are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by ISO 13485:2016 that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to ISO 13485:2016 reflect any exclusion of design and development controls.

If any requirement in Clauses 6, 7 or 8 of ISO 13485:2016 is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in Clause 4.2.2. of the Standard.

The standard is applicable to a very wide range of products, such as implants, screening and diagnostic equipment, invasive surgery products, dressings, laboratory and other research materials, medical equipment, and even medical diagnostic software. The main focus of the standard is to achieve full compliance with regulatory requirements.

ISO 13485 is applicable to all organizations engaged in the design, development, manufacture and marketing of medical devices, as well as companies engaged in the design, manufacture, delivery, installation and maintenance of medical equipment.

Although ISO 13485 is a stand-alone standard, it is based in addition to regulatory requirements and those of ISO 9001:2017, but includes some specific ones, which are directly connected with the Medical Products. There are such requirements as:

- Risk analysis and management;
- Full traceability of production;
- Hygiene and sterility of production;

ISO 13485 is usually required by the departments approving the manufacture and market ISO 13485:2016 is prepared by ISO/TC 210 - Quality management and corresponding general aspects for medical devices.

LIFE CYCLE
A standard is reviewed every 5 years
REVISIONS / CORRIGENDA
Previously ISO 13485:1996
Now withdrawn ISO 13485:2003
Corrigenda/Amendments ISO 13485:2003/Cor. 1:2009
Revised by ISO 13485:2016.

4. ISO 13485:2016 –Implementation in TSD as a part of the multinational corporation CX

Very important and decisive step in creation QMS in Technical Service Department/TSD/ as part of World Wide Engineering (WWE) was when WWE started to become component of the Corporation X Business Network. One of the requirements to join the Corporation X Business Network was the implementation of ISO 13485:2016 – Quality Management Systems for Medical Devices.

In 2018 in TSD started the process of implementation of Quality Management System, based on ISO 13485:2016. For that purpose, a training was provided for the persons in TSD, who are directly involved in the process of ISO 13485:2016 implementation. Further are demonstrated the instructions and regulations on the base of which the above mentioned persons were trained.

Objectives of the Training concerned ISO 13485:2016 Implementation
Participants have to:

• Review the ISO 13485:2016 Standard and why it's necessary for TSD to comply;
• Express the consequences and impact of not complying with the ISO 13485:2016 Standard;
• Understand the responsibilities of TSD;
• Understand how the Implementation of ISO 13485:2016 Standard will influence the TSD Quality Policy and how it relates to the job responsibilities in TSD.

Important Key Points…
Get trained - Follow your procedures!
•
Know the effect/impact that not doing your job correctly has on the end customer and do your job to the best of your ability!
•
Don't "get ready" … Be prepared!
•
Know the Quality Policy – what it means to you.
•

If you don't understand a procedure, policy, or why we do things the way we do, please ask your supervisor, or management, your questions are always welcome…

Why Annual Training?
- Refresh and remind;
- Changes in regulations;
- Review internal and external audit results;
- Reinforce your commitment to Quality and Compliance

What are the regulations?
- US – 21 CFR;
- Part 820 – Quality System Regulation;
- Part 11 - Electronic Records & Signatures;
- International – ISO 13485:2016;
- Canada – CMDCAS;
- Europe – MDD.

Quality System Regulation (QSR)
1. Subpart A – General Provisions
2. Subpart B – Quality System Requirements
3. Subpart C – Design Controls
4. Subpart D – Document Controls
5. Subpart E – Purchasing Controls
6. Subpart F – Identification & Traceability
7. Subpart G – Production & Process Controls
8. Subpart H – Acceptance Activities
9. Subpart I – Nonconforming Product
10. Subpart J – Corrective & Preventive Action
11. Subpart K – Labeling & Packaging Control
12. Subpart L – Handling, Storage, Distribution & Installation
13. Subpart M - Records
14. Subpart N - Servicing
15. Subpart O – Statistics

ISO 13485:2016 – Key Procedures
1. Measurement, Analysis and Improvement
- Corrective and Preventive Action

2. Management Responsibility
- Management Review

3. Product Realization

• Design > Distribution
4. Resource Management
• Staffing/Training
5. Quality System Management
• Document Controls/Change Control

Why different sets of rules…
• US and International;
• System Approach vs. Process Approach;
• Global Harmonization

Notified Body
BSI - British Standards Institution
• Review Technical Files and Design Dossiers
• Issue Certificates to allow CE Marking

Audits for compliance (conformance to ISO 13485:2016 and MDD)
CE Mark
Required on labeling to sell product in other countries
• Legal representation that we comply
• Advertising

We are "allowed" to place CE Mark by:
• Submitting Technical Files and Design Dossiers
• Reviewed and approved by Notified Body (BSI, KEMA)
• Attestation that we comply
• On-going assessments to ensure compliance

Other Applicable Regulations
GLP - Good Laboratory Practices - 21 CFR Part 58
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58

GCP - Good Clinical Practices - 21 CFR Part 54 Financial Disclosure by Clinical Investigators; and other applicable sections.

[B] Quality System = Documents
Define
• Quality Manual, Quality Policy
Document
• SOP, WI, PI, PS, ECO, NCMR, IQ, OQ, PQ, DQ

Implement

• Train, understand, perform job accordingly

[B] Quality System Requirements

Management Responsibility

• Establish a Quality Policy;

• Maintain adequate Organizational Structure;

 Establish appropriate responsibility and authority;

 Provide adequate resources;

 Management representative for Quality System;

• Management Review;

• Quality Planning;

• Quality System Procedures;

Quality System Framework

The Quality System is intended to ensure that TSD provides safe and effective products and services in conformance to specified regulations and those products are made available to the worldwide medical community, customers, and patients.

What is the Quality Manual?

• TSD-QM is interpretation and summary of the Regulations and Laws, which pertain to the design, manufacture and distribution of our medical devices, and our policy on compliance with these regulations;

• A Roadmap of the Quality System

Quality Policy

• Meeting our customers' expectations;

• Delivering innovative solutions to improve the quality of life for our patients;

• Collaborating with our worldwide partners to advance healthcare standards;

• Complying with all applicable regulatory laws and standards;

• Maintaining an effective Quality Management System.

For executing the important task of QMS Implementation in TSD was created special task-group under the supervising of the World Wide Engineering TS Director. The EMEA regional Technical Service Manager as a head of the task-group is directly responsible for the activity and for the results of the work of the task-group. The WWE Quality Manager plays an important role as councilor for the task-group.

The first step of the task-group, which furtherly will be mentioned under the abbreviation TG, is the creation of Quality Manual. Basic principles of the Quality Management System in TSD are that, which are expressed in the Quality Policy of CX. Key SOP were developed concretely for the organization and the processes of TSD.

The Task-group consists from five members with different professional orientation, namely:

- EMEA regional Technical Service Manager
- Engineer;
- Engineer;
- Marketing Specialist;
- Logistic and Distribution Specialist.

As an illustration below is demonstrated the title page and page 1 of the Quality Manual.

Table no. 1 Quality Manual - Corporation X, Technical Service Department

Corporation X

World Wide Engineering (WWE)
Technical Service Department (TSD)
QUALITY MANUAL
WWE-TSD
ISO 13485:2016

Copy 1

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1.0 Purpose

The Technical Service Department/TSD/ Quality Manual describes the Quality System implemented throughout the CX family of companies. It outlines the intent and direction of TSD for providing safe and effective products to the worldwide medical community, and it has been prepared to be consistent with the guiding principles set forth in the Thompson & Thompson Quality and Compliance Core Objective. The TDS Quality Manual is comprised of the CX family of companies Standard Operating Procedures and Franchise Shared Procedures listed in FFR-2887.

2.0 Scope

2.1 This document is applicable to all activities at the US, Israel, Belgium and Mexico World Wide Engineering TSD sites. Clinical Research associates located in Jersey are part of the CX family of companies Clinical Research organization and comply with all applicable requirements of the CX family of companies Quality Manual.

2.1.1. CX sponsors clinical and pre-clinical research studies under applicable Health Authority regulations. As such, CX is responsible for the initiation and monitoring of outsourced clinical/pre-clinical studies.

2.1.2. Written agreement(s) specifying obligations and applicable quality/regulatory requirements for the provision of clinical and pre-clinical research are maintained by CX.

2.1.3. TSD is responsible for reporting adverse events associated with approved products for clinical studies to applicable health authorities.

2.2 The Quality Manual applies to all administrative personnel associated with the design and development, manufacturing, processing, packaging, storing and delivery of the CX family of companies' products and Own Brand Labeling (OBL) products. Any reference to CX, throughout this Quality Manual applies to all organizational units and locations as outlined within this document.

THIS IS PRE-RELEASE VERSION FOR TRAINING PURPOSE ONLY.

5. Conclusion and Recommendations

In conclusion, it is necessary to summarize the following: Modern quality management, systems expressed through the regulations of a number of international standards form the key conditions for large organizations to achieve highest level of functioning, as well as to follow the efforts for continuous optimization of activity.

In the case of the proposed example of a large multinational organization dealing with medical products, the highest level of quality is ensured by the the international standard ISO 13485: 2016. In this sense, a guarantee of high quality is the existence of a managerial will, which is following the regulations of the implemented QMS and is using the instruments offered by it for the functioning and the optimization of the performed activity.

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