1. Introduction

Subject of this process description is the Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports between Notified Bodies of the European Union (EU) and Taiwan Food and Drug Administration (R.O.C. TFDA) Authorized Medical Device QMS Auditing Organizations under the "Technical Cooperation Programme“ (TCP) – Taiwan.

1.1. Background

The TFDA of the Ministry of Health and Welfare demands manufacturers of certain manufacturers of certain medical devices and in vitro diagnostic medical devices that are classified as Class I (sterile, measuring, reusable), Class II and Class III under Taiwanese regulations to comply with Taiwanese Good Manufacturing Practice (GMP) before their products can be marketed in R.O.C.

For this purpose Taiwanese manufacturers shall be audited by TFDA Designated Auditing Organizations in accordance with GMP regulation. Foreign manufacturers shall demonstrate their compliance with GMP regulation by submitting Quality System Documentation (QSD) including various documents such as quality manual, general quality system procedures, list of quality management system documentation, factory layout, production diagram, list of major facilities and equipment and ISO 13485 certificates to TFDA. The submission of the documents shall be in Traditional Chinese or English. TFDA may perform overseas on-site inspection when necessary.

1.2. Benefits of the Technical Cooperation Programme

The Technical Cooperation Programme (TCP) was initiated in order to reduce duplicate audits and thus to reduce time and costs by the exchange of Taiwanese GMP and ISO 13485 audit reports.

As the Taiwanese GMP regulation is harmonized with ISO 13485 European manufacturers may utilize the programme to submit

- an English certificate according to ISO 13485
- an English ISO 13485 audit report issued by EU Notified Body Partners of the TCP
- along with manufacturing and free sales certificates from the highest competent health authority of the manufacturer.

as part of the documentation in demonstrating compliance with R.O.C. regulatory requirements.

Taiwanese manufacturers may utilize the TCP to provide TFDA QMS regulation audit reports to EU Notified Body Partners as part of the documentation in demonstrating compliance with regulatory requirements of the EU.

In addition, TFDA Designated Auditing Organizations may delegate their foreign audits to participative EU Notified Body Partners. Participating EU Notified Body Partners may delegate their audits to auditors of TFDA Designated Auditing Organizations, if they are individually qualified by the respective Notified Body.

In any case, each party shall keep confidential all technical, commercial and scientific information, including trade secrets and proprietary information provided by other party.

2. Geographical Scope of the TCP

The TCP is only applicable for manufacturers based in the EU, Liechtenstein, Switzerland and Taiwan.

3. Description of the Process at mdc

Thanks to the acceptance of mdc’s EN ISO 13485 audit reports due to the participation in the TCP, the submission of extensive quality documents in Taiwan can under certain circumstances be avoided.

3.1. General Procedure

The order for the "Technical Cooperation Programme" – Taiwan comprises exclusively the once-only issue of the aforementioned documents (audit report, certificate). These are, as a general rule, accepted for three years in Taiwan. After that, a renewed assignment at mdc is required. Since all sections of EN ISO 13485 must be checked in these audits, additional costs may under certain circumstances arise. The aforementioned service is invoiced with a rate as per price list, with issuing of EN ISO 13485 audit report in the English language assumed as agreed upon. Should German have been agreed upon as report language, translation costs as per price list will arise. Translations initiated by customers are not accepted by mdc.

Communication with the Taiwanese authorities is not routinely intended by mdc – if this is required, payment will be charged at cost at the daily rate agreed upon in the current certification contract.

The auditing of national Taiwanese requirements is not necessary, since the importer in Taiwan is solely responsible for the implementation of the same. The abovementioned documents (see chapter 1.2) are submitted in Taiwan by the client along with the product licensing documents. Further documents required for licensing, e. g. Letter of Authority, Letter of Marketability, are not part of the TCP process at mdc.

In case of Taiwanese contract manufacturers mdc will evaluate their qualification based on information available at the legal manufacturer (client). Based on the data mdc will decide whether there is a need for a supplier audit or not. In the decision how to audit such a supplier the provisions of TCP regarding audits performed in Taiwan will be considered.

3.2. Procedure for European Manufacturers

Based on the completed questionnaire medical device or questionnaire IVD or the update of company data (for existing clients), the client receives a written quote for use of the "Technical Cooperation Programme" – Taiwan. If the quote is accepted, the client sends the assignment back to mdc in the form of an application or the countersigned quote (for existing clients). A certification procedure as specified in the Process Description Certification of Quality Systems is implemented in the normal way. The client receives a certificate according to EN ISO 13485, the audit report and a cover letter (both in English) for submission in Taiwan.

3.3. Audit Procedure

Within the framework of the audit the client has to keep available a list of products for approval in Taiwan. Random samples of these products are checked in the audit.

In the audit, all sections of ISO 13485 are fully assessed. In particular the following aspects will be examined with regard to the products intended to be marketed in Taiwan:

- Availability of respective medical device licenses and manufacturer registration in Taiwan
- Effectiveness of control over subcontractors/qualification of subcontractors
- Ensuring that only products registered in Taiwan are delivered to Taiwan
- Ensuring the correct labelling of products shipped to Taiwan
- Exchange of information with the distributor in Taiwan concerning:
  - Post market surveillance (PMS)
  - Handling of complaints
  - Ensuring correct labelling (labelling control)
  - Reporting and handling of incidents (advisory notice/recall information)
  - Corrective measures regarding the nonconformities

The audit results will be documented in the above mentioned audit report. The audit report lists the products that are relevant for approval in Taiwan and states that these products were included in the audit and contains the following note: "*This Audit Report has been issued under the Technical Cooperation Programme on Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports between EU Notified Body Partners and R.O.C. TFDA Authorized Medical Device QMS Auditing Organizations*."

4. Procedure for Taiwanese Manufacturer who are already certified by a TFDA designated Auditing Organization

Currently there are four TFDA designated auditing organisations (Electronics Testing Center, Taiwan (ETC), Metal Industries Research and Development Center (MIRDC), Center for Measurement Standards/Industry Technology Research Institute (CMS/ITRI), and Plastic Industry Development Center (PIDC)) to perform GMP inspection and QSD review.

In case Taiwanese manufacturers intend to utilize the Programme to provide TFDA QMS regulation audit reports to EU Notified Body Partners as part of the documentation in demonstrating compliance with regulatory requirements of the EU the procedure at will be the same as for all clients who are not yet certified by mdc according to EN ISO 13485 (see chapter 3.2). In consideration of the provided documents and data as well as the provisions of TCP regarding audits performed in Taiwan, mdc determines the required audit scope and will reduce the audit time if possible.