Function Description_Quality Assurance & Regulatory Affairs Specialist

Applicable related procedure: PRC_3.

1 Major revisions

Version 1.0 - New document.

2 Function description

1. Function: Quality Assurance & Regulatory Affairs Specialist.

2. Reports to*: Quality Assurance & Regulatory Affairs Director.

*Not applicable to external human resources e.g. consultants, advisors, etc.

3. Team member of: Quality Assurance & Regulatory Affairs.

4. Responsibilities:

a. Ensuring IDEVAX' products and services meet customer and requirements such as quality control, and assisting in Design control activities.
b. Maintaining the compliance of the Quality Management System (QMS) to applicable requirements including ISO 13485:2016, while also enabling agility where possible for unregulated products
c. Provide guidance and support to businesses on regulatory policies and procedures.
d. Ensuring compliance to applicable EU MDR 2017/745, US FDA, Harmonized Standards, and other International Ministry of Health requirements applied to approved products and products under development.
e. Interact with the competent authority FAMPH, NB, FDA, and international regulatory agencies or third parties on matters related to establishment registrations, site licensing, product marketing applications, facility inspections, etc.
f. Preparation and maintenance of medical device product marketing applications.
g. Manage vigilance activities under supervision of QARA Director (MDR/Vigilance reporting to FAMPH, FDA, European and international agencies (eg EU Competent Authorities, etc.) and Notified Body as required including performing the assessments of adverse event reports to determine if reportable.
h. Monitors European and international regulations and standards for changes that may affect products or the quality system and maintains a library of such documents.
i. Write, review, and approve Procedures, Instructions, Forms, and other QMS documents.
j. Evaluation & approval of supplies; work closely with cross-functional teams.
k. Quality and overall KPIs
l. Support the management of change requests, CAPAs, NCs, and customer complaints
m. Support internal and external auditing activities.

5. Tasks:

a. Completes and submits necessary pre-market applications (eg 510(k), IDE, PMA) for products to the FDA under supervision of QARA Director.
b. Develops and maintains technical files/design dossiers in accordance with the applicable regulations and local law.
c. Compile device master records, technical files, design dossiers, FDA and European submission documents, and/or any other related documents/reports, ensuring timely submissions, to meet Company product(s) and regulatory requirements, and compliance to all approved licenses.
d. Review of marketing and scientific materials for regulatory compliancy.
e. Reviews and assesses change control documentation for regulatory impact. To review Change Control requests, deviation requests, quality system reports for adequacy and compliance with company and regulatory requirements. To provide regulatory support as required in the evaluation of customer complaints, ensuring complaint reports are closed out in accordance with the approved procedure.
f. Provides regulatory input on topics related to health and safety.

g. Assists as needed in the development and implementation of study protocols (clinical and non-clinical) intended to support product submissions.
h. Participating in Inspections and/or Audits by various Notified Bodies and Regulatory Agency representatives (eg FDA) and other Authorized parities.
i. Plan and execute Post-market surveillance (PMS) activates according to regulatory requirements and internal procedures under supervision of QARA Director.

6. Diploma / degree: Master (Biomedical) Engineering or Life (Biomedical / Pharmaceutical) Sciences or equal by experience.

7. Essential know-how:
   a. Medical device sector
   b. Quality assurance and control
   c. Regulatory affairs
   d. EU MDR 2017/745, CFR Title 21 Chapter I Subchapter H including Part 820
   e. ISO 13485:2016
   f. Excellent computer skills

8. Languages:
   a. English: Excellent writing, reading, conversation
   b. Dutch: Basic knowledge is considered a plus
   c. Other: not necessary, but considered a plus

9. Expertise:
   a. Experience in a QA&RA, preferably in a Medical Device environment
   b. Experience in GxP environment
   c. Knowledge of ISO standards and regulations
   d. Experience with Statistical Process Control (SPC) and root cause analysis.
   e. Ability to conduct formal presentations in group settings and convey technical information.

10. Profile:
a. Strong planning and organisational skills
b. Strong project and time management skills
c. Excellent communication (written and oral) skills
d. Excellent analytical and problem solving skills
e. Independent learning
f. Quality-minded and detail oriented
g. Team worker