mantrasystems

Description of work

Medical Affairs Associates Program

Edition 4.0

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1. Introduction

Mantra Systems Ltd offers consultancy services that provide professional support to medical device companies. We advise on building frameworks and systems that will enable medical device manufacturers to comply with the terms of the Medical Device Regulation (MDR) 2017/745.

Specifically, all medical device manufacturers will need to undertake a number of activities/build a number of systems to comply with the MDR. These include:

- Developing a Post-Market Surveillance (PMS) system for every device
- Undertaking Post-Market Clinical Follow-Up (PMCF) on every device
- Performing a Clinical Evaluation of every device and summarise the findings in a Clinical Evaluation Report (CER).

PMS is the process of monitoring the performance of a device following its release onto the market. PMCF is a component of PMS whereby clinical investigations are instigated to prospectively capture clinical data on device safety and performance.

Clinical evaluation is the process of collating all data on a device (whether from PMS/PMCF, external studies, risk analysis, complaints, etc) and establishing whether or not compliance with all requirements for that device have been met. A CER is a technical document that follows an established structure, and outlines the findings of the clinical evaluation.

2. Premise

All of the tasks outlined above – PMS, PMCF, clinical evaluation, and writing CERs – are primarily clinical or medical in nature. For example, writing a Clinical Evaluation Report involves the assimilation, assessment and appraisal of clinical evidence.

As such, medical doctors are extremely well placed to perform this work. Yet, there is a real shortage of medical doctors within the medical device industry. Mantra Systems will deliver MDR-trained medical doctors to support medical device companies in implementing PMS, designing PMCF studies, performing clinical evaluation and writing CERs. Given appropriate training, these tasks are comfortably within the capabilities of medical doctors from all types of speciality.

The Mantra Systems CEO and founder, Dr Paul Hercock, is a doctor with 14 years clinical experience. He also has a legal qualification. He has worked in the medical device industry for over 4 years and has spent most of that time supporting medical device manufacturers in performing the tasks outlined herein. As such, he meets the requirements in the MDR for "person responsible for regulatory compliance".

Mantra Systems will offer MDR training to medical doctors that will provide knowledge essential to the conduct of key tasks in MDR compliance activities. Subject to the quality of submitted assessed post-course work, completion of the program will enable them to join project teams on an *ad hoc* basis, without any long-term or ongoing commitment. Initially, scope of work will focus on the following areas:

- Writing Clinical Evaluation Reports
- Writing PMCF study protocols
- Performing medical device Gap Analysis

As the business scales, the scope of work available to successful associates will also expand to include designing PMS systems, writing PMS reports, performing risk analysis and risk management activities, and performing vigilance system activities.

Work will be offered on the basis of merit and the quality of prior submissions. All work will be performed within tightly-controlled parameters - following completion of the formal training programme, associates will be provided with templates and guidance documents that must be followed when producing work.

3. What does the training involve?

The training is done online and takes place in three phases - a pre-course manual, the completion of several online video workshops, and a post-course exercise involving a 'mock' literature review. Completion of the course will give three hours of training credits and will enable the associate to apply knowledge gained in their pursuit of non-clinical career options. Associates whose post-course submission is of a high standard will be invited to become a medical reviewer / writer with the Mantra Systems Associates Program, providing immediate access to paid client work.

4. What is the nature of the working relationship?

All and any paid work through the Associates Program will be strictly on the basis of a contractor-contractee relationship, with the medical affairs associate functioning as an independent practitioner. It is not an employer-employee relationship. Mantra Systems Ltd will not be responsible for the tax affairs or other administrative affairs of the contractor. Specifically, the associate has full control over the location and hours of work and the right to substitution. Where necessary, the Associate may need to purchase access to paywalled literature sources (up-front costs) and Mantra Systems will reimburse the Associate at the completion of the work.

5. What will be the remuneration structure?

Remuneration will be according to a fee agreed in advance of each work package. The fee will reflect (amongst other factors) the complexity of the device, the complexity and depth of work involved, and expected time to perform. The following guidelines are indicative only and are intended simply to highlight the likely range of payments:

- Lead author, CER - £3,000 - £5,000
- Medical reviewer / writer, literature review - £1,600 - £3,500

Time taken to perform work will reduce as the associate becomes familiar with the work required.