mantrasystems

Description of work

Medical Affairs Associates Program

Edition 3.2

This document is for information only. It will not be taken to constitute a formal offer of work or employment, a contract, or any other form of agreement. It is not binding on any party.

Contents

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:

- Performing systematic literature reviews to evaluate safety and performance of medical devices
- 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).

Literature reviews form vital inputs into clinical evaluation, risk management and ongoing scrutiny of medical device safety and performance.

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 – literature reviews, 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 performing literature reviews, 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 7 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 to enable them to perform the above functions 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
- Conducting systematic literature reviews

Work will be offered to Associates based on the level of training completed as well as competency and alignment with clinical area of expertise.

Completion of the Foundation Training enables you to work as a member of a project team, conducting literature reviews for clinical evaluation and other purposes.

Completion of the CER Lead Writer program will enable you to become principal author on CER-writing projects, heading up a team of Associates.

With experience, you will also have access to extended opportunities within the Mantra Systems scope of activity.

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3. What does the training involve?

The training comprises sets of online videos followed by a post-course exercise relating to each phase of the Program. It is necessary to complete the Foundation Training before advancing to other modules. The post-course work is assessed and full, personalised feedback will be given. Following successful completion of each phase you will be granted access to live client work and wider resources within Mantra Systems.

4. What is the nature of the working relationship?

This is not an employer-employee relationship. The relationship with be a contractor-contractee relationship, with the medical affairs associate functioning as an independent contractor. Mantra Systems Ltd will not be responsible for the tax affairs or other administrative affairs of the contractor.

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:

- Writing a CER - lead author: £3,500 - £5,000 per project
- Literature review team member: £2,000 - £3,500 per project

6. Registration

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