Effective Risk Management Programmes

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Far too many medical device companies are failing to reap the benefits of an effective risk management programme. Thus, patients, users and the companies themselves are continuing to suffer the consequences of device problems that could have been identified and resolved before products are placed on the market. This article discusses how to implement an effective programme.

Benefits of risk management

The United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA) reports that in 2003,[1] it received 8795 adverse incident reports. Of this total, 2% involved a fatality, 5% involved serious injury, 18% prompted in-depth MHRA investigations, and 36% were investigated by manufacturers under MHRA supervision. As a result of investigations made

- 46 safety warnings were issued
- 29 notifications were shared with authorities in European Union Member States
- there were 420 product recalls, field corrections involving MHRA supervision or active involvement and monitoring of cases
- 268 cases required advice on safer device use or improved staff training
- there were 958 manufacturer undertakings to improve designs, manufacturing processes and quality systems.

Some may argue that these data represent a relatively small fraction of medical devices and medical device uses in the UK. That may be true, but these problems are significant for the affected patients and users, for taxpayers funding government programmes to manage these problems, and for medical device companies trying to resolve these problems or manage costly product recalls. Of course, it is not possible to determine the number of adverse incidents that could have been or were prevented by risk management activities.

It is also recognised that the European Directives for medical devices oblige manufacturers to analyse and control risks. However, apart from regulatory obligations, medical device companies should recognise the ethical and business benefits of an effective risk management programme. This will not only help ensure safer medical devices, but can also limit product liability exposure, reduce operating costs, and increase profits by identifying and preventing problems before products are marketed. Effective risk management programmes can also help reduce costs when problems occur by providing a systematic framework for understanding the causes of problems, which allows more rapid and cost-effective resolutions.

Given the need for reducing the risks associated with the use of medical devices, why are many medical device companies continuing to struggle with the development of a cost-effective risk management programme? This can be because they do not assign adequate resources to address the issue; fail to understand the relationship between risk management and the quality system, or to adequately consider clinical risks; or have poor understanding of the role of risk analysis tools for complying with regulatory requirements and conforming to related standards, and a lack of clear and convincing risk management documentation. Each of these topics is discussed below.

Assigning adequate resources →

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Company management and executives with budgetary decision-making responsibilities need to be fully informed about the regulatory requirements related to an effective risk management programme and the pitfalls of failing to implement the programme. If they understand the need for this type of programme, they are more likely to assign adequate resources to its development. For example, in many companies it may be entirely appropriate that the person responsible for regulatory affairs assumes responsibility for documenting compliance with risk-related requirements. However, this work can rarely be effectively performed by one person alone. A multidisciplinary team consisting of personnel representing all relevant functions is generally required for this effort. Depending on company structure and the products involved, personnel representing quality assurance, quality control, clinical research, design, production, process validation and other disciplines may need to be actively involved in performing risk management activities. In addition, selected personnel need to possess adequate knowledge or receive training in risk management principles and the techniques and activities needed to meet regulatory and company requirements.

Risk management and quality systems

Risk management is a fundamental component of quality management systems. Thus, if risk management activities are properly defined, documented and effectively managed as part of the quality management system, meeting regulatory requirements related to risk are greatly facilitated. For example, Clause 7.1 Planning of Product Realisation, of ISO 13485:2003, Medical Devices, Quality Management Systems, Requirements for Regulatory Purposes, requires the establishment of documented requirements for risk management throughout product realisation. In addition, a guidance note refers to the international standard on risk management for medical devices; this is discussed later in this article. Therefore, companies should understand the importance of risk management activities as they relate to all the various product realisation and other processes.

For example, Clause 7.3.2, Design and Development Inputs, specifies that inputs relating to product requirements shall be determined and records maintained. One of the listed design input requirements is the output of risk management. That is to say, requirements for the design of the device need to be defined, at least in part, on the basis of appropriate risk management activities such as hazard and risk analyses. In addition, an evaluation of the possible effects of device design changes on existing hazard and risk analyses should also be conducted. A detailed discussion of the importance risk management activities in the management of various organisational processes is beyond the scope of this article; however, a quality system guidance document[2] is under development that provides examples on the risk management considerations as they relate to those processes. This document will help companies understand some of the aspects to consider when integrating risk management into organisational processes.

Clinical research and risk analysis

The European harmonised standard for risk management is not the only harmonised standard that addresses risk. The following two harmonised standards on medical device clinical investigations specify the need to identify risks to patients: EN ISO 14155-1:2003, Clinical Investigation of Medical Devices for Human Subjects, Part 1: General Requirements, and EN ISO 14155-2:003, Clinical Investigation of Medical Devices for Human Subjects, Part 2: Clinical Investigation Plans. For example, Part 1 states that the clinical investigator's brochure should include possible risks and the results of a risk analysis. The investigator's brochure is a compilation of the clinical and nonclinical information on the device under investigation, which is relevant to the clinical investigation. For this reason, the information provided on risks and the results of risk analysis included in the investigator's brochure should consist primarily of clinical risks that must be taken into consideration by the clinical investigator when using the device and treating subjects during the clinical investigation. Part 2 states that the clinical investigation plan must include the results of a risk analysis and assessment, which describe expected clinical benefit against the risks associated with the use of the device and the procedures involved in its use, as identified by the risk assessment. A detailed discussion of risk-related requirements in these standards is beyond the scope of this article; however, companies should ensure that the risk management programme addresses clinical risks.

Role of risk analysis tools

Failure Mode and Effect Analysis (FMEA) and Fault Tree Analysis (FTA) are established techniques used for the identification of hazards and failures. However, before attempting to use these techniques, companies need to grasp the intent of the medical device Directives regarding the identification and control of risk. Once regulatory requirements are understood, companies should ensure that their risk management programmes conform to the provisions of EN ISO 14971:2000, Medical Devices, Application of Risk Management to Medical Devices, which is the harmonised standard for risk management. Although the use of this standard is voluntary, its status as a harmonised standard means that regulatory and other bodies must presume that companies conforming to the standard comply with the risk-related requirements in the Directives.

The harmonised standard for risk management provides a broad and comprehensive framework for the effective management of risks associated with the use of medical devices. It also provides guidance on the use of FMEA, FTA and other techniques that can be useful in this effort. However, many companies do not understand exactly how these techniques should be used. In part, this may be because hazard and failure analyses originated in engi- →

neering disciplines unrelated to the medical technology sector. In any case, these techniques are described in international and national standards and references and should be thoroughly studied before being used to comply with medical device risk management requirements.

Clear and convincing documentation

Another problem regarding the risk management effort is that some companies believe that the documentation of FMEA or FTA results in the absence of other records and documentation described in EN ISO 14971 largely fulfills medical device risk management requirements. However, documenting results of FMEA, FTA or other types of analysis in the absence of developing the processes, records and documentation described in the risk management standard should not be expected to fulfill the risk management requirements of the European medical devices Directives. A more effective approach is to document the results of FMEA, FTA and any other technique used for failure, hazard and risk analyses and then to use these results in the development of the type of documentation described in EN ISO 14971. Other approaches may be equally or more successful, but companies should ensure that risk management documentation clearly demonstrates compliance with regulatory requirements and the establishment of an effective risk management programme. This is often not the case.

References

1. Information on UK medical device adverse event reports can be downloaded from www.medical-devices.gov.uk
2. AAMI/CDV-2 TIR14969, Quality management systems, Medical devices, Guidance on the application of ISO 13485:2003; available for purchase from the Association for the Advancement of Medical Instrumentation (AAMI) www.aami.org mdt

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