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The Benefits of a Regulatory System, for In Vitro Diagnostic Medical Devices, based upon essential requirements plus quality systems

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INTRODUCTION

In-vitro diagnostic medical devices (IVD MDs) are a group of medical devices that were specifically excluded from harmonising directives 90/385/EEC and 93/42/EEC due to their different nature. Accordingly, a proposal for a harmonising directive specific to IVD MDs has been drafted by the European Commission, and is currently being considered by the European Parliament and Council of Ministers.

When the proposed IVD MD Directive becomes mandatory, it will be a legal requirement that manufacturers of IVD MDs must affix the CE Marking to products for which it has been demonstrated that the essential requirements concerning products safety and performance (contained within Annex 1 of the proposed directive) have been met.

To date, European member states have differed widely in their approach to regulatory control of IVD MDs; most countries do not have specific controls or have controls for only the most critical products (e.g. tests for hepatitis and HIV). Where regulations do exist, they are based upon pre-market product approval, and/or approval of individual production batches by national agencies. Post-production surveillance and quality systems play a minor role, with the exception of a very few European countries.

In contrast, the IVD MD directive (and the other medical device directives) places much greater emphasis on product safety by introducing the concept of quality systems, essential requirements and post-production surveillance. Although product and batch approval will be an *option* in the IVD MD directive, it is anticipated that IVD MDs can be brought to the European market without such pre-market product or batch approval if (and only if) these products are manufactured under rigorous quality system requirements *and* satisfy essential requirements of the directive.

EDMA believes that the quality-system-based regulatory approach, augmented by post-production surveillance, is an effective and modern approach to regulatory control of IVD MDs; it represents a step forward in comparison to the traditional regulatory system based upon product and batch pre-market approval. The reasoning behind this view is set out below:

Main aspects of the regulatory approach based on essential requirements and quality systems

A quality system is a process which assures the consistent quality of products produced by a manufacturer. The quality system is policy driven and defines roles and responsibilities throughout a company from the senior management downwards.
All products produced by the manufacturer are subject to quality

system control mechanisms and the entire product life cycle, from design to production and post-production surveillance is covered. Key aspects of the system are the procedures adopted, in both product design and manufacture, to ensure that products consistently meet the essential requirements.

For those IVD MD listed in Annex 2, the quality system approach provided by the draft directive, requires the involvement of a notified body to certify the manufacturer's quality system - by means of external audits - for conformance with all the relevant annexes. These assessments are intensive and include detailed assessments of procedures for ensuring conformity to essential requirements. Follow-up assessments to ensure continued compliance take place on a regular basis after initial certification.

The type testing approach relies upon the intervention of an agency to review the design through the examination of a design dossier and testing of production samples provided by the manufacturer. Through this process the agency defines and certifies the type. Thereafter the manufacturer must supply samples of *each* production batch to the agency for approval prior to release to the market.

Advantages of a regulatory approach based on essential requirements and quality systems.

Historically, the first concerns of manufacturers to offer good products were met by the establishment of "end-of-line" quality control which focused on finished product testing to detect poor quality products. However, this approach has now been superseded by more modern, and effective, techniques that are based upon quality assurance and quality system management ***in addition*** to quality control. These modern techniques emphasise the need to improve the quality and consistency of products at all phases of production (and development) in order to prevent poor quality; these techniques reduce costs by minimising the number of defective products at the end of the production line and give greater assurance that only high quality products are delivered.

The adoption of a regulatory system based on quality system criteria would ensure that new products put on the market would be safe and of consistent quality. In addition, it would allow for a flexible approach to regulation that limits administrative and bureaucratic hurdles by focusing effort where it has most benefit on improving quality (and not just in detecting poor quality).

The quality-system-based regulatory approach ensures that quality is built into products starting right at the beginning of the manufacturing phase and (for Annex 2 products even from the design and development phase). It has much in common with modern principles of quality management, being based upon the premise that quality begins with identification of the requirements of the user and the development of robust solutions to convert these requirements into viable products.

The quality system assures product consistency through a rigorous approach to process management that includes validation, document control, batch traceability, operator qualification (through training) as well as end product controls.

The quality system includes monitoring methods through programmes of process monitoring and internal audit. In addition there are procedures for collection of information from users in the post-

production phase. All this information is used in the formulation of action plans for continuous improvement of both the products and of the quality system itself. The nature of the system allows for such improvements to be implemented rapidly.

A quality-system/essential requirements based regulatory approach is more extensive than an approach purely based upon type testing; it is more powerful in ensuring product quality. Moreover, this regulatory approach has already been considered by all European Competent Authorities and the European Commission, in the approval of the three Medical Devices Directives, to be a complete and comprehensive system for ensuring product quality and compliance to legal requirements.

Summary

EDMA believes that a regulatory approach based upon quality systems and essential requirements represents a modern method of control which ensures product quality and reliability and allows for a more effective use of the available resources (both within industry and health authorities) for the overall improvement of public health.

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