

# EVALUATING SERVICE PARTNERS FOR MEDICAL MANUFACTURING

Turning a good idea into a marketable medical device demands expert assistance, including product engineering and manufacturing skills. Triteq's Ken Hall offers selection advice

The total global market for medical devices is at least €84 billion according to figures published by Eucomed, a body representing European medical technologies industries. Medical device design, as a discipline, is surely as old as medicine itself, but markets and applications are now growing quickly, as modern medical professionals seek long-term cost savings through increased uptake of medical device technologies.

Although medical professionals and researchers are usually in the best position to conceive technological solutions to medical challenges, in-depth engineering skills are essential to turn the idea into a practical, usable medical device that fulfils its intended function and can be built in the required volumes at a realistic price. A skilled design services specialist can provide valuable assistance, for example by contributing experience and knowledge of applicable manufacturing and testing techniques, electronic and software design tools, and suitable components.

Product developers from the medical domain who are looking to bring a concept to market need to be aware of the range of design and manufacturing services that may be available. Moreover, it is important to be able to assess the systems and competencies of candidate service providers, to choose the right partner for a smooth and successful product introduction.

## Commercial design: medical standards

The development path for a medical electronic device is more complex than for the majority of commercial products. Not only must all normal practical obstacles to production be overcome, but the end product and design processes used must also pass the raft of acceptance tests surrounding medical devices. These include the EU Medical Device Directive (MDD) or comparable tests applicable in the USA and other world markets, most of which also demand compliance with international safety standards for medical devices.

A consultant bidding to undertake design work on safety critical projects including medical devices must have suitable quality systems in place. ISO9001 is the minimum quality

standard to which a design services organisation should be qualified, but ISO13485 is an extension to ISO9001 that was created specifically to ensure higher standards of integrity and protection for users in relation to medical equipment. For example, ISO13485 stipulates the requirement for a technical file, risk based design procedures and stringent change control to minimise risks to patients and users.

Even though formal certification to ISO13485 is not necessarily mandatory, a suitable design services provider should at least be able to apply the principles and methodologies set out. Triteq is the first independent design services specialist in the UK to be formally certified by the independent notified body TÜV Rheinland as compliant with ISO13485 for medical product design.

Of equal importance, the design partner must know how best to apply established safety standards and performance requirements to ensure the end product will meet the applicable acceptance criteria. Applicable standards, for example, include EN60601-1-4, which sets out general requirements for programmable electrical medical systems. IEC61508 is another powerful standard applicable to safety critical systems including medical devices.

At a more basic level, some one-person organisations are not able to take on aspects of safety critical design when the applicable standards call for peer review processes by more than one engineer. This is a little-known fact, apparently even among design consultants offering services to safety-critical projects. The costs of failure to meet the requirements of an acceptance document such as the MDD, through insufficient reference to safety requirements or standards, can be extremely high. On the other hand over-engineering the device, for example through indiscriminate application of safety-critical standards in non-critical aspects of the design, can also precipitate marketplace failure. Hence, it is important to ensure sufficient knowledge and understanding of medical device requirements are in place, plus suitable quality systems.

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## Services for commercial success

In addition to assessing credentials that are specific to safety critical design and medical systems design in particular, it is also important to verify that sound engineering principles and practices will be applied. These should pervade the entire project.

For example, documentation that is clear, concise and unambiguous should be established at the beginning and a good design partner will ask searching questions to establish the best possible understanding of the objectives. Triteq, for example, has compiled a guide to the process of defining the product as a deliverable. This can be used to underpin an efficient, structured approach to preparing comprehensive documentation.

## Engineering expertise

The processes and techniques chosen to assemble the product have a critical impact on cost and profitability in relation to planned production volumes. For example, in a recent Triteq project the original product, as designed by another contract designer, was not manufacturable at the target cost and volumes required. Triteq optimised the design to allow component cost reduction, less complex manufacturing processes and equipment, leading to cost savings and faster assembly. Even including the redesign cost, it was possible to halve the delivered product price.

A thorough approach from a design and manufacturing partner also adds value by heading off common manufacturing pitfalls. These may be design-related issues such as preventing the accumulation of worst-case tolerances from causing functional failures or ensuring the PCB layout is dimensioned to accept equivalent components from a number of alternative vendors. A design-for-manufacture (DFM) specialist can anticipate challenges

to manufacturability and plan cost-effective solutions in advance. On the other hand, the true costs of failing to identify potential issues until later in the project, or even after volume production has begun, can be extremely high.

The design services partner should also be able to advise on advances in manufacturing technology and techniques when the time comes to redesign an existing product.

## Software design practice

Formal software design practices are important to any project (whether medical or commercial) and deliver tremendous advantages in terms of reliability, flexibility, testability, maintenance and extensibility. They are relatively inexpensive to implement compared with the true costs of poor software design, which can include project delays, undiscovered bugs and failures in the field. Following best practices also reduces the design owner's dependence on individual software designers or specialist software skills.

However, software requirements relating to safety critical products such as medical devices are much more exacting than for commercial products. For instance, a high standard of fault tolerance is required. Software safety standards include DIN V VDE 0801, which is widely accepted throughout Europe as the de facto standard for medical device software. Designing software to this high standard ensures robust and failsafe code that will meet demanding acceptance criteria and perform reliably in the field. Acceptance tests can be extremely rigorous. For example, when testing software for safety critical equipment TÜV Rheinland reserves the right to replace any line of code in a routine with erroneous code, and expects the device's safety system to detect this.

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Hence, it is vital to be sure that sufficiently high standards of software design and documentation are maintained. For example, Triteq follows DIN V VDE o8o1 to meet the TÜV stipulations for all its software design (not only for medical products) as the safest and most reliable route to producing functional software that is robust, testable and maintainable. There is no additional development cost associated with this approach because the produced code is self-checking and hence reduces the validation costs incurred in unstructured 'spaghetti code' based systems.

## Staying on track

As the project progresses, the desire to change the design is commonplace. However, ongoing finessing of a product definition or design risks delaying product introduction and increasing costs. The design services partner should discourage this 'creeping elegance'. In any case, good groundwork at the beginning of the project should substantially eliminate the need for unplanned engineering changes.

On successful completion of the design and prototyping stages, decisions must be made on how to assemble production volumes. Triteq, for example, has in-house manufacturing capabilities, plus partnerships with UK and Far East-based assemblers. Offshore assembly may make sense if the product is price sensitive, such as a simple non-invasive monitoring device for unsupervised consumer use.

On the other hand, the value and complexity of professional medical devices often mean the objectives are best served by working with a manufacturing specialist closer to home.

## Interactive evaluation

Finding the best design services partner is not a formulaic process. It is important for stakeholders to meet a number of candidate partners to the project, to assess the capabilities and competencies on offer. Medical designers seeking to turn their ideas into IP need to take the time to understand the contributions that a design services partner should be able to make, to ensure all-round success.



*Triteq's Ken Hall guides readers through the process of selecting a medical device design and manufacturing partner*

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