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Medical Devices: Avoiding Compliance Test Failures

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Introduction

As medical device manufacturing companies work to embrace the sometimes complex factory production control and extended documentation requirements that the IEC 60601-1(3rd edition) Standard brings - on top of traditional testing - many organisations have found that despite their preparations the compliance process is longer than it was against the 2nd edition. This means opportunities to increase speed to market are potentially extremely valuable in terms of financial returns.

As well as getting your technology out into the market place before your competitors, speed to market means you have less time to wait on showing return on your development investment and it establishes you as a technology leader in the sector – which is excellent for supporting and developing your brand identity.

The easiest way to speed time to market is to get products successfully through the compliance testing programme the first time. Developing a redesign takes time and then retests can take anywhere from 4 to 10 weeks. You also have to rely on the availability of bench space at your partner test lab – and this isn't always available. The delays can add up and before you know it months have passed.

Whilst designing for compliance with the Standard 'in hand' goes a long way to achieving a first-time-pass, this paper will look at the other way manufacturers are optimising their time to market during the test and certification process; preliminary design review.

Medical equipment development

Medical equipments are highly regulated and held to a higher level of safety requirements than nearly all other types of equipment on the market. The main reasons for this are that medical equipments may be used on patients who are not able to respond to hazardous conditions or pain, an actual electrical connection between the equipment and patient may exist, and certain types of medical equipment function as life support, the failure of which could result in the death of the patient.

While Engineers spend years in universities and workplaces learning about how to design medical equipments, they usually do not learn about the certification and regulatory requirements that medical equipments must meet to comply with the international codes and laws.

Engineering medical electrical equipments to meet the complex safety certification and regulatory requirements can be very costly and time consuming, especially if these requirements are not known in the early stages of design.

Comprehending these certification and regulatory requirements before the design phase of the equipment will result in development cost reduction, faster certification turnaround, and increased product safety.

There are a few common non-compliances that could have been easily avoided had the designers been made aware of the applicable standards and this is the major reason that Preliminary Design Review of medical equipment should be conducted in the design phase.

Testing failure can be avoided

Over 90% of electrical medical devices that Intertek has tested have failed to comply with the required standards on the first submission.

Test failure can have a profound impact on manufacturers, the most common being:

- Delays to getting to market
- Re-design, re-tooling and changes to build standard
- Cost overruns
- Loss of market share
- Reduced profitability
- Lowered brand ranking

The 10 most common failures include the following:

Failure Type	% Fail
Electromagnetic Compatibility (EMC)	97%
Marking of Packaging	90%
Symbols, Labels, and Markings	90%
Operator's Manual	85%
Creepage and Clearance	80%
Indicator Colours	70%
Transformers & Power Supply Units	70%
Wiring Cross sectional area	65%
Cleaning, Disinfection, and Sterilization	50%
Colours of Earth Wires	40%

One of the most common non-compliance items for medical devices relates to the accompanying documents. All the medical Standards have very specific requirements for the accompanying documents or 'Information for Use' (IFU).

Since most companies have separate departments that create their IFU, they are often not aware of the requirements.

Another common (and most costly) non-compliance is the power supply selection. The best advice is to use a suitably approved power supply unit (PSU). By doing this, compliance with spacing, leakage current, and mains component requirements is assured. Also, the cost to evaluate the power supply and the required quarterly inspections at the power supply manufacturer is avoided. Some designers begin with a non-approved power supply, only to change to an approved one when they discover the associated costs of using a non-recognised supply, or when they realise that it does not comply with the requirements.

When designing medical equipment, it is also important to be aware that there are minimum spacing requirements for electrical barriers. Inadequate spacing on circuit boards is another typical mistake.

For equipment with plastic enclosures, there will also be flammability requirements for the plastic material. Make sure the plastic material is rated suitably for the task.

Finally, a typical mistake that manufacturers make relates to indicator lights, e.g. yellow must only be used for caution and red for emergency.

Over the years it has become apparent that many of these failures could have been easily prevented if products were submitted for review or assessment much earlier in their development and design cycle.

Increased competitive advantage through Preliminary Design Reviews

To help manufacturers significantly reduce their chances of product test failure and meet their market delivery timelines, they can now work with their test and certification partner earlier in the design cycle to conduct a 'Preliminary Design Review' (PDR).

This is where an engineer examines a product sample, the schematics, and instructions for use, design drawings and a list of critical components in order to determine whether the sample complies with the requirements of the applicable standards.

These reviews can be either conducted at a client's facility or at the test partner's laboratory. A PDR is a desk review of the product with no actual testing - so it can be easily done in a day. Preliminary Design Review includes:

- Construction review

- Insulation diagram generated
- Critical component list started
- Test plan generated (preliminary)
- Major non-compliances identified
- Manual(s) and labels reviewed
- Risk Management documentation review

Once the review is complete, the manufacturer receives either meeting notes outlining general engineering observations or a summary report detailing current non-conformities against the Standard. This means manufacturers can resolve them during the design phase rather than just before product launch.

How early in the design cycle can you have a PDR?

The submission of product should ideally happen at the early stage of the design phase. Early prototypes are often evaluated, but even computer generated 3D models can be assessed as long as they come with appropriate documentation.

Given the current failure rates of medical devices undergoing compliance testing the only way to reverse the current trend is to give priority to the regulatory requirements during the design phase – rather than after design has been finalised.

Final result: improved product lifecycle management and timely product launch

Safety V Compliance

Compliance

In the EU, medical devices must comply with the appropriate Standards that govern them in order to carry CE Marking. Compliance covers everything from electrical safety, electromagnetic compatibility to the correct labelling and documentation to accompany the product.

Safety

Although safety is widely referred to in discussing medical electrical equipments, it is important to keep in mind that absolute safety would be the complete absence of risk. In practice, zero risk is unattainable – even with a complaint product. Rather, each risk level shall be made sufficiently low to be acceptable.

Almost any medical equipment design could be modified to make it safer by applying additional control measures or test/procedures. However, such improvements are likely to involve additional cost or loss of utility. Therefore,

deciding whether a risk is acceptable in the Preliminary Design Review stage is vital to the design process.

Conclusion

By performing Preliminary Design Review the time to obtain compliant test reports and certifications can be considerably reduced. Non-conformities can be 'designed out' early in the design phase and time to market can be improved to give a manufacturer more selling time – which ultimately contributes to his return on investment and bottom line.

How can Intertek help?

Intertek is committed to helping our customers with their time to market by assisting them to develop product design that complies with the regulations and is most appropriate for their own design and development processes, via our Preliminary Design Review service.

Flexible logistic arrangements

Design reviews can be arranged at short notice by our dedicated sales team. The preliminary design review can take place either at your location or ours - as you require. An on site assessment may be beneficial though as your designers, quality and regulatory teams would be on hand to provide discussion and prompt answers to questions from our engineer.

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For more information on specific testing and certification information, please contact Intertek at 1-800-WORLDLAB, email icenter@intertek.com, or visit our website at www.intertek.com.