Compliance Testing is NOT Reliability Testing

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SUMMARY

The medical industry is one of the fastest growing segments of US economy. Health care spending is increasing all over the world due to increased life expectancy and consequently the increased aging population. To maximize profits and increase market share in this ever expanding market, medical device manufacturers want to be first to introduce innovative products. However, device manufacturers need to get approval from the Food and Drug Administration (FDA) before they can sell a medical product in the USA.

FDA is the U.S. Government agency that oversees and approves the introduction of most medical products into the market. Prior to getting approval from the FDA to market a device in the USA, a PMA (premarket approval application) or a 510(k) (pre-market submission) has to be made to the FDA. These submissions include a substantial amount of documentation, analysis and results of tests outlined in the FDA recognized consensus standards, which takes a fairly long time to perform and report on. Due to budget and schedule constraints, and the desire to be first to market, medical device companies tend to focus on performing only the FDA required compliance tests and then tend to incorrectly draw conclusions about the reliability of their product from the results of these compliance tests.

Erroneously drawing reliability conclusions from compliance test results can negatively impact a medical device manufacturer's warranty program, part replacement stocking program at repair/service centers, and staffing levels at customer support centers. In the worst case scenario it can lead to product field recall and product liability lawsuits, especially in the US. This can have an adverse impact on company reputation, sales and profits.

This paper describes the FDA approval process, the difference between compliance and reliability testing, the pitfalls of incorrectly drawing reliability conclusions from compliance test results and developing use-misuse model to drive reliability testing. It also provides real life examples that practicing reliability engineers can use to make a strong case for reliability testing in addition to compliance testing, in spite of budget and time constraints.

1 INTRODUCTION

The medical industry is one of the fastest growing segments of US economy.

In 2008, health care spending in the United States reached $2.4 trillion, and is projected to reach $3.1 trillion in 2012 and $4.3 trillion by 2016 [1]. In 2008, the United States spent 17 percent of its gross domestic product (GDP) on health care. It is projected to reach 20 percent by 2017 [1].

The US medical device market is the world's largest, at an estimated US$91.3 billion in 2009, accounting for 41% of the global total. [2].

However, United States is not the only country in the world spending large sums of money on health care. Countries all over the world are spending more and more on health care every year. According to the Organization for Economic Cooperation and Development, health care spending accounted for 10.9 percent of the GDP in Switzerland, 10.7 percent in Germany, 9.7 percent in Canada and 9.5 percent in France [3]. Health care spending is increasing all over the world due to increased life expectancy and consequently the increased aging population.

The data mentioned above points to an explosive and sustained growth in the medical device and medical services market in the world in the next few decades. Medical device manufacturers are trying to increase their market share in this expanding market by bringing innovative products, as quickly as possible into the market place at the expense of reliability testing. Due to cost and schedule constraints, manufacturers avoid long term reliability testing with large sample sizes. Instead, they try to estimate the reliability of their product by using the results of the short term FDA compliance tests that use small sample sizes.

2 FDA APPROVAL PROCESS

As the use of medical devices increases, governments around the world are regulating their design, manufacture, quality, reliability, proper use and disposal. The Food and Drug Administration (FDA) is the U.S. Government agency that oversees most medical products, foods and cosmetics. Within FDA, the Center for Devices and Radiological Health (CDRH) oversees the safety and effectiveness of medical devices and radiation-emitting products.

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. Hence device manufacturers need to get approval from FDA before they can sell a medical product in the USA.

Nowadays, similar types of regulations concerning medical devices are being followed in other countries as well. For example, the Medical Device Directive (MDD) of the

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European Union (EU) outlines the requirements for medical devices in the EU countries.

To get approval to market a device in the USA, a PMA (premarket approval application) or a 510(k) (premarket submission), has to be made to the FDA by the manufacturer.

510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). 510(k) submission to FDA is required at least 90 days before marketing unless the device is exempt from 510(k) requirements.

Premarket Approval (PMA) is the most stringent type of device marketing application required by FDA. Unlike a 510(k), PMA approval is to be based on a determination by FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses. Typically a PMA takes at least 180 days to get FDA approval

The PMA application and the 510(k) submission includes results of tests outlined in the FDA recognized consensus standards which supports a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices. The number of standards that apply and the tests that need to be performed are dependent on the regulatory class of the device, as described in section 2.1 below.

2.1 Medical Device Classification

The FDA has established three regulatory classes for medical equipment based on the level of control necessary to assure the safety and effectiveness of the device. The class to which a device is assigned determines, among other things, the type of premarketing submission / application required for FDA clearance to market.

Device classification is based on the risk the device poses to the patient and/or the user. All classes of devices are subject to General Controls which are the baseline requirements of the Food, Drug and Cosmetic (FD&C) Act.

The three classes and the requirements which apply to them are

- Class I - General Controls

Class I devices are subject to the least regulatory control. They present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Class I devices are subject to "General Controls" as are Class II and Class III devices. Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.

- Class II - General Controls and Special Controls

Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls. Special controls may include special labeling requirements, mandatory performance standards and postmarket surveillance. Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.

- Class III - General Controls and Premarket Approval

Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Class III is the most stringent regulatory category for devices. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls. Premarket Approval by FDA, is required for this class of devices. Examples of Class III devices include replacement heart valves, implanted cerebella stimulators etc.

Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval (PMA).

2.2 Required documentation for PMA or 510(k) submission

This section provides guidance, on the documentation and information that should be provided in a 510(k) submission for a ventilator (Class II device). This information can be applied to other devices too.

Recommended documentation includes an executive summary of description of the device and its indications; the intended uses of the device, including patient population, clinical indications, and environments of use; a complete description of the basic principle of operation, the control and phase variables, modes and output waveforms, and device specifications (including engineering drawings of the pneumatic and electrical subsystems of the device); a comparative analysis (tabular comparison and discussion) of how the intended use, performance characteristics, and specifications of the new device are similar to other legally marketed predicate ventilators; a critical element fault-tree analysis (or FMECA) documenting all potential failure modes of the device and the potential outcome (hardware/software); a description of the test protocols and procedures, data, and analysis of results associated with all testing (including tests from FDA recognized consensus standards) related to device performance and functional testing, reliability testing; EMC/electrical testing, and environmental testing (Mechanical, temperature, humidity, and fluid ingress); clinical data if required, software documentation and system testing results, biocompatibility information if the device includes any component that is intended to contact the patient, information regarding disassembly, cleaning, and sterilizing components of the ventilator and patient circuit which prevent cross-contamination between patients; labeling (promotional literature, operator's manual, and maintenance manual); a 510(k) statement or summary; and a truth and accuracy statement.

As seen from the list above, FDA submissions include a substantial amount of documentation, analysis and results of compliance tests that take a fairly long time to perform and report on. This leads to medical device companies focusing on FDA compliance testing and ignoring reliability testing.

2.3 FDA Consensus standards

The PMA and 510(k) submission requires results of tests outlined in the FDA recognized consensus standards, as mentioned in section 2.2 above. The FDA believes that conformance with these recognized consensus standards can support a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices.

These standards can be used as a reference guide in non-medical industries too, because they describe good design and test practices that help assure a minimum level of safety in any type of device (including non-medical devices). Examples of such standards are given below.

IEC Standards:

- IEC 60601-1:1988 + A1:1991 + A2:1995--Medical electrical equipment - Part 1: General requirements for safety
- IEC 60601-1-2:2001 + A1:2004--Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-4:1996 + A1:1999--Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
- IEC 60601-1-6:2004--Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
- IEC 60601-1-8:2003--Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60529 Degrees of Protection – Enclosures
- IEC 60068-2-27 Environmental Test Procedures - Shock
- IEC 60068-2-6 Environmental Test Procedures - Sinusoidal Vibration
- IEC 60068-2-34 Environmental Testing Procedures - Random Vibration
- IEC 60068-2-32 Environmental testing procedures – Free Fall

ISO Standards:

- ISO 13485 - Medical Devices - Quality management systems – Requirements for regulatory purposes
- ISO 14971 – Medical Devices – Application of risk management to medical devices

UL Standard:

UL 1977 – Component Connectors for use in data, signal, control and power applications

3 DIFFERENCE BETWEEN COMPLIANCE STANDARDS TESTING AND RELIABILITY TESTING

Typically compliance testing, outlined in the standards mentioned in section 2.3 above, is performed on extremely small sample sizes, sometimes even just one sample; while reliability testing is performed on larger sample sizes.

In compliance testing, test time is generally short and number of test cycles is low; which is just the opposite of reliability test requirements.

In some cases, the pass criteria for the compliance test may be that a product does not pose a safety hazard when it fails or becomes non-functional. So, even if the product becomes non-functional after the test, it is considered to have passed the test because it failed in a safe manner. However, this is not the case in reliability testing. If a product becomes non-functional, leading to a return for repair or replacement, it is considered as a failure in the test. You want to ensure, through reliability testing, that the product performs its intended function over its intended life period.

Compliance testing does not consider intended use or unintended misuse of the device while reliability testing should consider use/misuse scenarios.

In conclusion, the goal of compliance testing is to ensure a minimum level of safety; while the goal of reliability testing is to derive quantitative estimate of product return, warranty cost and overall reliability of the product over its intended life period.

3.1 Examples to highlight difference between compliance testing and reliability testing

- ESD tests – IEC61000-4-2 compliance standard mandates that while performing ESD testing on electrical medical equipment (e.g. CPAP devices) 6kV test voltage be used during contact discharge test and 8kV be used during air discharge test. However, 12 to 18kV are generated on a dry day, in a home environment, while walking on carpet. So, one could see an unexpectedly high failure rate in the field, if a product is designed and tested only to the compliance testing level. Reliability testing should test to real life requirements.
- Free fall tests – Free fall drop testing is not a specified FDA requirement. The reviewers' guidance document which is considered the "FDA Bible" lists only shock and vibe tests as the required mechanical tests. IEC-60601-1 safety standard recommends hand-held devices be dropped from 1 meter height but its pass criteria is that it does not pose a safety hazard and not that it remain functional. A good reliability test plan should require drop tests to be performed and the device remain functional after drop, to minimize product returns.
- Shock & Vibe test – IEC600068-2-27 standard requires medical devices to withstand 100g shock pulse. But research in the transportation industry has shown that product can experience 120g shock impact, when in transit, during transportation. Reliability testing should test up to 120g level to account for the higher real world stress level.
- IPX1 water test – IEC 60529 compliance standard requires any medical device that uses water, to be able to withstand 1mm/minute water for 10 minutes, rotating at 1 rpm/minute on a test turntable, in an upright position while turned off (or non-functioning). This is equivalent to an extremely light rain drizzle. However, if the product is a portable medical device, it will need to withstand a lot

more water if it is caught in a heavy rain shower while being carried from a building to a car. Reliability test should account for this heavier, longer, downpour and should ensure that the unit is on during the test and remains functional after the test.

To summarize, FDA required compliance testing should be the minimum level of testing that should be performed, to ensure a safe product. Reliability testing should set the bar higher and perform more stringent testing to account for real world stresses.

4 PITFALLS OF DRAWING RELIABILITY CONCLUSIONS FROM RESULTS OF COMPLIANCE TESTING

Due to budget and schedule constraints, and the desire to be first to market (to maximize their market share); medical device companies tend to focus on performing only the FDA required compliance tests and then tend to incorrectly draw conclusions about the reliability of their product from the results of these compliance tests.

For example, a heart monitoring device manufacturer may decide to perform only compliance safety testing and not reliability testing on their product. The FDA requires documentation that there is no harm to the patient, in case the product fails. One of the ways this can be proved is by ensuring that the alarm system, that alerts a caregiver of a potentially hazardous situation, is single fault tolerant and that it alarms appropriately in case of a fault condition. The compliance test requires fault insertion testing be performed on 3 samples, for 72 hours, at 20C and 60%RH. The device may pass the FDA mandated safety test from a consensus standard but the product may end up having an extremely high failure rate within 6 months of being in the field because of the high failure rate of a critical component in the alarm system at 40C and 85%RH, due to oxidation. The component experiences 40C, 85%RH inside the product enclosure, when it is in operation, in humid coastal areas. Depending on the severity of the effect and the occurrence level of this failure mode, the manufacturer may have to recall this potentially unsafe and unreliable product from the market. A separate reliability test, with a larger sample size, at different stress levels, for a longer period of time, should be performed to accurately estimate the robustness and reliability of the alarm system over its intended life of 5 years.

To develop an effective service program, one needs to know the failure rate, the failure trend and the failure mechanism of the components in the product. This failure data can be obtained only through reliability testing and not through compliance testing. Incorrect extrapolation of compliance test data over the life of the product can lead to some very expensive replacements within the warranty period.

If the manufacturer guarantees a repair or replacement of a failed medical product within 72 hours, having insufficient spare parts at the service centers due to underestimation of failure rates, can have a negative impact on customer satisfaction. The manufacturer may also incur additional expenses of managing a “loaner replacement” program where they may have to loan a replacement medical device to a customer, for the additional days that they keep the product in their service center, waiting for spare parts to arrive.

Based on the expected failure rate of the product, the manufacturer will need to estimate the right staffing level at their customer support centers to handle calls on product issues/failures and requests for RMA (return merchandise authorization) number that a user needs to return a failed product. Understaffing at these centers can lead to customer dissatisfaction and consequently customer loyalty while overstaffing can unnecessarily increase operating costs leading to reduction in overall profit.

In summary, erroneously drawing reliability conclusions from compliance testing could negatively impact a medical device manufacturer’s warranty program, part replacement stocking program at repair/service centers, and staffing levels at customer support centers. In the worst case scenario it could lead to product recall and product liability lawsuits which result in an adverse impact on company reputation, sales and profits. Hence, having a good reliability program and test plan is crucial.

5 USE-MISUSE MODEL

A good reliability test plan should consider all the possible stresses a device will experience in the field, which could result in failures, throughout its life. The use-misuse model captures how, when, where, and by whom the product may be used or misused over the life of the product. In other words, it considers the environment of use (temperature, altitude, humidity, cleanliness, home/hospital, height from floor, portable/stationary, country of use etc), the user demographics (seniors/adults/pediatric users, non-responsive or responsive patients etc) and the frequency of use (continuous 24X7 operation or 8 hours a day operation, number of cycles on a part that moves etc).

Examples of developing a use-misuse model and using it to drive reliability testing are given below.

- Example 1: While developing the use/misuse model for a CPAP device with attached humidifier, used to treat OSA (obstructive sleep apnea), consider the following factors: Placement Scenarios (above or below the bed, in a drawer, on plush carpet or tile etc), handling scenarios (picking up unit with tubing or power cord, dropping the unit, overfilling the humidifier etc), traveling scenarios (bumping travel bag, spilling water in travel bag, using in campers, boats etc.), usage scenarios (open/close the humidifier lid and push the on/off power button 2 times per day, turn the humidifier setting knob 180 degrees once a day, use the device 8hrs/night, etc) and environmental conditions (0 to 40C, 95%RH, dusty environment etc). After developing the model, use it to drive reliability testing. For example, as per the model, if the humidifier lid will be opened and closed twice a day, to fill water in the water chamber; over 5 years which is the life of the product, the humidifier hinge and latch will have to withstand at least 3650 open-close cycles. Deterioration in the sealing capability of the humidifier lid due to wear-out of the hinge or latch could result in a leak which impacts

output pressure and therapy resulting in a return of the product. Hence, the reliability test plan should consider the 3650 cycle requirement (from the use/misuse model), while calculating test time and number of test samples.

- Example 2: Consider a portable ventilator that will be used in a hospital or ambulance in South Africa as well as in the US. The use-misuse model should capture the fact that the ventilator will be operating in a hot, humid, dusty environment, with a 220V power source, in South Africa. The ventilator should be able to withstand the high vibration/shock level when the ambulance is traveling on pothole filled roads and should be able to withstand a freefall to an uncarpeted concrete floor. This data from the use-misuse model should then drive design and reliability testing. FDA recognized consensus standard compliance tests might involve testing only for US conditions of a clean, hospital, controlled temperature and humidity environment, with a 110V power source; but a device manufacturer should test under all other conditions too, to accurately assess overall reliability of the product.

Developing and implementing a reliability test plan that considers all use-misuse scenarios takes time and effort. The next section provides tips on reducing overall test time.

6 TIPS TO REDUCE OVERALL TEST TIME

To reduce overall project cost and time, the compliance department and reliability department should work together to find common ground between compliance testing and reliability testing. Try to leverage reliability testing off of compliance testing. Reliability testing will always take longer and require more samples than compliance testing. Reuse compliance test devices for reliability testing. Use the compliance test condition as one of the stress levels in an accelerated reliability test. For e.g. if IEC-60068-2-32 free fall test mandates dropping 2 devices, once on each face, from a 1m drop, on a concrete floor and the use-misuse model and reliability plan recommends dropping 10 devices, 3 times on each face; reuse the 3 devices from regulatory testing and drop them an additional 2 times per face as part of the reliability testing. This way you will need only 7 additional devices for reliability testing and will need only 2 additional drops per face on the 3 compliance devices. This will lead to time and cost saving for the project. The less impact you have on project schedule and cost, the more likely you are to get support for a reliability test program.

7 CONCLUSION

In conclusion, ensure that reliability testing is performed in addition to FDA required compliance testing. Find synergy between compliance testing and reliability testing and encourage the compliance department and reliability department to work together to reduce overall project cost and time by sharing resources.

Develop a use-misuse model and let it drive reliability testing. And most important of all, do not erroneously draw reliability conclusions from compliance test results.

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