Perspectives on the FDA Review Process

MDT

Should the FDA review process be more relaxed in favor of faster review times at the expense of potentially greater impact to the well-being of patients when a device does fail?

Dan Walsh

Member of Management, Life Sciences & Healthcare Practice, PA Consulting Group

The short answer is, “Of course not!” Relaxing the review process is not the answer. However, there are tools and techniques already in the device developer’s arsenal of which the FDA should be requiring more rigorous use. Patient risks are the first and last things that device developers should be assessing in Hazard Analysis. If this effort is honest and rigorous, the hazards can be mitigated or dealt with in the development effort.

Hazard Analysis and it’s related technique, Failure Modes and Effects Analysis (FMEA), are living processes that should commence at the requirements definition or feasibility stages, and be upgraded regularly throughout the development cycle. The FMEA(s) should incorporate the design (dFMEA), the instructions for use (uFMEA), and manufacturing process (pFMEA). These allow the development team to assess the impact of failures of design, use, or manufacturer with regard to patient safety and other hazards (like the user, operator, calibrator, or assembler).

The FDA can and should adapt a more sophisticated approach to evaluating the QSR artifacts that developers submit in either 510(k) or IDE/PMA submissions. If the Hazards Analysis is “light,” then a reviewer should become even more vigilant.

We suggest that applying the rigor that these well-established engineering disciplines invoke should enable faster review of “good” submissions (meaning those that follow the discipline rigorously and respond to the findings throughout the lifecycle), and more robust identification of “bad” ones (where the real hazards are not recognized or underrated) before being presented with incidents, complaints, and MAEs. And this, after all, is consistent with the FDA mandate.

Kevin M. Quinley CPCU

Vice President Risk Services, Berkley Life Sciences LLC

If the price of faster FDA review is a higher incidence of adverse patient events, this may represent a fool’s bargain of a trade-off for medical device firms. While faster FDA review may mean enhanced speed to market and expanded sales opportunities, it may also invite added product liability claims and lawsuits, offsetting any purported marketing benefit. Further, when some medical device firms defend product defect claims by pointing to the rigor of the FDA approval process, diluting such rigor may likewise weaken their legal defense. Perhaps another way to frame the choice is faster FDA review through added resources (i.e., additional staff and technical expertise on the part of reviewers). This adds qualitatively to the review process in ways that may enhance deliberative decision-making and, in some cases, may accelerate device approvals. Enhanced resources at the FDA review stage, not a “more relaxed” or superficial FDA review process, may be a saner means to the same goal.

Alan Cohen

Medical Practice Team Lead and Director, Systems Engineering, Logic PD

The FDA should not loosen up the approval process. My experience has been that the FDA approval process can be both timely and thorough; the key is to make the FDA's job easy.

The crux of the FDA submission is demonstrating safety and efficacy. Efficacy is a matter of demonstrating that marketing claims can be backed up with data. As early in the process as possible (often one or more years before submission), it's critical to understand the claims that need to be made to achieve commercial success, along with the data that is needed to support those claims. If the claims and the data don't line up when the submission is made, the FDA's response is likely to be disappointing.

Safety is usually (but not always) a matter of following consensus standards from IEC, ISO, AAMI, and other similar bodies. Again, early planning is critical for understanding the standards to be met; redesigning a device because of a forgotten standard or clause is painful and time-consuming.

Finally, it's important that submissions be organized and clear. If it's easy for a reviewer to understand how a device is safe and effective, it's easy for them to grant approval.

Newton Defaria

Business Development Manager for Life and Analytical Sciences, National Instruments

One lost life is already too many but does the FDA need faster and more effective review times? Absolutely. Should this come at the price of overlooking safety? No. The industry and FDA need to promote a mutual reform.

The industry, with few exceptions, must stop using regulatory loop holes and the adoption of outdated processes and technology. It should start following guidelines and applying standards for quality and safety rather than for the sake of compliance. Overall, it needs to more actively promote, develop, and adopt technology processes as enablers of better design, development, deployment, and test of medical devices.

In the same vein, the FDA needs to modernize itself by providing a bit more teeth to its “guidelines” and making them more current and dynamic. It should participate, mediate, and expedite the development and adoption of standards. Additionally, it would be beneficial to create and maintain a more automatic process for documentation and data exchange combined with a more intelligent process to better define what to ask or look for in each review.

Bottom line, industry and the FDA shouldn’t compromise safety but rather optimize the review procedure to help create and deploy the best medical devices possible.

Jacques Hoffmann

President, InterTech Development Company

There is far less substance to questions of trading off speedier FDA approvals vs. speeding time-to-market for new medical devices. Presumably, we can all agree that compromising patient safety is simply unacceptable. The differences come to play when one gets into the details of quality assurance steps that are required to safeguard patient safety. That the FDA plays a role in ensuring the public interest along these lines is a side issue; patient safety is a non-negotiable in our litigious society, no matter what the FDA does or does not do.

Gabriel O. Adusei, MSc, PhD

Founder, International Association of Medical Technology Consultants

The emerging medical technologies require extensive review during the approval process by the FDA and Regulatory Authorities. The relatively new technologies in

the areas of drug-device combination that incorporate nano-pharmaceutucals and devices containing animal material are stringently regulated, with the former having the potential to release nanoparticles that can get into various types of cells and accumulate there or travel along blood and lymphatic vessels to cause oxidative stress and inflammation whilst the regulatory emphasis on the latter is in particular regard to the minimization of risks relating to transmitting Transmissible Spongiform Encephalopathies.

The rapid developments in the areas of drug-device combination products, including antimicrobial catheters, biologic wound care products, bone graft substitutes and bone cements, drug-eluting stents, and photodynamic therapy in the past showed that the regulatory authorities had to catch-up in some areas with new or revised compliance requirements.

With reference to the TGN1412 incident in the UK 2006, there is still the need for the regulatory authorities to employ inherently stringent but simplified regulatory review procedures to facilitate optimized processes in bringing better and safer medical technologies to the markets. The cost of device failure is minimised and safer at an early stage its development prior to regulatory approval than post-regulatory-approval at the point of clinical or patient use. A word to the regulatory authorities is enough.