

To Release, or Not to Release: An Engineer's Perspective

Background

X Medical (XMed) is an established premier medical device company, launching a new device. The device is non-invasive and not life supporting, and is therefore considered low-risk. Regulatory submission is not required but the device does fall within FDA Design Controls. The XMed team working on the project consists of a Project Manager, a Lead Product Development Engineer, a Quality Engineer, a Regulatory Affairs associate, and a Marketing Product Manager. The device is simple from a technology standpoint, and it is outsourced to a third-party original equipment manufacturer (OEM): CNA, Inc. While CNA's expertise lies in manufacturing for other medical device companies, they are trying to do more value-added work by moving into the original design manufacturing (ODM) of products as well.

Due to its simplicity, the project was envisioned to take only six months of development time. CNA does the majority of the design and development work, as well as the manufacturing. A plan had been put into place to manage the integration of the two quality systems:

- During development, CNA uses their quality and design control system.
- Post-commercialization, CNA would manufacture the product to XMed's specs, but XMed would own all of the support activities (sales, complaint handling, risk management, etc)
- A Joint Quality Plan is drafted to specify each company's responsibilities. The Joint Quality Plan specifies that each of CNA's design reviews must be approved by at the Project Manager, the Lead Product Development Engineer, and the Quality Engineer.

The project has already been delayed once to resolve a technical issue. The project is now six months behind schedule and the project team (and especially the team leader) are getting pressure from senior management to release the product. The Lead Product Development Engineer is uncomfortable with CNA's design control methodology, which appears to be lacking in detail and thoroughness. This Lead Product Development Engineer has requested changes to the documentation at each of the design reviews (phase 0, 1, 2) (each design phase review has to be approved by XMed's Project Manager, Lead Product Development Engineer, and Quality Engineer).

Situation

One day, Project Manager (Keith) sends an email to the whole company to celebrate the successful launch of the product. The Lead Product Development Engineer (Ian) is surprised, as he has not signed the final phase review. Looking over the documentation at XMed, Ian is unable to find documentation that states the final review was approved by any XMed representatives. When Ian asks Keith about the final design phase documentation, Keith says that it was sent back to CNA after being Keith's review. He argues that it isn't really required since CNA's design controls don't state that XMed approval is required (which is the case) and asks Ian to ignore it and sign the Product Release Authorization (PRA – the final approval that authorizes product to be available for commercial distribution), so the team can meet their final milestone. Even though CNA's design control procedures do not require outside approval, the joint Quality Plan is clear that each design review requires approval by XMed representatives.

Ian contacts the CNA liaison, who says that she defers to the client (XMed) on what is required for PRA. Ian reviews the final phase review materials, and notes that although the testing done was completed successfully, and there are no glaring omissions, he has some questions around the documentation of engineering rationales (testing not completed). The issue does not seem to be serious, but Ian believes that it may take more time and energy to resolve to make sure it is documented adequately.

Ian first consults the Quality Engineer (Ron) for his viewpoint. Ron admits that he is overworked (he is resourced on two other, higher priority projects), and will not be able to get to reviewing the paperwork for another week. Ian then checks with the Regulatory Affairs Associate (Mike), who is responsible for filing the actual PRA documentation. Mike is uncertain about the correct course of action, but he sees your viewpoint and would be willing to hold off on the PRA. Finally, Ian speaks with the Marketing Product Manager (Yvonne), who thinks the product was ready for sale three months ago when testing was completed, and is not sure why there should be any more delay.

Ian meets with Keith again to mention his concerns but Keith notes that the PRA can still be signed that day and that any remaining "small" issues will be resolved at a later date. Ian believes that the safety risk is pretty low, especially considering the class of device—however, the rationales to avoid certain tests were not documented carefully, and something that was overlooked might come up.

Questions

1. What are the potential consequences of the product's malfunction: on patients; on XMed's reputation; on your responsibility for the product?

2. What are the potential consequences of your actions on your role/reputation/position in XMed?
3. What would you do? What are your options?
4. How do you assess the issues you were concerned with at CNA?
5. Should you escalate your concerns to Keith's boss?
6. Whom can you turn to for advice?