Papers

Can compliance help marketing and business development?

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Abstract

In many FDA-regulated companies, the marketing and business development departments have a quietly antagonistic relationship with their quality and regulatory affairs colleagues. While compliance is supposed to ensure that a safe, efficacious and high-quality new product reaches the marketplace, marketing and business development executives are left to grumble: how are consumers – much less partners and investors – supposed to learn about and get excited about a new product if their work is so constricted? This paper suggests that there is a way to turn compliance from the millstone around Marketing's neck to the whetstone that helps hone a sharper competitive edge. HydroGel Burn Products tackled that question by shifting quality and regulatory affairs further upstream in their product development process to a point where to be overly restrictive was to stop development altogether; in other words, to a point where the focus had to be on finding a way around obstacles. The results pleased investors, partners, customers and marketers alike.

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INTRODUCTION

In many FDA-regulated companies, marketing and business development executives have a quietly antagonistic relationship with their quality and regulatory affairs colleagues. All too often a company's compliance professionals short-change marketing and business development by disallowing multiple ideas, this or that claim, this phrase, that word and those implications.

While compliance is supposed to ensure that a safe, efficacious and high-quality new product reaches the marketplace, marketing and business development executives are left to grumble: how are consumers – much less partners and investors – supposed to learn about and get excited about a new product if their work is so constricted? Is there a way to turn compliance from the millstone around marketing's neck to the whetstone that helps hone a sharper competitive edge?

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HydroGel Burn Products[1] tackled that question by shifting quality and regulatory affairs further upstream in their product development process to a point where to be overly restrictive was to stop development altogether; in other words, to a point where the focus had to be on finding a way around obstacles. The results pleased investors, partners, customers and marketers alike.

Why involve quality and regulatory affairs?

Several years ago, the US Food and Drug Administration (FDA) published its *Good Manufacturing Practices for the 21st Century* and the International Conference on Harmonisation (ICH) published its Q8 guidance, *Pharmaceutical Development*. Both of these initiatives, while overtly aimed at pharmaceutical companies, have been understood as applying to both biotechnology and medical device firms, as the FDA moves towards a consolidated, risk-based approach to regulatory enforcement. Both ICH and FDA officials have argued that by building quality, safety and efficacy into product design from the beginning (eg 'Quality by Design'), companies will achieve faster time to market and more regulatory flexibility, including in marketing and post-market compliance.[2]

Even after publication of the FDA and ICH guidance documents, involvement of quality and regulatory affairs in product development have, so far, largely been more of an afterthought, tacked onto the current development process in roles limited to quality control, validation and rule enforcement. These roles are not the collaborative incorporation of quality and compliance into product design that FDA and ICH officials had envisioned.

Executives at HydroGel Burn Products, however, took the FDA and ICH guidance to heart, and shifted quality and regulatory affairs further into the design process to work alongside the scientists and engineers. The result was a series of collaborations that gave marketing and business development a significant head start in developing programmes attracting investors and likely customers, all before the manufacturing facility was even built.

What it looked like

As the CEO of HydroGel put it earlier this year, 'After a few months, it became clear that quality and regulatory affairs folks who knew only quality and regulatory affairs had too difficult a time adjusting to the more proactive, solutions-focused outlook we needed.' After trying several different FDA compliance consulting companies, all of whom took traditional risk-averse approaches, HydroGel's executive team approached my firm.

Together, we designed and put in place two tactics that netted positive results: the creation of a product concept document and the incorporation of marketing and business development discussions into quality systems and product design reviews (see Figure 1).

Product concept document

The product concept document stems from my years spent supporting a research and development organisation that licensed, rather than commercialised, its new intellectual property. At its essence, the document summarises the new product in straightforward language: it's designed to be read and understood by general investors, scientists and auditors alike.

Typically, the product concept document has three major sections – an executive summary, specific high-level synopses and then a longer supporting detail summary that may reference external documents. Depending on the nature of the product, the synopses might cover the new product's intended market, development history, desired features, benefits and even reimbursement strategy.[3]

Quality systems and product design reviews

In new product development, design reviews – sometimes termed 'stage gates' – occur on a regular basis to ensure that the product's development programme is on track, the

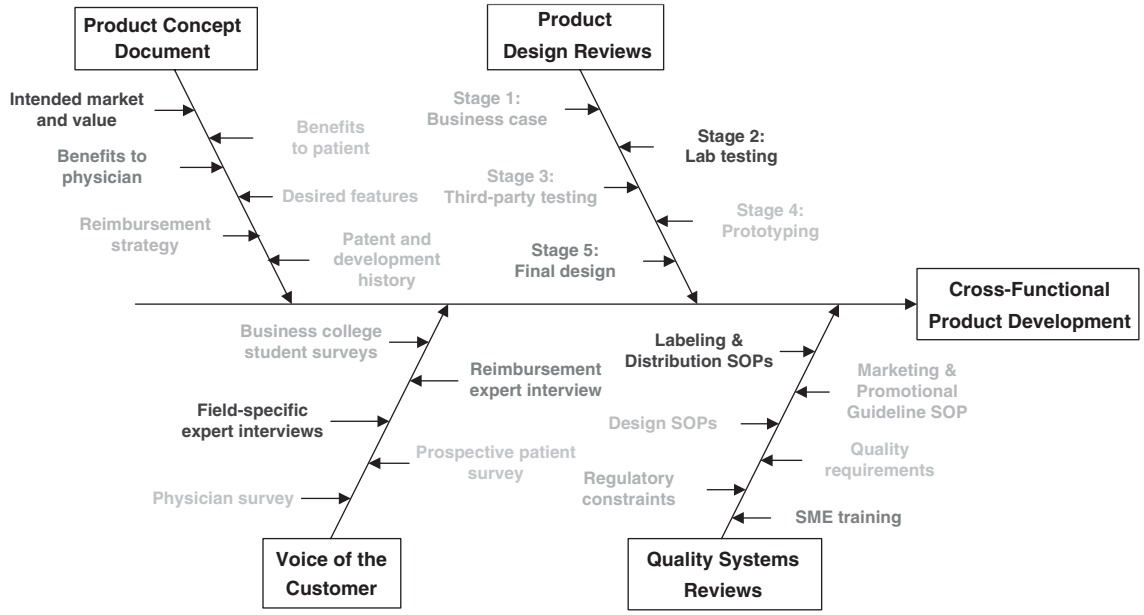

Figure 1: Adding marketing and compliance to product development

product's business justification continues to be sound and everyone involved is focused. HydroGel implemented a similar design review process for the development and implementation of its quality system. Because HydroGel was not a big company at that time, rather than have multiple meetings with many of the same people, the quality system design review was structured to be a blend of product design review, quality system review and manufacturing start-up review. Marketing and business development were also brought in at first just to learn about the new product and its startup dates, but later to collect feedback from prospective customers.

With the product concept document in hand, marketing got to work on outreach programmes to healthcare providers to capture the 'Voice of the Customer' and build this feedback into product design and manufacturing distribution discussions. Because marketing participated in the product development and labelling discussions, they were also present for discussions on quality systems implementation and training on FDA expectations. By then, marketing executives knew the boundaries within which to craft their product demonstrations, surveys and so forth. This knowledge also laid the groundwork for the advertising to be launched after final FDA product approval. And because quality and regulatory affairs were attuned to product development and quality systems implementation, they had a solutions-focused, 'how to make it work' mindset that meshed with, rather than against, marketing.

The bottom line

Eight different presentations around the country had been scheduled with multiple venture capitalists. And yet, after one meeting, HydroGel Burn Products had to cancel all the other presentations – they were in danger of overfunding. One hundred per cent of the venture capitalists at the first meeting put up all the necessary funding.

Among the many positive aspects of the meeting, the executive team pointed out three things that visibly perked up the ears of investors:

- The product concept document provided to all attendees provoked a lot of excited discussion about future products (and as any good salesman knows, once you get a

prospect discussing future activities that might result from a purchase, the deal is done);
- With quality assurance and regulatory affairs programmes already underway, including involvement in design reviews, many of the prospective investors concluded that any safety and regulatory risks associated with the current product were well under control; and
- Marketing's 'Voice of the Customer' presentation, with its insights into product design and distribution, not to mention quality, safety and efficacy, provided clear demonstration of the integrated, cross-collaborative nature of the company's personnel and their focus on launching a successful product. For the investors, this helped lower the business risk.

By involving compliance and marketing executives together in a nonconfrontational setting (product design, the implementation of quality systems and the construction of the production facility), the company was better able to capture and speak to the Voice of the Customer, resulting in a better product with a growing set of potential customers waiting in the wings, as it were, for word of final FDA approval so that product ordering could begin.

Final thoughts

Pushing quality and regulatory affairs further upstream shifts the focus away from black and white rules and regulations into the more amorphous grays of business development and marketing, making cross-functional conversations and collaborations easier.

If you want more effective product commercialisation, maybe it's time you asked your compliance and marketing executives to sit in on product development meetings together. You may find the executives who once argued over marketing and sales copy working together on faster product commercialisation.

Are you ready?

Notes

1. The name HydroGel Burn Products has been substituted to protect the confidentiality of the company discussed in this paper.
2. FDA recently announced a pilot programme to evaluate quality by design-based submissions for new biotechnology products (see FDA Docket No. FDA-2008-N-0355, July 2008).
3. A roughly analogous document can be found on the technology marketplace, yet2.com. This site has a technology licensing form called a 'TechPak' used by members to help make licensing decisions.