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MAKING YOUR VOICE HEARD IN REGULATORY AFFAIRS
With Hasnaa Fatehi

>> David Filmore

Hasnaa Fatehi, PhD, runs QARALOGIC, a consultancy that supports medical device company regulatory clearance strategies in Europe, Asia, North America, and other markets. Fatehi has previously served in regulatory positions at multiple device companies. She has a background in biomedical engineering, mathematical biology, and fine arts.

Regulatory professionals are sometimes sidelined within companies, and labeled as barriers to innovation and profit. In this edition of Consultants Corner, QARALOGIC's Hasnaa Fatehi discusses how regulatory affairs specialists can better frame their role in the context of a company's commercial priorities and be relied on as a partner in market success.

The Question: Why Aren't My Business Leaders Listening to Me?

Regulatory affairs is a crucial part of how the medtech ecosystem operates, but too often the role doesn't hold a badge of honor and respect within companies, Hasnaa Fatehi laments.

"There's this culture that if you sit with R&D, they hear regulatory and the understanding is you're not creative, you're just a paper pusher and you don't understand innovation, that you're stifling innovation," Fatehi said in an interview.

She spent the first part of her career as a regulatory affairs manager at both small and large medtech companies and currently owns her own medtech regulatory/quality consulting business. Fatehi makes clear that, in her experience, the largest global medtech firms, by and large, do give regulatory teams an influential seat at the decision-making table.

But when it comes to the smaller companies that make up most of the medtech sector, the record is more mixed. In companies' drive to innovate and sell more devices, regulatory affairs employees who present demands and concerns that regulators are likely to raise can feel silenced or even threatened, Fatehi says. In one case, she lost a job over regulatory disagreements with management and she knows other colleagues in the regulatory community who have had a similar experience.

"These are daily fights that regulatory people have," she explains. "You are basically sandwiched between the regulator and management, especially in the case of start-ups that [are] wanting to cut corners basically, and over-deliver to the investors."

In Fatehi's view, there are several reasons this dynamic develops. For one, the regulatory department is typically viewed as a cost center, rather than revenue-driver, within the business. Regulatory is also often perceived as risk-averse and as a naysayer. And finally, it shouldn't be ignored, she says, that regulatory affairs is a female majority profession. "I still think there is a massive gender bias in the way we decide who has the right to be at the table."

No matter the factors, however, people in regulatory also have a responsibility to assert their role within an organization and to explain the contribution they make to a company's bottom line, Fatehi asserts.

Nowadays, as a consultant, Fatehi often finds herself having to make the case to potential clients to increase investment in regulatory. And she sometimes serves as a support structure for in-house regulatory staff who are facing pushback from their management. "Without a regulatory approval, the marketeer can't market, the sales person can't sell, the business is not going to take place," she points out. Regulatory staff should "feel entitled, because you are in a regulated industry, to say what you think and also understand your part of the business and integrate that with your work."

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Regulatory = Market Access

For many executives, regulations are associated with cost, and the goal is often to minimize the cost by finding shortcuts around regulatory standards when possible. There are many instances of "people sort of over confidently, especially in the culture of start-ups, thinking that they can outsmart the regulator," Fatehi notes.

That can set up a dynamic where regulatory affairs, which can serve as the voice of the regulator within a company, is reflexively viewed as something to push back against or ignore. This can come up, for instance, when the regulatory team presses to hold off on a submission until certain data comes in or advocates for more study subjects to meet guidelines from a relevant authority, or any other position that is perceived as working against commercial goals.

Regulatory specialists in some cases are kept out of conversations, Fatehi says, "because people think that if you put a regulatory person in a meeting with finance for example, or with sales, they will stop you from selling."

A company's culture, of course, is important to driving how these situations play out, but regulatory affairs professionals nonetheless should proactively position themselves to make clear that they are working toward the same goals as everyone else in the business, the consultant argues.

"I think a lot of regulatory affairs people, when they go to management to discuss things, they mostly discuss boring stuff like Article Y, Regulation X," she explains. "What you need to tell them is more, 'If we get clearance in Market Z, then you can enter this market and this market, and this market is this big, etc." And, on the flipside, if management wants to pursue a strategy that doesn't align with regulatory recommendations, regulatory should make the case that the authority is likely to ask more questions, which could delay product launches and revenue.

As a consultant, Fatehi has gone as far as to put together a formula for calculating the ROI for regulatory consultant costs (*see Figure 1*). The framework might also have value for any regulatory affairs staffers trying to make the case for their role in the company.

Fatehi suggests the regulatory staff seek to engage leaders in discussion about business goals. "I typically ask questions like, 'How much money is this market worth for you?'"

Figure 1
Calculating the ROI for Regulatory Consultant Costs

$$\text{ROI} = \frac{\text{Total benefits} - \text{Regulatory Consultant fee}}{\text{Regulatory Consultant fee}} \times 100$$

Total benefit = Company and team time saved

+ Revenue generated
+ Business risk mitigated
+ Compliance penalties avoided
+ Operational efficiency
+ Brand equity and client trust gained

Source: Hasnaa Fatehi, QARALOGIC, QARALOGIC.com

From "No" to "Yes, If"

Paying close attention to the language one uses is an important strategy for changing perceptions. And one word that regulatory affairs experts should try to avoid as much as possible, Fatehi emphasizes, is "no."

Early in her regulatory affairs career, before she delved into medtech-specific work, Fatehi was employed at Proctor & Gamble, where she had an influential mentor. "He taught me that as a regulatory person,

you're always perceived as the showstopper," she explains. So he advised to "train yourself not to say the word 'no.'" Instead, you should favor "yes, if."

"When they say, 'I want to go to China in two months,' you can [say], 'Yes, you can go to China in two months, no problem, if we do this, this, this, this, this, and that.' And once you give them the 'if we do this, this, this, this, this, and that,' they're like, 'Oh, we can't do that.' And then it's not you saying 'no.' It's them realizing that it's not possible."

The more you can make yourself part of the market-focused conversation, the more your input will be sought out by different stakeholders within a company, Fatehi suggests.

At Proctor & Gamble, she recalls, they went as far as changing the name of the regulatory department to "Global Product Stewardship" to move away from the perception that the unit was focused on creating barriers. While such a name change might not be likely to happen at most companies, it underscores what Fatehi sees as a productive shift in thinking for regulatory "to walk away from the police mentality."

Closing Message: Communication and Cross-Training

Senior regulatory executives, particularly those who have climbed the organizational ladder at multinational device firms, generally understand the value of engaging leaders on business goals and alignment with regulatory priorities. But this type of effort is not necessarily ingrained in the profession or practiced routinely by younger employees.

In Fatehi's view, regulatory affairs professionals at all levels should be more proactive about communicating their role to sales, marketing, business leaders, and others throughout a medtech firm.

One specific strategy she recommends is to schedule training sessions for colleagues who work in nonregulatory departments. While regulatory specialists participate in a lot of training on technical topics in the field, they "typically don't train cross-functionally," Fatehi laments.

"I love training people. And I think it's really important to take all the people who don't understand or believe in your function and just give them a one hour training, just to explain to them why these regulations are in there. And also why regulations possibly help your device get to market much faster," she says.

"I'm making a business case for compliance. The idea is not me asking you to do something because it makes me happy or to see you suffer through it, but because that's how we're going to get to market quickly, and this is how we're going to bring this solution to people."