Small Business–Big Opportunities

By Mukesh Kumar, PhD, RAC

There are two ways of looking at today's biomedical industry. There is the doomsday scenario based upon dwindling revenues, increasing competition from generics and pipelines drying up, leading to corresponding stock plunges and job cuts. Then there is the rosy picture of small businesses rising up to replenish faith in the industry through focused product development that leads to better therapies and increasing profits. In this month's *Regulatory Focus*, we decided to go with the latter.

According to the US Food and Drug Administration (FDA) more than 90% of regulated industry is comprised of small and medium-sized enterprises (SMEs). Regulated industry includes not only pharmaceutical manufacturers but also biological products and medical devices, but excludes companies that do not have a history with the agency because they are involved in early-stage product development. FDA recognizes the importance of SMEs in creating innovator products and has instituted a number of activities aimed at easing interaction with the agency for regulated small businesses.[1] These include establishing the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) in the Center for Devices and Radiological Health, small business assistance programs in the five FDA regional offices, and small business assistance offices in each of the centers. These units provide technical assistance to small companies; hold meetings to hear the views and perspectives of small businesses; conduct educational workshops; develop informational materials; and provide an accessible, efficient channel through which small businesses can acquire information from the agency.

Similar trends have been seen in other regions where SMEs comprise the bulk of the industry. Regulators and legislators worldwide are developing assistance programs to encourage the growth of this segment. These include grants, financial incentives and special guidance/mentoring programs. Numerous bioparks and business incubators have sprung up around the globe to attract SMEs.

Despite all the support, by all estimates the failure rate in this sector remains quite high. Failure can be defined not just by the loss of business assets, but also by shelving of products due to lack of resources, lower profit margins and delays in development. This issue of *Regulatory Focus* features articles on how to avoid those problems.

Kazem Kazempour, et. al. discuss formulation of a business strategy for product development that includes not only scientific analysis but a variety of other components such as target product identification, business development and potential exit strategies. Evan Siegel explores regulatory strategy for products intended for the US market, emphasizing the importance of interaction with FDA. The myriad of activities required for European market approval are discussed by Salma Michor, who also looks at issues specific to generic products. Richard Morroney and Mukesh Sabarad close the loop on this discussion, by reviewing at length the logistics of developing a global market clearance strategy for medical devices.

One major reason for the increase in small businesses trying to develop big opportunities is the availability of for-hire talent to overcome a lack of internal resources. In the final feature, I discuss various factors a company developing a new product must consider when deciding which functions to outsource and when looking for the right strategic partner.

Although this issue focuses on SMEs, the points discussed here apply equally well to product development by large enterprises as well. The articles cover a wide array of topics geared to the needs and requirements of SMEs; however, we believe they will also be appreciated by the larger players in the industry.

References

1. http://www.fda.gov/CDER/about/smallbiz/default.htm

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