"Connecting Business Needs with Marketing Excellence"

DANA E. THOMAS
3204 Waterford Court
Pittsburgh, PA 15238-1141
direct 412.406.7675
cell 609.775.5260

Role of Business Development Pre & Post FDA Approval

by Dana E Thomas

Regulatory Synopsis

The medical device, instrumentation, reagent and disposable business in the diagnostics industry is regulated by the FDA domestically and by an equivalent regulating body everywhere else in the world (i.e. EMEA in Europe). Depending on the diagnostic being performed the level of scrutiny by the FDA varies between a regular 510k (predicate technology/test already reviewed and approved) to the highest level of scrutiny a Pre-Market Approval Application (or PMA). Additionally, depending on which diagnostic test or procedure is being performed will dictate which group within the FDA will review the company's application, i.e. Center for Biologics will review all blood borne pathogens such as HIV, HB, etc. The FDA and other regulating bodies have very strict rules and penalties which companies are required to follow to gain marketing approval. It should be noted that the FDA does not approve or disprove any product; all the FDA does is provide the company with marketing approval based on the data submitted by the company in their application. The term FDA approved is typically used to indicate that FDA has reviewed the company's application and data and has granted marketing approval to the company allowing them to sell the product in the US market deeming it safe for use.

In order to collect the necessary data to complete the application to the FDA and other regulating bodies, companies must complete a series of clinical trials for the diagnostic test including all the instrumentation, reagents, and software used to generate a patient test result (only a physician can actually provide a diagnosis based on a test, i.e. the test does NOT provide the diagnosis). These clinical trials typically go through a series of three increasingly difficult trials ranging from safety to efficacy and finally to statically relevant data (or a volume of tests which has proven statistical relevance based on the total number of cases versus the number of cases tested, this is also used to calculate sensitivity and specificity of the product).

Role of Business Development Prior to FDA Approval

Business Development will get involved prior to the last phase of the clinical trials where large numbers are tested at multiple sites. These sites are selected on the basis of three parameters, scientific capability, access

to the appropriate patient population and reputation in the market. R&D will typically have input for the first two parameters and Business Development for the third. For instrumentation and reagents, Business Development can also setup Beta Test Sites prior to approval. These test sites will run tests concurrently with their established procedure and compare the data similarly to the trial sites.

These Beta test sites accomplish many functions for Business Development. First these Beta Test Sites will validate performance of the test outside of the clinical trial sites, i.e. in the hands of actual users. Second, it allows for the Beta Test site to publish or present their results to others in the diagnostic community, i.e. word of mouth. And third, it establishes a readymade customer base after approval. The Beta Test Sites DO NOT pay for the tests from the company and in most cases are paid to perform the testing by the company.

However, the rules of the FDA now come squarely into play. If the FDA discovers that a company is ***selling or promoting*** a product prior to their regulatory review, the FDA can and has shut down a company! Companies in the industry are acutely aware of this and therefore only allow the sales department to promote and sell products that have already received FDA approval. Business Development fills this role by identifying not only Beta sites and gaining their acceptance to perform the testing, but also identification of Key Opinion Leaders (KOLs), Key Accounts (such Cleveland Clinic, Mayo, Johns Hopkins, etc.), Group Purchasing Organizations (GPOs) and strategic partners to accomplish such essential functions as marketing, distribution, or even sales. It is also Business Development that will begin the process of establishing a pricing strategy based on reimbursement. In many cases, it will be required that Business Development work directly with Health and Human Services to establish or confirm CPT (Common Procedural Terminology) codes used by users to get reimbursement from Medicare and Medicaid to perform the test. After this has been established with HHS, Business Development will then confirm reimbursement with other third party payors, such as Blue Cross/Blue Shield, AIG, etc. Additionally, business development will also evaluate strategic collaborations with other companies. These collaborations could be in the form of a licensing agreement, both in and out licensing, or a development agreement for further development of a key technology which compliments a collaborators technology. Obviously, these strategic alliances vary widely.

Business Development Role Post FDA Approval

Prior to FDA approval or before submission of a regular 510k (typical review is only 90 days), Business Development should have a readymade customer base established with Beta test sites, pricing and reimbursement established, any strategic alliances or collaborations completed (i.e. sales

and distribution) and depending on how the product will be sold a complete sales training and customer training program completed.

After approval the implementation phase begins for Business Development. This will include forecasting used for revenue generation and manufacturing, contract completion (critical for GPO inclusion), Key Account relationships, and strategic alliance/collaboration relationships. At this point Business Development will turn over responsibilities for product management to marketing where forecasting, product improvement, promotional activities and other daily functions are managed. Business Development will now begin the process of leveraging the technology/product through gaining entrance into other markets (Rest of World (ROW), veterinary, food and water testing, industrial, etc.). Once again this can be done through strategic alliances, licensing, or marketing directly by the company. Business Development will perform the analysis and make the recommendation to the company for strategic direction. Business Development will and has been also looking for complimentary technologies which can be acquired or a strategic alliance can be made to further address the needs of the company, the customer and most importantly the patient.