

RegAff

What RegAff can do for you in the OTC business.

We are a global regulatory affairs company populated at the country level regulatory affairs with personnel experienced in OTC products.

We have a recent track record of regulatory activities in OTC products including switches.

We are doing trend setting OTC switch activities, not merely obvious ones.

We offer cost efficient solutions to small and big companies.

Examples of what RegAff can do for you.

Analysis

- look at your product and give you a view of its OTC Regulatory Authority approvability
- advise you of the indication and dosing likely to be acceptable (might only be part of the current Rx approval)
- tell you when the success probability is low
- advise you of the claims you make be able to make
- give you a time and cost estimate (range) for all activities through to Regulatory Authority approval and license maintenance

Strategy and tactics

- propose the strategy and different tactical approaches to approach the authorities

- act as the liaison with authorities
- create strategy, tactical documents and an operational plan
- keep you up to date on an upcoming and/or approved new regulations that that may impact on your business (regulatory intelligence)

Pre-submission meeting with Health Authorities

- arrange, organize, prepare Briefing Documents, negotiate, reach conclusions

Design and undertake any local clinical studies

- if Regulatory Authorities require or you choose to do for commercial reasons, we can design, manage and write-up the studies

Create and publish the dossier (paper or electronic) in our system and submit

- we have our own Sharepoint based emerging electronic dossier Central File by which we can build the dossier through easily communicating with your Regulatory documentation; we then use a E CTD tool to publish and submit to Regulatory Authorities in electronic or paper versions.

- we offer top-notch translation services in many countries to allow you to meet your local requirements on schedule

Negotiate marketing approval/switch from health authority

- we are used to negotiating with Regulatory Authorities

Act as your regulatory agent through our legally established local RegAff company

- we have established (and will create more) local RegAff companies so that you can hold a product license without having any local resources or company; a tremendous saving for you; we are establishing partnerships with local distributors/sales and marketing to allow the registration approvals to be granted but also to enable marketing

Business development/Find a local commercial partner

- we know the local companies engaged in sales and marketing of OTC products; indeed, several RegAff staff have worked for them; thus we are well placed to find and negotiate Terms documents if licensing out is your preferred option; we have business development capability in several countries.

Maintain your product license

- RegAff believes that your staff should be focused on the growth of the business, so we offer to handle the routine license maintenance; importantly, because RegAff staff have led global Regulatory Affairs groups we understand the impact that an issue in one country can have on another particularly through the media; thus, we offer personnel who have dealt with the non-routine as well.

Provide a Singapore based, UK trained Chief Medical Officer to deal with medical product issues on the market

Strategic Partnership

- what would be most efficient for us and drive timely product approvals for you would be a strategic partnership agreement with a minimum of two years; this would enable RegAff to provide the right quality personnel to you over the period of time from analysis of product to delivery of Regulatory Authority approval.

- in this situation we would like to do ALL of the regulatory activities at the particular country level for OTC products. This will allow you to have a business strategies including focusing on your own sales and marketing activities in other countries; strengthening your hand in licensing negotiations; getting licensing out revenue with no large, local fixed costs; or building a registered OTC portfolio before you commit to spend fixed costs on local companies or JVs.

Benefits

You get global access to top class experienced regulatory affairs people with lots of prior and on-going OTC experience

Because of the global nature of RegAff, you get 'one-stop shopping' increasing the efficiency of your central resources

Because we can act as a local regulatory agent, we can provide you with a much stronger position for licensing-out if you choose not to do it yourselves by having a regulatory approved OTC product , not one in development.

Our business development capability locally in China, Japan and Latin America has years of experience in doing deals in the OTC product area.

You don't need local country resources or need to pay for agents to give you a local or cultural understanding how to operate in a country. We do it and communicate with in English and use our staff near to your central office to help reduce your time.

You avoid further fixed costs by dealing with us. Our costs are geared to the amount of work we do-no contract cost. In Europe, because we have Small Company (SME) status from the European Medicines Agency we have a fee reduction from them.

Interested??

See: www.regaff.com

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