CTP SYSTEM
INTEGRATED COMPETENCES

PharmaFortis

REGULATORY AFFAIRS OUTSOURCING

WHY SHOULD YOU OUTSOURCE?

Regulatory Affairs Unit in a pharmaceutical company is a vital and dynamic unit that drives the R & D efforts of the company to the market successfully. It works with a focus to get products onto the market with a commercially viable label in the least possible time and expenses.

Today the world has become a global village and many companies are in a race to place **new products onto the world markets** and to gain market share and increase earnings. In such a scenario a small delay in gaining market access means huge loss in terms of market share and revenue generated. The key to success for pharmaceutical companies lies in obtaining timely **marketing approval from regulators**. So to obtain timely marketing approval companies can either strengthen they regulatory department or outsource the tasks to regulatory affairs consulting firm.

With changing global regulatory environment and requirements, outsourcing regulatory affairs work seems a more beneficial option both in terms of time and money. Maintaining a large regulatory affairs department can be very expensive and scope of knowledge can be limited to certain aspects. On the other hand, a regulatory affairs consultant keeps on updating himself with the current regulations and has vital experience in the field to expedite the approval process.

SHORT-TERM VS. LONG-TERM OUTSOURCING

Regulatory affairs services can range from simple tasks to very complex projects involving detailed consultation with the relevant guidelines and/or concerned Health Agencies.

Outsourcing basically breaks down into two categories:

1) SHORT-TERM
2) LONG-TERM

The first step in the decision to outsource is determining into which category your needs fall.

The need for short-term outsourcing can result from a special situation within a company providing temporary relief of bottleneck situations when a regulatory affairs department is overwhelmed by large volume of projects, suffering from shortage of personnel or of slow output.

LONG-TERM OUTSOURCING, on the other hand, involves a long-term partnership. By utilizing this type of outsourcing, a regulatory affairs department can gain many long-term benefits, including decreased fix costs of human resources and the ability to with projects of lower priority.

Identifying what services will best suit your needs is a critical step in the decision to outsource and in the selection of right partner.

SOME KEY FACTORS FOR SELECTING A REGULATORY AFFAIRS PARTNER

EXPERIENCE: Experience in pharmaceutical industry is an essential factor for pharmaceutical regulatory consultants. Consultants should have experience in strategic planning and implementation of regulatory plans as well as in preparation and submission of regulatory documents.

CONFIDENTIALITY: A Confidentiality agreement has to be in place to protect your company's proprietary knowledge. A consultant's confidentiality can be evaluated by requesting previous studies, and information shared can be used to judge the same.

RESOURCES: A company must have adequate staff and/or collaboration with other service providers to serve ongoing projects without delay. The involved staff must be highly skilled and trained to carry out regulatory work.

FLEXIBILITY: The regulatory affairs services should be "tailor-made" meeting the specific needs of the clients. The services should be available an a modular basis.

INFRA-STRUCTURE: The service company should have in place standard system/technology and infrastructure to carry out the work effectively..

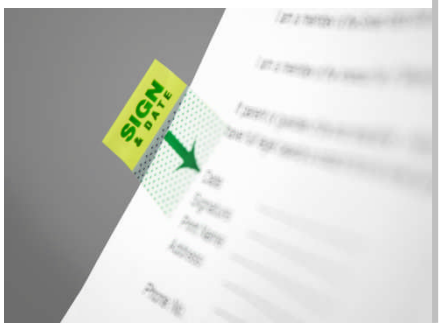
OUR REGULATORY AFFAIRS SKILLS

EFFICIENT REGULATORY STRATEGY MAKES THE DIFFERENCE

Our team works **proactively** and proposes the regulatory strategy which will bring the product to market on the desired day. Taking into account all relevant parameters, including the client's timelines, marketing plans, budget and other special arrangements, we complete and implement the regulatory plan in order to ensure timely product launch in each concerned country.

E-CTD PREPARATION

eCTD submissions are increasingly preferred by the European regulatory authorities. We offer dossier preparation in both CTD or eCTD as well as converting paper CTD to fully compliant eCTD.



CTP SYSTEM IS THE RIGHT CHOICE

SITE COMPLIANCE & REGULATORY

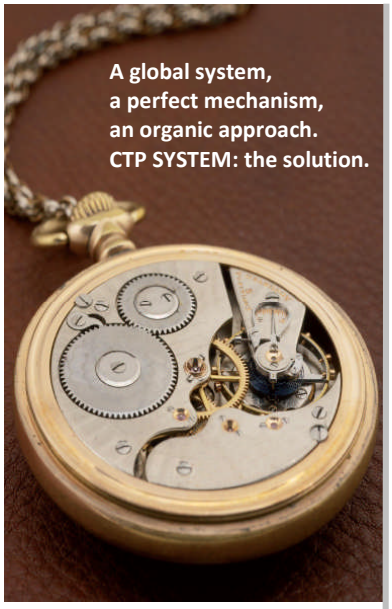
- GAP Analysis
- DMF, CTD, TF compilation and review (all modules)
- Post marketing applications (Variations and renewals)
- Regulatory support from development to MA granting and beyond

SUBMISSION SUPPORT

- Marketing authorisation applications National, DCPs and MRPs
- Regulatory support in FDA procedure

eCTD

- Training
- Software Validation



PLANNING FOR THE FUTURE

Regulatory Affairs outsourcing is on a growth worldwide: many large and small companies have adopted this strategy to get a timely approval. Even multinational firms are outsourcing their regulatory work to lessen the pressure on their in-house team or to support the same.

Outsourcing is "one of the greatest organizational and industry structure shifts of the century."

www.ctpsystem.com
info@ctpsystem.com

Località Salceto, 91/93
53036 Poggibonsi (Siena)
Tel. +39 0577 98481
Fax +39 0577 980762

Via G. Stephenson, 94
20157 Milano
Tel. +39 02 49681311
Fax +39 02 49681344

Via Campobello, 7
00040 Pomezia (Roma)
Tel. +39 06 9122873
Fax +39 06 9120289