REGULATORY

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TPRAC

The Pharma Regulatory Affairs Consultancy

One-Stop Solution to all your Pharmaceutical Development & Manufacturing needs

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Pharma Regulatory Consultancy

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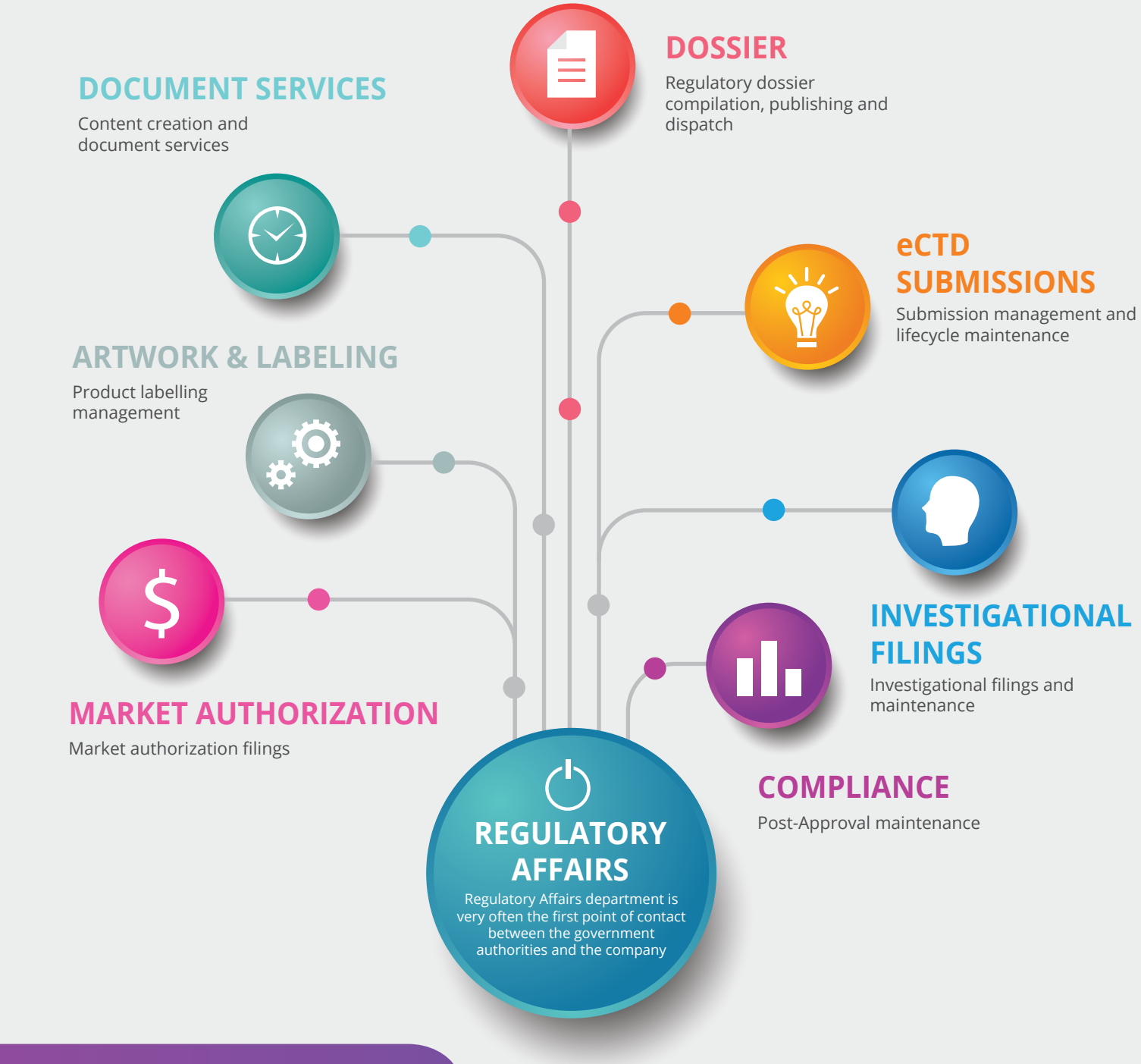
TPRAC Pharma Regulatory Consultant is an India based Pharmaceutical Regulatory consultant, Located in Perungudi and Alathur - Chennai (India). TPRAC Pharma regulatory consultant is involved in a wide variety of regulatory consulting assignments with Regulated markets e.g. U.S.A, Europe, Canada, Australia etc. and Semi regulated markets e.g. India, Asia Pacific, CIS, Middle- East, Africa etc.



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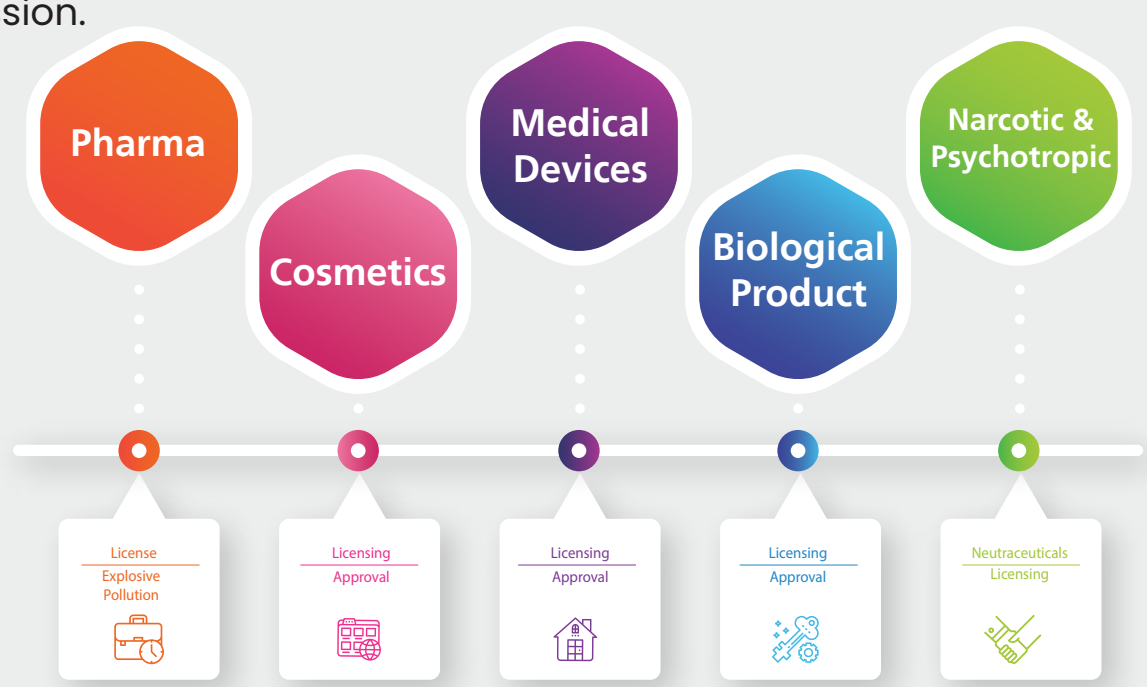
TPRAC Pharma regulatory consultant assist clients by guiding the product development in line with the country specific requirements, data generation, document compilation for submission to various Regulatory Agencies all over the world, responding to the queries and finally obtaining the approval or registration of the product all under one roof. Our core focus is to offer supportive services to Regulatory Departments of Pharmaceutical Companies in the field of Registering Pharmaceutical Dossier Writing. We are have been involved with all aspects of regulatory affairs, from supporting Clinical trials, bioequivalence reports, validation data, Expert reports, Data for Overview, PSUR through registration activities, compilation of Pharmaceutical dossier / application for registrations of medicines and E-Filings to post-marketing regulatory obligations for Pharma Industry. We also offer 'Gap Analysis' which is a meticulous review of the dossier ready for submission.



We have excellent contacts all over India and therefore we also provide liaison services for those who wish to search for suppliers of raw materials, products and processes, as well as for those who wish to expand their global presence in a very telling manner. Business consultancy is provided on various aspects related to imports, exports, regulations, market conditions, competition, product viability, etc. We also help overseas buyers for contract manufacture of various products on exclusive basis by using technical talent and expertise available with Indian manufacturers.

Categories in which we work

- New Chemical Entities
- Generics (Abbreviated New Drug Approval)
- OTC (Ayurvedic / Herbal & Chemical)
- Investigational New Drug (IND) Application
- New Dug (NDA) Application
- Medical Devices
- Nutraceuticals / Food Supplements
- Biotechnology Products
- Narcotic / Psychotic Product License
- Alcohol Licensing / Vaccines

Markets for which we work

Regulated Markets

- USA
- European Union
- Canada
- Australia

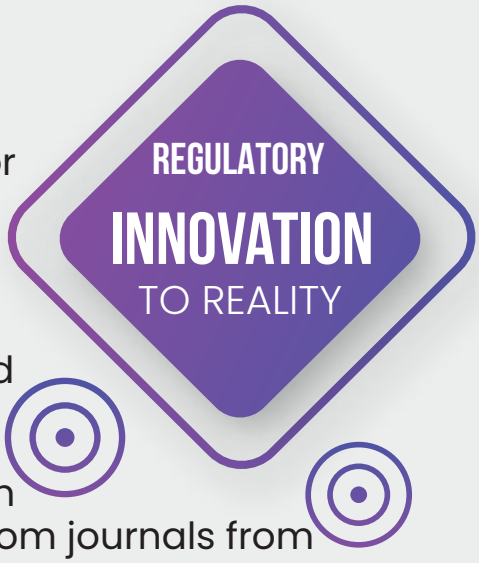
Semi-Regulated Markets

- Asia Pacific, Asian Countries, All CIS Countries,
- Middle- East, African Countries, Latin America.

Companies with whom we work

Foreign Pharma, food/food supplements and medical devices companies and who wish to enter the Indian market and other international markets. Indian Pharma companies who wish to enter International markets. Clinical research organizations who wish to seek Permission for Clinical Trials in India.

Services Offered



- Preparation and filing of Registration dossiers for submission to various regulatory agencies all over the world (including eCTD, CTD format & ACTD Format).
- Drug Master File (DMF) compilation for open and closed part.
- Preclinical and clinical overviews writing through literature search / published studies / articles from journals from different sources.
- Assisting the clients for development of new products and data generation in line with country specific registration guidelines.
- Registration dossiers for submission to various Regulatory Agencies all over the world (including CTD format)
- Assistance in Response to queries for submission to the Regulatory Agencies. Regulatory Assistance in Post-Approval compliance
- Assisting the clients to upgrade the existing products by additional data generation to the requirements of new countries.
- Assisting in finalization of suppliers (vendor) for active botanical ingredients used in various herbal formulations using Analytical Hierarchy Process.
- Assisting in product sale, distribution and warehousing for Prescription products, OTC (Ayurvedic/Herbal & chemical) and Food supplements from Regulatory perspective.
- Assisting the clients for product claims (OTC and Food Supplements) backed with scientific literature so as to get competitive advantage.
- Assisting the clients on advertising and marketing promotional material from Regulatory perspective.

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