SANGAM GLOBAL PHARMACEUTICAL & REGULATORY CONSULTANCY

Regulatory Affairs Worldwide

- An ISO 9001:2015 Certified Company

www.sgregulatory.com

Welcome to Sangam Global Pharmaceutical & Regulatory Consultancy (SGPRC) established in 2010, we are a group of Highly qualified professional having more than 10 years of vast experience in Pharmaceutical Regulatory Affairs, providing High quality Pharmaceutical Dossier Service to many Pharmaceutical companies. Our aim is to provide High Quality Pharmaceutical Dossier in all over the world.

- Vision:
- To become a leader in Compliance Service based industry and to provide an exceptional
- services to customer on Environmental and Safety Regulations.

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Mission:
To provide high quality Regulatory solutions to our customers on various Environmental and Safety Regulations to comply their products as per regulation and nurturing new process to reduce cost and providing end to end solutions, and to create a very healthy environment to live in for future generation.

- SGPRC addresses all categories of products and requirements including Environmental and Safety. We provide product compliance services to minimize the Environmental,Health and Safety impacts and comply with all relevant regulation and legal requirements globally.

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Methodology:
We follow a strategic methodology to comply international Regulatory Requirement to fulfill our customer Expectations. As part of our Regulatory Operations Managed Services, we monitor key metrics and results that focus not only on quality and compliance, but also efficiency - such as submissions processed per year, cycle time, lead time, touch time, number of defects, first pass acceptance rate, etc. - ultimately offering regulatory operations cost advantages.

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SGPRC work with clients to help build a comprehensive strategy for regulatory affairs oversight and implementation.

OUR SERVICES

Pharmaceutical Dossier
Service Benchmarking
CTD Dossier
CMC Documentation
ACTD Dossier
Outsourcing, Legal compliance

- ***Dossier Submission***
- ***Drug Master File***
- ***Process Validation***
- ***Analytical Method Validation***
- ***Development Report***
- ***PSUR (Safety Report)***
- ***Expert Report, Stability Study***

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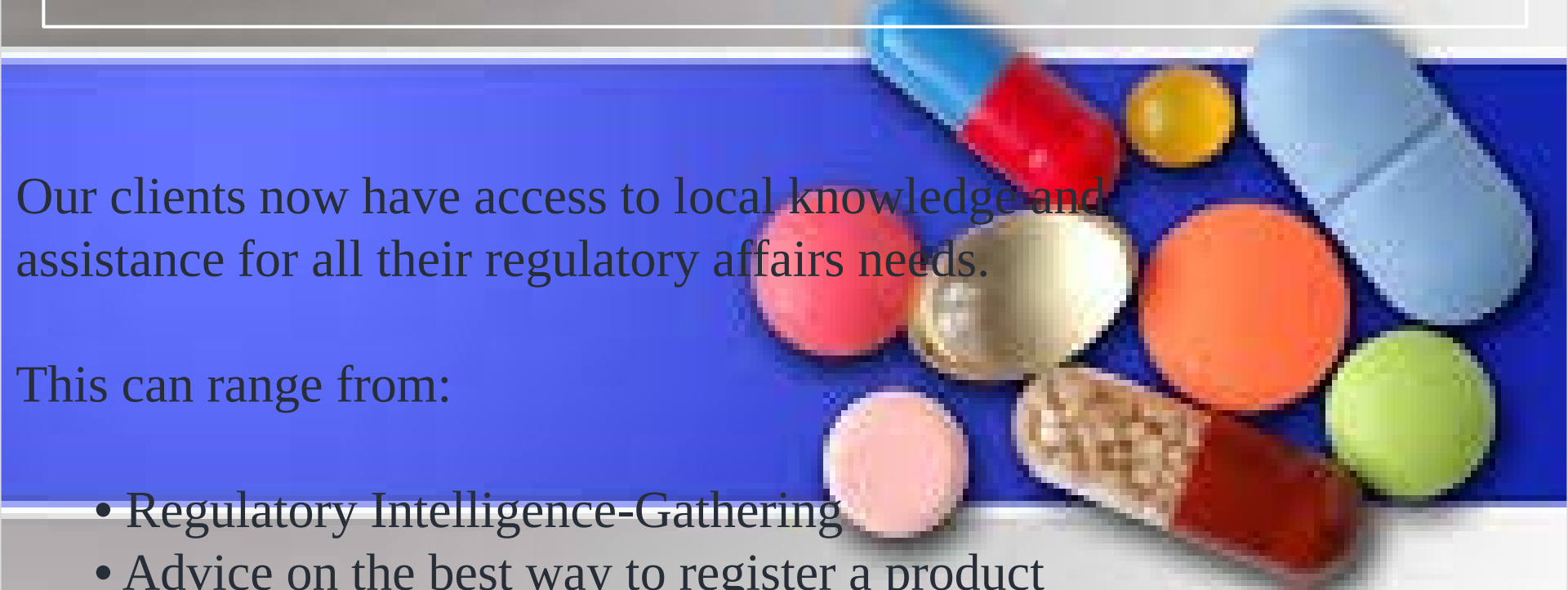
SGPRC Affiliate Network



Our clients now have access to local knowledge and assistance for all their regulatory affairs needs.

This can range from:

- Regulatory Intelligence-Gathering
- Advice on the best way to register a product
- Preparing and submitting applications
- Post-marketing activities.

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LIST OF COUNTRIES FOR WHICH DOSSIER AVAILABLE IN CTD, ACTD & IN COUNTRY SPECIFIC FORMAT

Asia	Africa	CIS Countries	EU Region	North America	South America
Afghanistan	Angola	Kyrgyzstan	Armenia	Canada	Bolivia
Bangladesh	Botswana	Uzbekistan	Azerbaijan	Dominican Republic	Colombia
Bhutan	Burkina Faso	Turkmenistan	Belarus	El Salvador	Peru
Brunei	Burundi	Georgia,	Belgium	Guatemala	
Cambodia	Congo	Tajikistan	Bulgaria	Jamaica	
China	Ethiopia	Belarus,	France		
Cyprus	Gambia	Kazakhstan,	Georgia		
Georgia	Ghana	Azerbaijan,	Germany		
India	Guinea	Ukraine,	Malta		
Indonesia	Kenya	Russia.	Moldova		
Iran	Madagascar		Romania		
Iraq	Mozambique		Switzerland		
Israel	Nigeria		Lithuania		
Japan	Rwanda				
Laos	Senegal				
Myanmar	Sudan				
Mongolia	Tanzania				
Nepal	Togo				
Philippines	Uganda				
Sri Lanka	Zambia				
Vietnam	Zimbabwe				
Yemen					

IF ANY FURTHER REQUIREMENT THEN CONTACT SGPRC

SGPRC Affiliate Network

- Access to local Regulatory Affairs expertise when and where you need it.
- **The best Regulatory Affairs professionals in every continent.**
- Covering every market from Argentina to Zambia.
- **Leading local consultants who:**
  - understand the culture
  - will ensure your requirements are met
  - save you time and money.

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NAMIBIA | SOUTH AFRICA | SWAZILAND | TANZANIA | ZAMBIA |
ZIMBABWE

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KOSOVO | MACEDONIA | MOLDOVA | MONTENEGRO | POLAND | ROMANIA
RUSSIA | SERBIA | SLOVAKIA | SLOVENIA | UKRAINE | UZBEKISTAN

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SOUTH KOREA | THAILAND

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NORTH AMERICA

CANADA

UNITED STATES: **NJ** (US HQ) | MA | CT | NY | PA | NC | CA | DC

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DOMINICAN REPUBLIC | ECUADOR | EL SALVADOR | GUATEMALA
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PANAMA | PARAGUAY | PERU | PUERTO RICO | TRINIDAD | VENEZUELA

LATIN AMERICA

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Pharmaceutical Registration Dossier & Format

Pharmaceutical Dossier is an Important & Critical part of Product Registration process, which is need to submit in Food & Drug Administration of the concerned Ministry of Health, of Regulatory Authority.

Different Regulatory Authority published their Standard format according to country Guidelines.

Common Pharmaceutical Dossier which is widely used in the Pharmaceutical Industry are:

- ACTD Dossier
- CTD Dossier
- eCTD Dossier
- Country Specific Registration Dossier

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