SANGAM GLOBAL PHARMACEUTICAL & REGULATORY CONSULTANCY

Regulatory Affairs Worldwide

- An ISO 9001:2015 Certified Company

www.sggregulatory.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 service 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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### Our Services

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

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

You can visit our website at [www.sgregulatory.com](http://www.sgregulatory.com)

### List of Countries for Which Dossier Available in CTD, ACTD & In Country Specific Format

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<th>Asia</th>
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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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AFRICA

ANGOLA | BOTSWANA | DEMOCRATIC REPUBLIC OF CONGO | LESOTHO
MADAGASCAR | MALAWI | MAURITIUS | MOZAMBIQUE
NAMIBIA | SOUTH AFRICA | SWAZILAND | TANZANIA | ZAMBIA | ZIMBABWE

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EASTERN EUROPE

ALBANIA | AZERBAIJAN | BOSNIA & HERZEGOVINA | BULGARIA | CROATIA
ESTONIA | GEORGIA | HUNGARY | KAZAKHSTAN
KOSOVO | MACEDONIA | MOLDOVA | MONTENEGRO | POLAND | ROMANIA
RUSSIA | SERBIA | SLOVAKIA | SLOVENIA | UKRAINE | UZBEKISTAN

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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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