



Managing Worldwide  
Regulatory Affairs  
In A World-Class manner

**DDReg Pharma Private Limited**

*Regulatory Expertise for Drug Products & Medical  
Devices for Global Markets*

**2015**

# January 2015

**DDReg** Pharma is India based pharma regulatory solution provider that help pharmaceutical companies to manage their worldwide regulatory affairs portfolio for Developed and Emerging Markets.

DDReg services include Regulatory Strategies, Feasibility Studies, Dossier compilation and filings, Agency follow ups & approvals, Post Approval License Management, Regulatory Compliance, Gap Analysis and Regulatory due diligence for Pharmaceuticals (Rx & OTC) and Medical Devices.

Established in 2009 with the aim to provide high quality services in RA DDReg has a proven record of over 200 MAs in EU & Emerging Markets.

## DDReg Pharma Private Limited

1007, Tower B4, Spaze-i-Tech Park, Sector 49, Sohna Road,  
Gurgaon – 122018, Haryana (INDIA)

Phone : +91 (0) 124 4361505, 4361506, Email: [Info@ddregconsultants.com](mailto:Info@ddregconsultants.com)  
Website : [www.ddregconsultants.com](http://www.ddregconsultants.com)



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# JANUARY 2015

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“Established in **2009**

**DDReg** has  
a proven record of  
over **200 MAs**  
in EU & Emerging  
Markets”



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# February 2015

## REGULATORY AFFAIRS

### Complex Function made easy for you

Regulations related to drug & drug products continue to pose a major challenge for the global pharmaceutical and allied industry. In such situation – a sound regulatory strategy is key to the success of product launch or business entry into specific market.

Any sound regulatory strategy stands on effective planning and implementation. Regulatory Operations by way of New Filings, dossier compilations or variations, running procedures on client's behalf, regulatory due diligence etc form the heart of Regulatory Affairs.

And once the product is in market Managing global compliance issues and post licensing activities is even more challenging

*"DDReg is your Regulatory Affairs department that monitors the dynamic regulatory environment and provide an expert, objective perspective on opportunities and challenges. We efficiently manage your regulatory operations, deliver top class dossiers and network with agencies effectively. We have made a name for ourselves in managing the post approval regulatory life-cycle"*

#### DDReg Pharma Private Limited

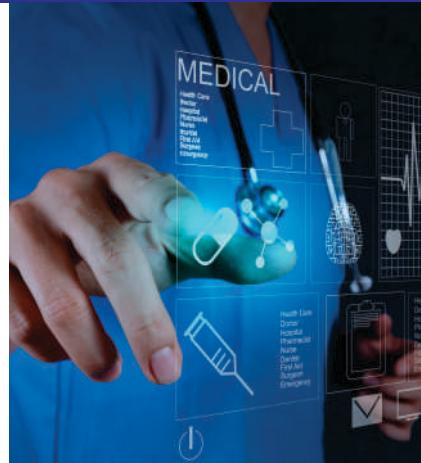
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**“REGULATORY AFFAIRS**  
– A Complex Function made easy for you by **DDReg”**



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# March 2015

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## CORE VALUES

There are five pillars of Core Values that support the strong DDReg Services platform

### Quality

By "quality," we mean more than just services meeting our own specifications. It means meeting customers requirements and ensuring quality in all dealings with our customers. Quality is, therefore, not just the responsibility of our leadership but is the responsibility of each one in our company.

### Integrity

We display integrity at all times in the business decisions we make, the work we do and the manner in which we conduct our Business.

### Excellence

We are passionate about people, process, product, and service excellence. At DDReg, Excellence is not only a value; it is a discipline and a means for doing the business in a better manner.

### Teamwork

We support that sense of doing what's right through a culture of open communications and a spirit of teamwork

### Commitment

We are committed to providing value to our clients and to those colleagues who rely on us for Quality Excellence. We are knowledgeable and passionate about what makes our

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# MARCH 2015

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**“Quality”**  
**“Excellence”**  
**“Integrity”**  
**“Teamwork”** &  
**“Commitment”** are  
among the Core Values  
of **DDReg**



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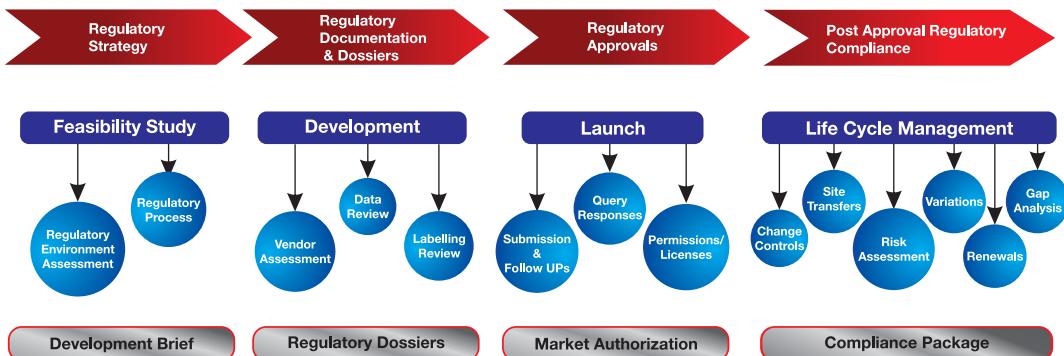
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# April 2015

## OUR SERVICES

### Product Life Cycle (From Lab to Launch until Post Approval)



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# APRIL 2015

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“**DDReg** Manages complete regulatory **Lifecycle** of a product”



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# May 2015

## REGULATORY STRATEGY

An effective Regulatory strategy aligns the regulatory activities to bring a new or modified product to market with the business strategy for that product. It provides overall definition and direction to the project team, for the product being developed, by identifying the important regulatory elements to be addressed to market that drug product or medical device.

We, at DDReg, monitor the dynamic regulatory environment and provide an expert, objective perspective on opportunities and challenges for pharmaceutical & Medical Device companies as its clients.

### Our services in this area include

- Registration Strategy in EU & Emerging Markets
- Regulatory Feasibility Analysis
- Strategies for product Filing and Variation
- Advisory on CMC data generation for successful filing
- Change Control Strategies
- Subject Matter Expertise
- Strategy for Query Responses

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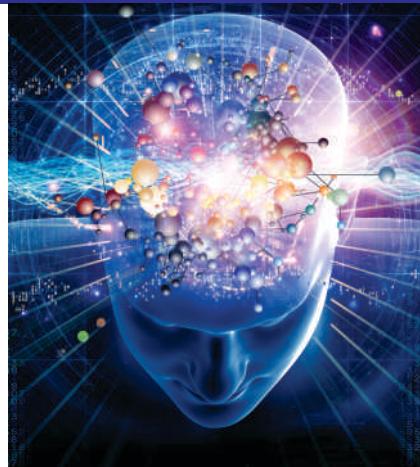
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“A sound regulatory **Strategy** is key to the **Success** of product launch or **Business** entry into specific market..!”



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# June 2015

## REGULATORY OPERATIONS

Any sound regulatory strategy stands on effective planning and implementation. Regulatory Operations by way of New Filings, dossier compilations or variations, running procedures on client's behalf, regulatory due diligence etc form the heart of Regulatory Affairs. We at DDReg have made a name for us, to run regulatory operations effectively and with top class quality for our clients.

### Services include

- Dossier Compilation for Emerging Markets/EU/US/Australia
- Types – eCTD, ACTD, NeeS, National Filing, Device Master Dossiers & CSDT
- Dossier conversions to CTD/ACTD for Drugs & to CSDT for Medical Devices
- PIL User Testing
- Labelling Reviews as per National requirements
- CPP Reviews
- API Related
  - DMF Review
  - API filing with EDQM for obtaining CEP
  - Assessment/Review and filing of Amendments/Variations

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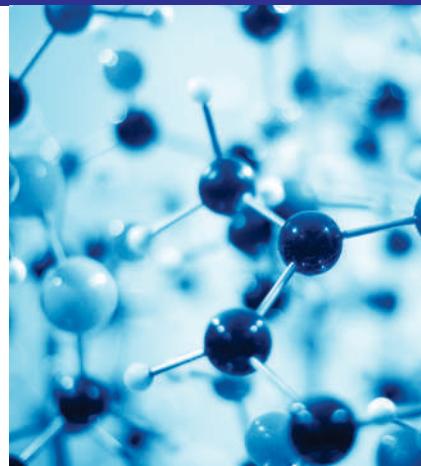
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JUNE 2015

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“ New Filings, dossier compilations or **Variations**, running procedures, regulatory due **Diligence** etc. Form the **Heart** of Regulatory Affairs..!”



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# July 2015

## POST APPROVAL LIFE CYCLE MANAGEMENT

Post approval Life Cycle Management (PLM) includes the lifecycle of a product once it has been launched in the market. It is about the maintenance of the product in the market in compliance to the regulation pertaining to its quality, safety and labelling. These maintenance activities provide little competitive advantage but are critically important to maintain sales. We, at DDReg, provide comprehensive post approval maintenance regulatory services to our clients

### We help manage the

- Change Control Management
- Regulatory intervention and Guidance
- Renewals
- Risk Assessment/Analysis
- Variation Applications – Regulatory Guidance & Compilations of
- Site Transfers
- Other Types of Variations
- Regulatory Gap Analysis & Remediation
- Compliance Dossiers

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# JULY 2015

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“Post approval  
**Life Cycle**

Management (PLM) is  
about management of  
**Global** compliance  
issues and post  
licensing **Activities..!**”



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# August 2015

## PHARMACOVIGILANCE

Every medicine is tested on a relatively small number of people before it is approved for use by the wider population, where previously undetected reactions can emerge. Each patient is a unique medicines user with a distinctive lifestyle and circumstances. Pharmacovigilance is the process of evaluating and improving the safety of medicines. DDReg helps its clients by processing and collating the safety information and adverse event data that may be required to be submitted to regulatory authorities. DDReg's Pharmacovigilance services include.

- Adverse Event Processing
- Periodic Safety Update Record (PSUR)
- Risk Management Plan (RMP)
- Company Core Safety Sheet
- Literature Search
- Signal Detection & Management

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“ Generate evidence  
that will **Inspire** public  
**Confidence** and **Trust**  
in medicines they consume...  
Evaluating and improving  
the **Safety** of medicines  
should be the top priority! ”



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# September 2015

## WHO WE WORK WITH

DDReg works with Organizations across the globe of diverse size and product mix that include.

- Pharmaceutical Organizations
- Consumer Healthcare Organization
- Medical Device -Manufacturing & Marketing Organizations
- Organizations dealing in Nutritional Supplements
- Contract Research Organizations

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**“DDReg Works** is proud to have with **leading** Pharma organizations, Consumer HC & Medical Device companies as its **Valued Clients**”



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# October 2015

## TEAM THAT WORK WITH DDReg

Success of any organization depends on the strength of its team. Team members at DDReg, work to build an innovative, creative and rewarding work environment. For last 5 years we have been working smart and hard - getting our work and service quality heard right across the pharma world. Working here means one can get stuck in right away, have ideas heard, work in collaboration with a young, dynamic and motivated team, and make a difference.

DDReg team includes professionals with Masters and Bachelors degree in Pharmaceuticals, with Extensive experience gained by working in a variety of organizations, that range from large multinationals through to small and medium sized companies, specialising in hard core pharmaceuticals, Consumer Healthcare, Medical Devices, Nutritionals & Cosmetics

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“**DDReg** pool of experts work smart & hard with **Quality** on top of their **agenda...!**”



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# November 2015

## DDReg MISSION & VISION

### “Our Vision

To become preferred partner by Top Pharmaceutical Companies, for their need of expertise in Regulatory Affairs and become 500Mn) INR (company by2020

### “Our Mission

To provide quality regulatory solutions in a cost effective manner ,to organizations, manufacturing & marketing pharmaceuticals and allied products ,to enable them expand their businesses in developed and emerging markets



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“Good business **leader** create a **vision**, articulate the vision, **passionately** owns the vision & relentlessly drive it to completion...”

**Jack Welch**

DDReg leadership lives its vision every moment



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# December 2015

## WHY DDReg?

"Regulatory outsourcing is not just a cost control measure but a key strategic management tool"

There are many good reasons as to why some of the leading global pharmaceutical organizations prefer DDReg as their partner, the key ones are highlighted as below

- Delivery of Quality Services which stretch beyond scopes agreed
- Cost advantage but with top class quality
- Highly respected technocrats leading the business
- Efficient service models customized to client requirement



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“**DDReg** is a unique organization that delivers **World Class** regulatory work, that can beat the **Best...!**”



**DDReg Pharma Private Limited**

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2016

CALENDAR FOR YEAR

January

S	M	T	W	T	F	S
			1	2		
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

February

S	M	T	W	T	F	S
		1	2	3	4	5
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29					

March

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

April

S	M	T	W	T	F	S
			1	2		
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
29	30	31				

May

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

June

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

July

S	M	T	W	T	F	S
		1	2			
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

August

S	M	T	W	T	F	S
		1	2	3	4	5
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

September

S	M	T	W	T	F	S
			1	2	3	
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

October

S	M	T	W	T	F	S
				1		
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

November

S	M	T	W	T	F	S
1	2	3	4	5		
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

December

S	M	T	W	T	F	S
			1	2	3	4
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31



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