



**Dr. Rashmi Kulshrestha**  
Regulatory Consultant (Food & Pharmaceuticals)

**Dr. Rashmi Kulshrestha, Ph D (Pharm.), MBA (Mktg.)** has a total of about 21 years of varied experience in pharmaceutical industry including regulatory, analytical and innovation management. She is also a correspondent for India for a reputed international journal, Regulatory Affairs Journal (RAJ-Pharma), PJB Publications, UK. She is an international consultant for Food minds, a food & nutrition company, USA.

For further information, please contact

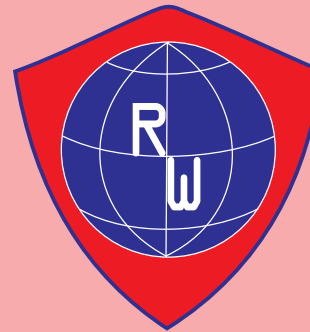
## **REGULATORY WISDOM**

**113-114, Vardhman Grand Market  
Sector 3, Dwarka  
New Delhi - 110 078, India**

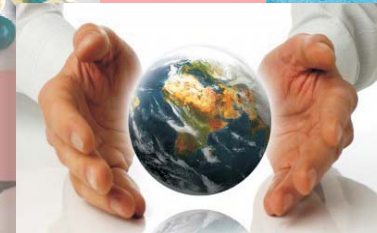
**Phone No:** +91 114 501 8515, +91 981 085 1700

**E-mail :** dr\_rashmi@regulatorywisdom.com

**Visit us at :** <http://www.regulatorywisdom.com>



# **REGULATORY WISDOM**



## **FOOD AND PHARMA REGULATORY CONSULTANTS**

## A Food & Pharma Regulatory Consultancy

Regulatory Wisdom assists the 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 queries and finally obtaining the approval or registration of the product all under one roof.

Registration/Approval being pre-requisite to market, Regulatory Wisdom assists its clients for faster entry to new markets, enhancing their market portfolio and revenues. Doing right at first time with no duplication of efforts, time and hence saving cost.

### Categories in which we work

- Generics
- OTC (Ayurvedic/ Herbal & Chemical)
- IND/NDA
- Medical Devices
- Food & Food Supplements

### Markets for which we work

- Less regulated markets e.g. India, Asia Pacific, CIS, Middle-East, Africa etc.
- Regulated markets e.g. U.S.A, Europe, Canada, Australia etc.

### Companies with whom we work

- Foreign food/food supplements and pharma companies 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

### Technical and Regulatory (pre and post marketing)

- 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

### Strategic Planning

- Assisting the clients in selection of product portfolio/product pipeline based on technical/regulatory filters and thus helps in finalization of product grid.
- Provide strategic, tactical and operational direction and support for working within regulations to expedite the launch of food supplements, OTC and generics.
- Monitor the impact of changing regulations on submission strategies. Advise management on the impact of current, newly finalized or proposed regulations, guidelines and standards and make recommendations accordingly.
- Provide regulatory input to product lifecycle planning.