Vision Regulatory Services

(Where Ideas Become Brilliant Solutions)

"Sarve No.: 273/2, Plot No.: 08, Collector Zone,
Behind Nisarga Hotel, Nisarga Hotel, Malegaon,
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¤ Company profile ¤

Vision Regulatory Services started in 2016 provides expertise in pharmaceutical Project Management for API (Bulk Drugs), Cosmetics and Formulations including upgradation of existing facilities, facility audit, complete cGMP documentation, validations, International marketing, improvement in operational efficiency, cost improvements and sourcing both men and materials coupled with our committed customer-focused approach means that we are well on our way to become the leading service provider to the pharmaceutical industry.

Vision Regulatory Services offers a complete pharmaceutical regulatory affairs support service during pharmaceutical development to assist in the implementation of a global regulatory strategy. The role of VRS is to tell you the current standards for your development and regulatory submissions, and what you need to do to meet them. We explain why you need to do what needs to be done, and help you to generate data which will successfully meet the requirements.

Our expertise team provides focused and integrated end-to-end solutions that exceed expectations and deliver added value on time and within budget.

We ensure

- Entire pharma necessities under one roof
- Reliable and Timely advice
- Cost effective and Practical Solutions
- Facilitating your growth plans

Mission, Vision and Company Values

Mission Statement

To be the global leader in providing high quality solutions to pharmaceutical industry which will help clients reduce R&D cost and deliver quality goods within time.

Our Vision

We will provide superior quality solutions to our clients based on data of impeccable quality. Our customers are our number one priority. We will pursue the cutting edge of innovation in the field of quality assurance, so our customers reap the benefits in competitive world.

Company Values

Service Excellence

The customer is our most valued asset. They are not dependent on us, we are dependent on them. We perform at a consistently higher level than other service providers. Professionalism has nothing to do with getting paid for our services.

Integrity
We strive to keep all promises and agreements. We value being truthful and non-deceitful with all employees, customers, and anyone we have external interactions.

Innovation
We desire to always be on the cutting edge of technology and emerging trends in the pharmaceutical industry. We continue to monitor the industry and venture into new, breakthrough areas of opportunity.

Services offered by Vision Regulatory Services (ARS)

1. Project Development

- Designing of plant Layout.
- Upgradation in exiting facility.
- Timely visit plans for site development.
- Provides various vendors for Equipment and Utilities.

2. Quality Management System (Plant Documentation Part)

VRS can guide to prepare various documents like:

- Redesigning of SOP and other documents of Plant

- Qualification and Validation: Qualification and Validation are integral steps in building quality into any facility. ARS provides an efficient and effective documentation system that meets the requirements of International Regulatory authorities.
  - Validation Protocol Preparation & Execution:
  - Validation MVision Plan
  - Deign Protocols
  - IQ protocols for all types of Equipment
  - OQ Protocols
  - PQ protocols
  - Conducting Process Validation at your site
  - Area Validation (HVAC)
  - Purified Water Validation Protocol & Validation

- Manual Preparation
  - Site Master File

- Validation Master Plan
- Quality Manual
- Safety Manual
- Training Manual

- Standard Operating Procedures (All department present in unit)
  - Quality Assurance Procedures
  - Quality Control Procedures
  - Warehouse/Store
  - Engineering/ Maintenance
  - Production
  - Human Resource

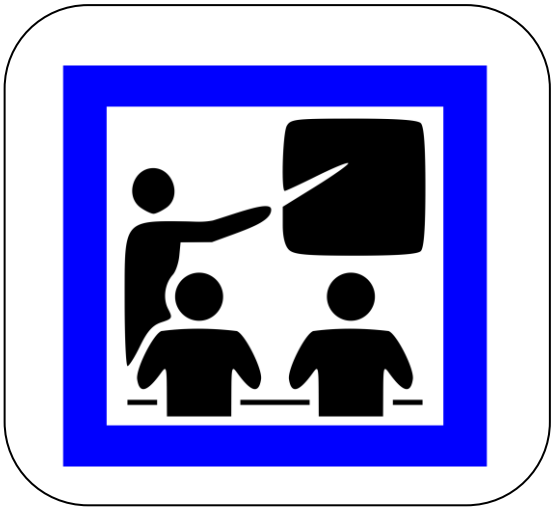
- Redesigning of Manufacturing batch records and Batch packing Record.

- Redesigning of Specification and Method of analysis.

- Redesigning of Master Formula Record

3. Onsite Training:

- Standard Operating Procedures –QA/QC/Manufacturing /Maintenance.
- On the job Training for QA/QC/Shop floor employees.
- Process Validation.
- Qualification of equipments.
- Method Validation.
- Facility Qualification.
- Purified Water validation.
- current Good Manufacturing Practices.
- Good Documentation Practices.
- Good laboratory Practices.
- How to prepare & FACE Regulatory audits.
- Data integrity and 21 CFR part 11.
- COST Improvement Projects
- Technology Transfer
- Statistical Process Control



- Product Failure Investigations

4. External Audits/ GAP Analysis.

- We will audit, plan, advice and help you in execution of your plan.

5. Other Audits

- Vendor Audit for API suppliers.
- External Lab Audit.

6. Regulatory Services

- Audit preparation as per various regulatory requirements.
- Drug Master File (DMF) Preparation.
- Drugs Master File - Development, preparation, assembly of complete common technical documentation (CTD).
- Dossier Preparation according to country specific guidelines.
- Dossier- Development, preparation, assembly of complete common technical documentation (CTD).
- Preparation of responses to regulatory authorities, comment letters, and assessment reports.
- Provision of support for scientific advice meetings, representation to regulatory agencies and meeting planning.
- Schedule 'M' Requirements & documentation for compliance to Indian FDA's norms.
- Preparation of analytical method validation for all type of pharmaceutical formulation.
- Preparation of various documents required for dossier preparation.

❖ **What we do:**

- We'll examine your manufacturing processes and submitted data.
- We'll carry out GMP reviews of manufacturing facilities and quality management systems.
- We'll audit your suppliers and contractors for compliance with GMP, GLP or other standards.
- We'll work with your in-house QA experts to improve presentation of facility and systems for Inspectors.

- We'll prepare response documents or appeals on your behalf.

7. International Business

- Being a Marketing based consultancy our core business is to initiate & establish business in different countries for Pharmaceutical Market.
- We share an excellent relationship with the importer in different countries around we have worked, and we are keen to expand the business around the world.
- We have a deep understanding of the regulatory & commercial requirements of our market, which enable us to register & successfully Launch the products in shortest possible period.
- We are having excellent relationship with MOH officials of different countries which enable us the trigger & successfully pass various countries audit.
- We understand the requirements of the importer well which help us in introducing them the suitable product range.
- We work very closely with manufacturer as well as importer /distributor / marketer in the given countries from the very first day of business introduction.
- Our team also assist to manufacturer to have an compliance audit before any strict country audit & try to improvise them.
- Third Party Contract Manufacturing from WHO – GMP Certified Plants
- Company product registration process
- Pre audits for Pics, NAFDAC, NDA, etc. with professional auditors who has having more than 20 years of experience.
- Pitch for various countries inspection.

8. Formulation and Development Services:

We ensure any forms we develop are scalable, compliant and commercializable for our customers. We can formulate a wide range of sterile and non-sterile dosage forms including:

- Oral Immediate Release – Solutions, Emulsions, Suspensions and Capsules
- Oral Controlled Release – Matrix based release, Multi-particulate systems, Polymer Film Coatings, pH Dependent Release
- Topical and Transdermals – Gels, Creams, Ointments, Lotions
- Sterile Liquids – Solutions, Suspensions, Colloids, Liposomes
- Powders – Sterile and non-sterile powder filling
- Sterile liquid dosage formulations (ophthalmic, oral, nasal)

- Injectable drugs (intravenous, and intramuscular, subcutaneous injectables)
- Lyophilized formulations
- All type of Pharma excipient

❖ **Formulation Services and Capabilities**

- Process Scale-Up
- Technology Transfers
- Batch manufacture
- Formulation development for new chemical entities (NCE)
- Optimization of existing formulations
- Product/Process Optimization
- Novel formulations for improved delivery of existing dosage forms
- Controlled release and sustained release formulations
- Feasibility Studies
- Excipient Compatibility selection and optimization
- Physico-Chemical Testing

Our expert formulation development group overcomes difficult formulation challenges in a rapid and cost effective manner. Our formulation development services can be utilized independently or with our fully integrated services to accelerate your drug development program.

Contact Us:

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