HAVISA HEALTHCARE

An Introduction

HAVISA HEALTHCARE

- Havisa is a vision, a group of experienced Professionals & Technocrats to assist the Healthcare industry.
- Havisa is diversified into Contract Research, CGMP Consulting Services, Regulatory Support and Contract Manufacturing, established to support growing companies in the age of stiff competition.
- The company is based at Mumbai in India with operations split over Mumbai and Northern states of India.

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Healthcare industry is passing through a Challenging phase now for the following reasons.

1. Drug Regulations in India are being re-examined to make them at par with any International standards, e.g. US & Europe.

2. Recent developments exhibit that the FDA is now becoming more rationale for considering the Drug Approval process. A New Drug Application is now first screened by the Expert committee before it is processed for Review & Approval. So life for small companies has become tough.

3. Nutraceuticals Business which was considered to be of great ease is now controlled through a Regulatory Agency i.e. FSSAI.

4. And Overall there is now a CUT THROAT Competition in the field for survival.

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Big Pharma companies are now operating either through :

- Developing and launching the Products with unique value addition as the Profits with the existing products are meager.
- Eyeing new business Areas Globally for Direct exports.
- Planning Business tie ups with oversees partners either for In-licensing or Out licensing.
- Offering their facilities for Contract manufacturing for overseas partners.

Havisa can help developing products with a USP thus providing an edge over the other market leaders.

India has an edge in this scenario, to act as the Contract Manufacturing location, as the Manufacturing cost in India is considerably less and hence if we can match their Quality Standards, we can well establish ourselves in the front line.

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So, What is **NEXT** to "Post Excise exemption era'.

If we take an example of a very small Zone, BADDI in Himachal Pradesh.

Excise exemption started in - 2003

Number of companies started was approximately 800

The Baddi industrial belt is the classic example of a sweet dream gone sour. Baddi, once a hotbed for the Pharma, currently has around 400 units in operational condition currently.

A massive tax Incentive package was offered in the year 2003, lately the tax holiday was extended beyond 2010 without bothering to develop the zone. The major attractions for investors included 100 per cent outright excise duty exemption for a period of ten years from the date of commencement of commercial production (the past budget stipulated it to industries starting on or before 31 March 2007).

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A majority of small and medium scale units were already under lot of debt from the banks due to the increased cost of upgrading their units to meet the revised Schedule 'M' requirements.

- With the excise free zones turning out to be less attractive and facing stiff competition from the non-excise free zones, about 35-40 per cent of small and medium scale Pharma units were closed down, but due to no further benefits and poor infrastructure, there are no buyers.

- Primary objective of companies getting in was to save money and improve upon profits. Considerable compromises were done.

- With the conclusion of Exemption period, as the companies might not be up to the CGMP standards, the business started reducing, resulting in closure of many of them.

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What we can do for you, is ..

- Find out Gaps
- Help you to make your VISIONS into a reality, by ..
  - Assisting you upgrading to the CGMP standards with rationale
  - Assisting you in exploring new Products, which can give your company a Firm base.
  - Assisting you in identifying New Markets outside India and helping you in penetration.

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Our Vision

- Develop and promote the Cost effective and High Quality Products with cutting edge Technology.
- To Support the Growing Healthcare industry by providing Technical & Regulatory support so as to ensure their sustenance in the highly competitive Global market.

Our Mission

Our Mission is to become most trusted partner in the Healthcare research in compliance with International Regulatory standards.

HAVISA HEALTHCARE

Our Values

- Professional excellence,
- Quality
- Commitment

Our Strengths

- Excellence in Quality
- Cost-Effectiveness
- Adherence & Compliance to the International Regulatory standards

HAVISA HEALTHCARE – Services

CONTRACT RESEARCH

- We perceive R&D differently at Havisa. The division is supported by a team of competent and experienced Scientists who continuously work for the development of Generic Drugs, Formulation trouble shooting, Cost reduction, Novel Drugs Delivery System (NDDS) and Abbreviated New Drug Application (ANDA) products.

We offer formulation development services across diverse dosage forms :

- Solid Dosage Forms
- Tablets
- Capsules
- Dry powder syrups/suspensions (In Sachets/bottles)
- Liquids Orals
- Ointments & Creams

HAVISA HEALTHCARE – Services

CGMP Consulting & Training

We provide the following services;

- Gap Analysis
- Gap Analysis and remedial action plans
- Auditing
- GMP Compliances, Schedule “M” implementation
- Facility Design with Environmental Classification
- Quality Management System Implementation
- Establishment of GMP, GLP & GWP.
- Establishment of ISO & HACCP standards with certification
- Third party audit on behalf of customers.
- Preparation of Master Validation Plan
- Identification of Validation requirements, Preparation of Validation protocols and execution of validations.
- cGMP Trainings
- Support to USFDA, WHO GMP, FDA, ISO, OHSAS certifications.
- Handling of Regulatory enquiries.

HAVISA HEALTHCARE – Services

Quality Control

- Evaluation of Quality Control systems
- Development of laboratory systems and specifications,
- GLP Compliance through Training & monitoring

HAVISA HEALTHCARE - Services

REGULATORY SUPPORT

- Preparation & Submission of Drug Master Files as per the recent ICH CTD guidelines for US, Europe, Canada, Korea, Japan in addition to other Technical Documents.
- Evaluation and handling of Post DMF changes.
- Handling of Regulatory and customer inspections.

HAVISA HEALTHCARE – Services

CONTRACT MANUFACTURING

We provide manufacturing support to our customers on Principle to Principle basis. We have contract with the cGMP compliant Manufacturing units in Excise free zones for manufacturing of our products.

The products are manufactured under technical guidance of Havisa Healthcare and Product quality is ensured by well experienced Quality Assurance personnel at Havisa Healthcare.

HAVISA HEALTHCARE - Team

- Havisa Healthcare has a synergistic pool of Experts, each with a specialization that has withstood the toughest tests of result-oriented International business environment.

- The company has a team of Professionals with proven track record in Healthcare Industry, specifically in Quality Assurance, Regulatory Affairs, Formulation Development. We have a Vision to utilize the expertize of team for the development of upcoming facilities to help them make at par with the Global standards.

HAVISA HEALTHCARE - Team

- The team includes the experts from various disciplines, to support the company as well as provide best services to our customers.
- Working with a spirit of “Business means Quality” HAVISA team is committed to provide best Quality Services to its customers.
- We emphasize on the quick Response Time & International Quality Standards to suffice our Customers.


Thank you