



**“Research Development and Innovation in  
Technology for Pharmaceutical Processing”**

**PHARMINTECH – 2007, Bologna, Italy**

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**“Indian Pharma Industry with Global  
Approach”**

**BY**

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# **Indian Pharma Industry**

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## **India**

- **Federal Republic, Democratic, 27 States +7 UT.**
- **Independent 1947.**
- **Regulatory Agency.**
- **Drugs Controller General of India.**
- **Chief Regulatory Agency (Import-Registration, Export, Manufacturing, Quality, Distribution, Price Control, New Drug (Product) Registration / Approval and Clinical.**
- **Each State has Commissioner / Director, FDA.**
- **Regulatory Agency for each State**  
**(For Manufacturing / Marketing Authorization**
  - **Manufacturing, Quality, Distribution, Wholesale and Retail).**



# Indian Pharma Industry

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## Journey to Advance Pharmaceuticals

**Pharma Industry**

**- 1947 ----- 2007**

**Galenicals**

**API**

**(Extracts, Tinctures  
and Spirits)**

**Dosage Forms**

**NDDS**

**Biotech**

**R & D, CRO**

**Clinical**

- 1) 1947 – Multinational Pharma Industry, Pre-dominant.**
- 2) 2007 - Indian Pharma Industry (Indian Multinationals), Predominates with 70% of Pharma Business (Pharma Industry – in Emerging Economy).**

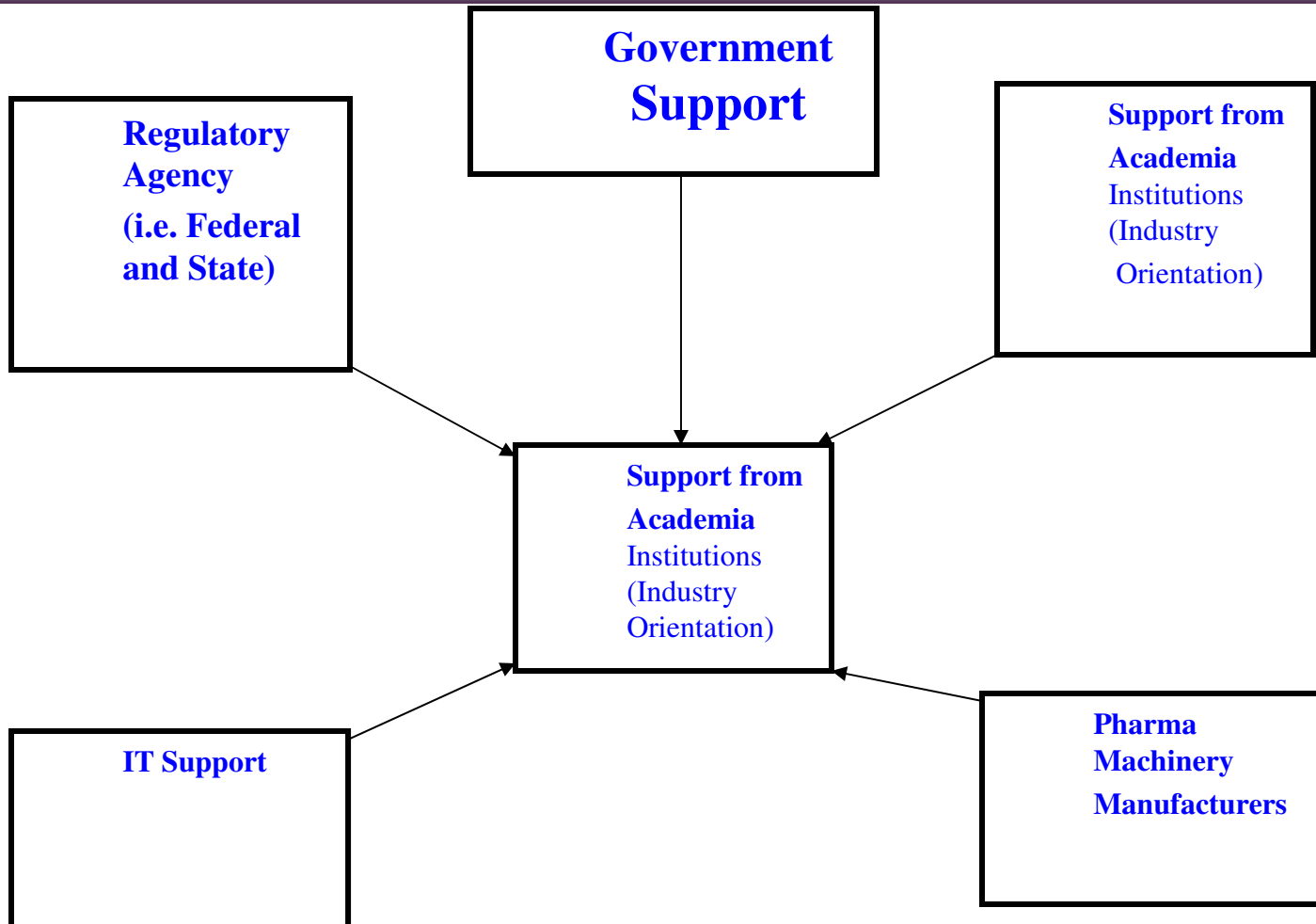


# **Indian Pharma Industry**

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- 3) Pharma Industry Heavily Regulated – Price Control  
(most Economical Cost of Medicines in India).**
- 4) IT, PT and BT ----- Priority Industries, Supported by  
Govt. Policies.**
- 5) Pharmaceutical Market in India – About US \$ 8.8 Billion  
(bn) (4th in volume and 13th in Value)**
- 6) Pharma – Biotech ..... 2007 – About US \$ 1.8 Billion  
(Biogenerics) (bn)  
(Vaccines – 60%  
Therapeutics – 30%  
Diagnostics – 10%)  
2010 – About US \$ 5 bn.**

# Indian Pharma Industry





# **Research Development and Innovation** **in Pharmaceutical Technology**

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- 1) Indian Pharma Majors – Launch average 10 – 15 Products (Innovative / Generic) per year.**
- 2) Projected Pharma Market by 2009 – about US \$ 12 bn.**
- 3) Automation – Innovative Cooperation between Pharma and Pharma Machinery Manufacturers (Process and Packaging Machinery – Intas and Pam).**
- 4) Innovation – Dedicated Oncology Facility (Solid Orals, Injectable – Liquid and Lyophilized) with Barrier Isolators – Contamination Control.**
- 5) PAT Compliant Machinery – NDA / ANDA, QBR Compliance.**
- 6) Bisect Angle Measurement – Assured Compliance to Ph. Eur. Divisibility Test for Tablets.**



# Advantage India

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- 1) **Jan. – Apr., 2007 – Foreign Institutional Investor (FII) Inflows to India cross US \$ 3 bn.**
- 2) **Out Sourcing Pharma from India – Cost Advantage of 30 – 40% in Site Transfer.**
- 3) **Setting up of World Class Pharma Facility (US - FDA) – Project Cost Reduction by 50% compared to that in US.**
- 4) **Next to US, Highest No. of US – FDA Approved Facility – API & Formulations (about 80), MHRA Approved Facility (about 75).**
- 5) **US – FDA, DMF (35%) and ANDA (25%) of the Total Filing from India.**
- 6) **ANDA – QBR and PAT Compliant Filing.**
- 7) **Outsourcing – Manufacturing, R & D, CRO, Pharma Education**
- 8) **Pharmaceutical Machinery – Economical, Exported to Western Countries.**
- 9) **English Speaking, Technically Qualified Human Resource.**



# Opportunities

## JVs / Tie up / Outsourcing / In-Licensing

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- 1) Automated – High Speed / Precision Pharma Machinery.
- 2) Outsourcing - Pharma Manufacturing.
- 3) Knowledge Outsourcing – R & D, Custom Synthesis.
- 4) Clinical Studies.
- 5) Biotech – Manufacturing, R & D, Development.
- 6) Area of Excellent Opportunity – Nano Technology, Genom, Automated Manufacturing Machinery and Quality System Equipment.





# Support from the Government

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- 1) US \$ 33.3 m Corpus Fund for Pharma R & D.
- 2) Patent (Third Amendment) Act, 2005.
- 3) Revision in Drugs & Cosmetics Act and Rules – Schedule Y, to permit Phase II – IV Clinical Studies in India.
- 4) Constitution of Indian Pharmacopoeia Commission.
- 5) Tax Holiday in certain Hill States for Pharma and Biotech Industry.



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**“Behind Best of the Technology There is a  
Human Factor which Revolves and Control  
Business Opportunity”**



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**Thank You  
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