

# Scope of Pharmacy & Clinical Research



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# Scope of Pharmacy

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- ❑ The **Indian pharmaceutical** industry at \$6.5 billion and growing at 8-10% annually, is **the 4th largest pharmaceutical industry in the world**, and is expected to be worth \$14 billion by 2010.
- ❑ Its exports are over \$2 billion. India is among the top five bulk drug makers and at home, the local industry has edged out the Multi-National companies whose share of 75% in the market is down to 35%.
- ❑ Trade of medicinal plants has crossed \$900M already.

# Scope of Pharmacy

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- ❑ There are **170 biotechnology companies** in India, involved in the development and manufacture of genomic drugs, whose business is growing exponentially.
- ❑ **Sequencing genes** and **delivering genomic information** for big Pharmaceutical companies is the next boom industry in India.
- ❑ India is also adorned by industry who are involved in Health Insurance, BPOs & Clinical Research including Clinical Trial, BA/BE studies, PK Studies, Data management, Pharmacovigilence.

# Scope of Pharmacy

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- India is most preferred country for clinical Research for several merits over other countries. Including domestic and MNC everyone is involved into it and it covers most of their R&D budget.

# Scope of Pharmacy

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## Statistics

- No. of Registered Manufactures=20,000
- 85% formulation sold in India and 60% of bulk drugs exported.
- After patent Act 1970, multinationals represent only 35% of the market, down from 70%.
- Highest US FDA approved Site = 74
- 20% of ANDA application to US FDA are expected to be filed from Indian Companies.

# Scope of Pharmacy

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## **Bill Gates words about India....**

- Gates emphasized that India had emerged as a major global IT hub not because of the availability of low-cost skills, as many believe. Rather, it had more to do with the "quality" and "world-class skills" to be found in India, he said. "The key is the quality of the human talent here. When people do software projects in India, they do so because this is the place they can find people with the latest skills. It is not on the (cheap) price (of labor)," he was quoted as saying by The Times of India newspaper. Gates had high praise for the "quality of educational institutions which could make India into an IT superpower." September 19, 2000

# Scope of Pharmacy

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- ❑ 1-Production and Manufacturing
- ❑ 2-Research and Development
- ❑ 3-Regulatory
- ❑ 4-Medico – marketing
- ❑ 5-Marketing and Sales

# Scope of Pharmacy

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- ❑ 6-QA/QC
- ❑ 7-Human Resource Management
- ❑ 8-Finance
- ❑ 9-Hospital Pharmacy
- ❑ 10-Community Pharmacy
- ❑ 11-Health Insurance Industries
- ❑ 12-Others (Herbal and Ayurvedic products, Gov. Jobs, IT, Research Institutions, Academics etc.)



# Clinical Research

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- ❑ 1-Preclinical and Toxicological studies
- ❑ 2-BA/BE Studies
- ❑ 3-Clinical Trial
- ❑ 4-Pharmacovigilance
- ❑ 5-Data Management

# Production and Manufacturing

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Those industries who are involved in preparation of

- ❑ 1-Bulk Drugs, Intermediates or formulations and dosage forms,
- ❑ 2-Blood and Plasma Products
- ❑ 3-Biological and Biotechnological Products
- ❑ 4-Veterinary Medicines
- ❑ 5-Cosmetics
- ❑ 6-Medical devices and machines
- ❑ 7- Others-Dental Products, Soaps, toiletries, Perfumery, Nutraceuticals

# Research and Development

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- New Drug Discovery Research
- Process and Development
- Formulation and Development
- Analysis and Testing

# Regulatory

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- Domestic and Local Regulatory
- International Regulatory

# Medico-Marketing

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- 1-Littrature Review
- 2-Collate Product Related Information
- 3-Preapre Training Materials
- 4-Plan and Arrange Marketing Meetings

# Marketing and Sales

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- 1-Marketing Plan
- 2-Product Management
- 3-Supply and Chain Management
- 4-Sale Management

# Quality Assurance and Quality Control

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- ❑ 1-Preparation and Review of Operation Procedures
- ❑ 2-Systematic and Independent Examination of Operational Activities
- ❑ 3-Standardized and Validate System as Required

# Human Resource Management

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- ❑ 1-Organizational Development
- ❑ 2-Employee Recruitment and Selection Process
- ❑ 3-Employee Compensation Benefits
- ❑ 4-Employee Relations
- ❑ 5-Policy Formulation



# Finance

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- 1-Preparation and Finalization of Budget
- 2-Preparation and Finalization of Finance Policy
- 3-Finalization of Agreements
- 4-Auditing of Finance Related Bills
- 5-Independent Monitoring of budget Allocation

# Job Opportunities

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- 1-Executives (4-5),
- 2-Sr. Executives (2-3),
- 3-Asst.Manager (1-2),
- 4-Deputy Manager (1-2),
- 5-Manager (1-2),
- 5-Sr. Manager (1),

# Hospital Pharmacy

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- 1-Main Pharmacy
- 2-Nuclear pharmacy
- 3-Satellite Pharmacy
- 4-Pharmacy and Dispensing Wing

# Community Pharmacy

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- 1-Apollo Pharmacy
- 2-Planet health
- 2-Medicine Shop
- 2-24 X 7 Pharmacy

# Job opportunities

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- ❑ Chemist,
- ❑ Jr. Pharmacist,
- ❑ Pharmacist,
- ❑ Clinical Pharmacist,
- ❑ Chief Pharmacist,
- ❑ Pharmacy Management

# Health Insurance Industries

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- ❑ ICICI Prudential
- ❑ Max Newyork Life Insurance
- ❑ Kotekmahindra
- ❑ LIC

# Others

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- **Government Jobs**
- 1-Drug Inspector
- 2-Food Inspector
- 3-Pharmacist
- 4-Chief Pharmacist
- 5-Gov. Laboratories

# Others

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## **Research Institution**

- ❑ CDRI, Lucknow
- ❑ NBRI, Lucknow
- ❑ CMAP, Lucknow
- ❑ ICMR, Delhi
- ❑ Dept. Of biotechnology, New Delhi



# Clinical Research

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- ❑ 1-No. of CRO in India – More than 150
- ❑ 2-No. of Pharma companies who are having their Clinical Research Dept. – 50
- ❑ 3-No. of Clinical Trials initiated per year - 80-100 (Phase-I to IV)
- ❑ 4-No. of Bioequivalence studies - 800-1000 (For Different Regulatory Submission)
- ❑ 5-No. of Preclinical and Toxicological Studies – 1500-2000

# Clinical Research

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## Why India .....

- ❑ The pull factors
- ❑ Speedy Regulatory Approvals
- ❑ Shorter Time Period
- ❑ Gene pool advantage
- ❑ Large and Faster Growing Talent and Resource pool
- ❑ Infrastructure
- ❑ 30–50% overall cost advantage in undertaking drug trials in India

# Clinical Research

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## Why India.....

- ❑ Credible Data Quality
- ❑ A wide range of diseases are prevalent in India
- ❑ Ethics
- ❑ Intellectual Property protection
- ❑ Growth of the global clinical research sector benefits the Indian patient
- ❑ Resource Development Initiatives

# Clinical Research

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- ❑ Preclinical and Toxicological studies
- ❑ BA/BE Studies
- ❑ Clinical Trial
- ❑ Pharmacovigilance
- ❑ Data Management

# Clinical Research

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- 1-Administration
- 2-Business development
- 3-Medical Writing
- 4-Pharmacy management
- 5-Clinical Operation

# Clinical Research

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- 6-Quality Control
- 7-Quality Assurance
- 8-Biostatistics
- 9-Bionalytical
- 10- Data Management.
- 11- Site management- Investigators, Nurses, Coordinators, Research Asst., and Pharmacist

# Clinical Research

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## **Job Opportunities**

- ❑ Executives,
- ❑ Sr. Executives,
- ❑ Research Asst.,
- ❑ Clinical Research Associate,
- ❑ Sr. CRA,
- ❑ Research Scientist – I-III,
- ❑ Asst. Manager,
- ❑ Deputy Manager,
- ❑ Manager,
- ❑ Sr. Manager.



THANK YOU !