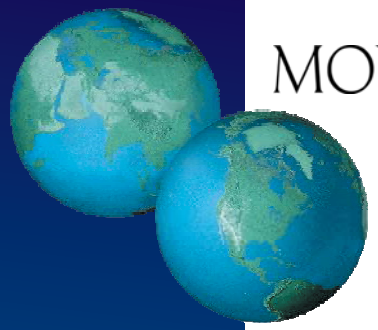

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Outsourcing Opportunities in Indian Pharmaceutical Industry

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Outsourcing Opportunities in Indian Pharmaceutical Industry

(iii) While every care has been exercised in compiling this report, OPPI / Monitor Group will not be liable for consequences of anyone's actions arising out of reliance placed on information contained in this Report.

OPPI MISSION

To serve the collective interests of the Members professionally so as to ensure a healthy environment for profitable growth while making a continuing contribution to Healthcare aims of the nation.

Foreword

The Pharmaceutical Industry in India is increasingly being recognised as a reliable source of quality medicines at affordable prices and is emerging as a global powerhouse. With U.S.$ 4.5 Bn. in domestic sales and another U.S.$ 2 Bn. in exports, it has acquired its place in the sun. Recent projections suggest a market size of U.S.$ 25 Bn. by the year 2010. Despite this success, the industry has not been able to attract sufficient foreign and domestic investment largely due to weak Intellectual Property Rights (IPR), stringent price controls and infrastructural weaknesses. Apart from this, in our experience many pharmaceutical companies in India find it difficult to convince their overseas affiliates to invest in India due to perceived lack of quality and reliability. This, however, does not portray the true picture as there are numerous examples of manufacturers that can deliver on the most exacting quality and reliability standards. While the usual focus of India's advantage is on the lower labour costs, other factors like the skills of Indian chemists at process chemistry, availability of large patient pool for clinical trials, well developed ancillary industry and the highest "intellectual capital per dollar" tend to get ignored.

It is to dispel these notions and highlight the opportunities offered by outsourcing to India in the pharmaceutical industry that we undertook this project in collaboration with the Monitor Group. Founded by Harvard Professors Michael Porter and Mark Fuller and a group of their colleagues in 1983, Monitor has vast experience in the healthcare and pharmaceutical industry.

This report is the outcome of extensive research conducted by Monitor and OPPI in India and overseas. I hope that the report not only helps provoke thought but also results in an increase in outsourcing to India.

I look forward to your critical evaluation of this maiden exercise and invite your comments and suggestions to improve it further.

Dr. Ajit Dangi
Director General
OPPI

Executive Summary

- The global pharmaceutical outsourcing industry has shown rapid growth in the recent past and all indicators portend a similar growth going forward. The attractiveness of outsourcing lies in its ability to reduce costs, share risks and improve time to market

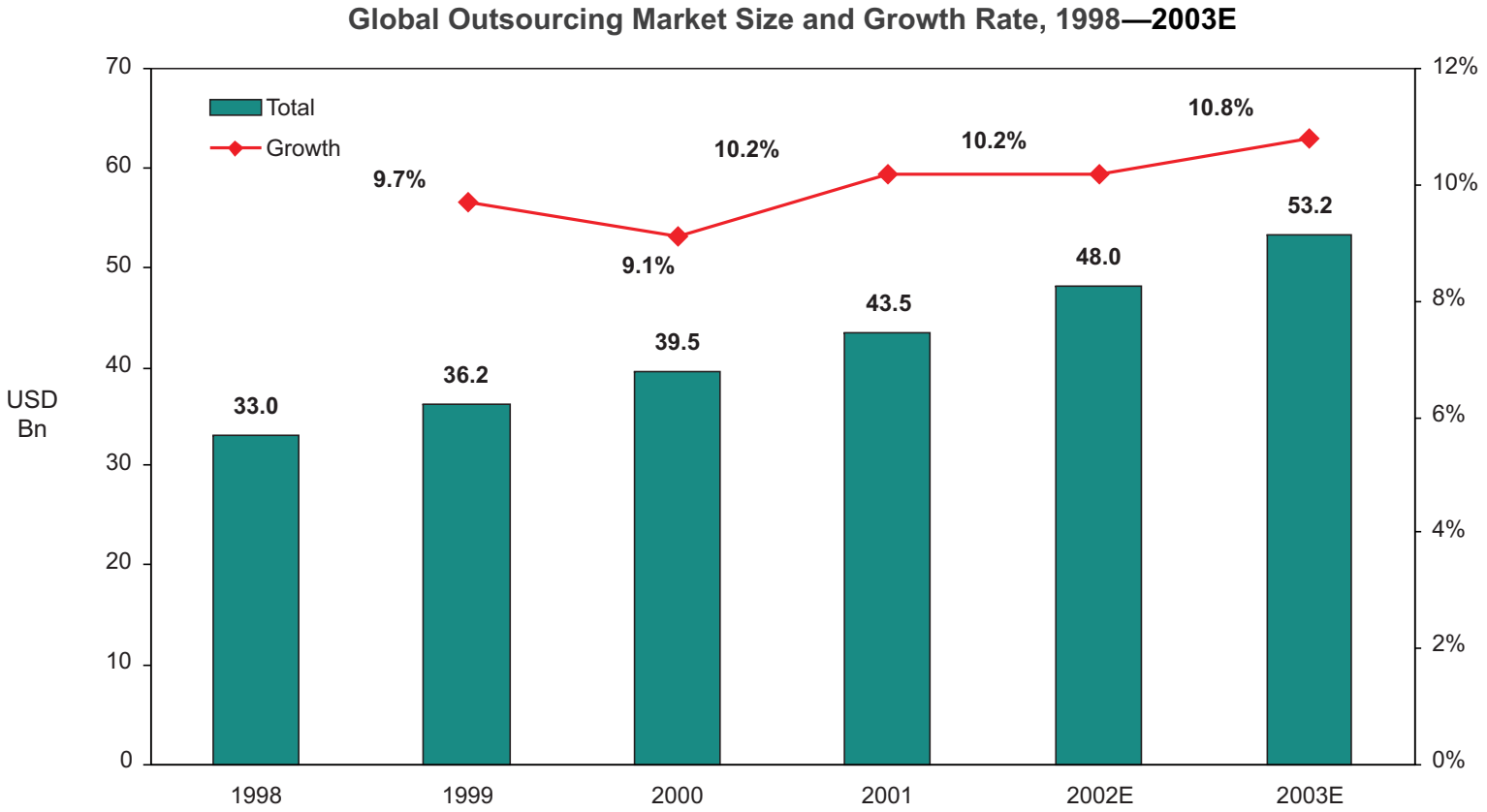
- Opportunities for outsourcing exist across the entire pharma value chain
  - Contract manufacturing is the traditional outsourcing activity and accounts for the bulk of outsourcing today
  - Other activities like contract research, contract sales and informatics are small but expected to grow at a fast pace

- India offers multiple advantages to potential outsourcers:
  - Cost advantage: for all factor inputs including labour (at all levels), raw materials, equipment
  - Technical skills: in chemistry, biotechnology, process engineering and IT
  - Availability of abundant English speaking skilled manpower
  - Large patient population: providing a diverse pool for clinical trials

- Despite these advantages, India has barely scratched the surface of the outsourcing opportunity. There is immense potential to grow the outsourcing market to India
  - A conservative 5% share of global contract manufacturing will more than double India's pharmaceuticals exports

Contents

Global pharmaceutical outsourcing market is growing at a rapid clip



Source: Monitor analysis

Increasing pressure to reduce costs and enhance efficiencies has been instrumental in driving this growth…

- Pressure on pharmaceutical companies from investors to boost efficiency — develop greater quantity of new drugs at faster speed and lower cost

- Ethical manufacturers have had to focus on R&D and marketing, where they are likely to generate the most value for shareholders. Spiraling R&D and marketing costs have forced them to evaluate cost reduction options like outsourcing
  - Global pharmaceutical and biotechnology R&D spending grew at 11% CAGR from 1998 to 2001
    - Global R&D spend in 2002 was estimated at USD 40 Bn
  - Marketing costs grew at CAGR of 10% during same period

- Additionally, increasing pressure on prices point to a squeeze on margins
  - Government managed care plans aim at reducing the costs of prescription drugs or limiting their distribution or usage
    - Managed care plans, government programs (e.g., Medicare and Medicaid), and employer groups have been instrumental in promoting the usage of generic drugs to reduce the costs of healthcare

Source: Merrill Lynch; Advest; OPPI; Monitor analysis

… other strategic considerations have also led to an increased reliance on outsourcing

- Access to technology
  - Decision to outsource API is often made in order to access special technology(s) that requires substantial capital investment

    "We are most likely to go out at the beginning [of the product life cycle] if a new technology is required or the product has high uncertainty"
- Reduce time to market
  - Shortening patent exclusivity periods have increased pressure on pharmaceutical companies to reduce time to market (for new molecules)
  - Removing potential production bottlenecks — by outsourcing the new drug or some of the older drugs (to free up capacity) — help reduce time to market
- Opportunity to share risks
  - Outsourcing some of the process research and development activities effectively passes on a portion of the risk to the contractors
- Access process development and production capabilities
  - Emergence of numerous small research companies (often small biotech companies carrying out drug development) with limited process development and production capabilities

Source: Merrill Lynch; Chemical Market Reporter;
Interviews with major global pharma companies; Monitor analysis

Notwithstanding the attractiveness of outsourcing, certain systemic issues limit its use

Overcapacity

- Many large pharma companies currently have excess capacity in some areas that they would like to utilize before considering outsourcing

  "We are awash in excess capacity in standard chemistry and fermentation"

  "[Our] preference is to bring production back in-house to leverage infrastructure and competence"

Supplier Quality and Compliance

- Concerns about supply reliability and compliance outweigh the perceived advantages of lower costs from outside contractors

  "Quality is by far the number 1 issue. The biggest weakness of the contract manufacturers we have worked with, has been their lack of understanding of quality standards and their commitment to achieving them"

Potential Loss of Tax Advantage

- Fear of losing tax incentives offered in countries like Singapore and Ireland

  "Tax is a primary determinant in our outsourcing decisions. We currently have a very good tax structure for both API and formulation facilities"

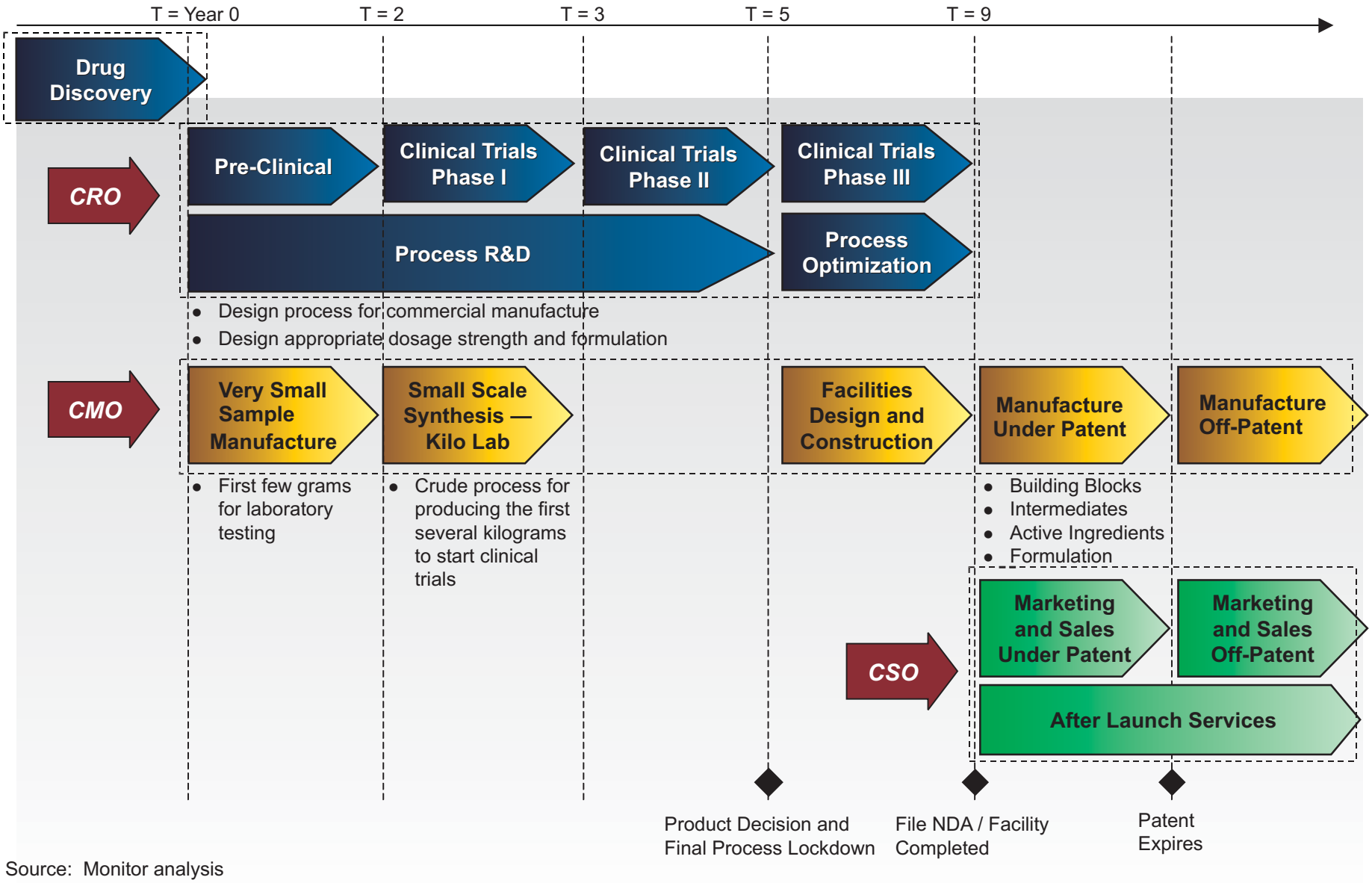
  "We put our final four API steps in tax advantaged locations"

Organizational Structure

- In most global pharma companies, country heads still have major say in location of manufacturing thus bringing in an "emotional" aspect to the outsourcing decision
  - However, global manufacturing function is gradually taking a stronger role in most MNC's allowing decisions based on economics

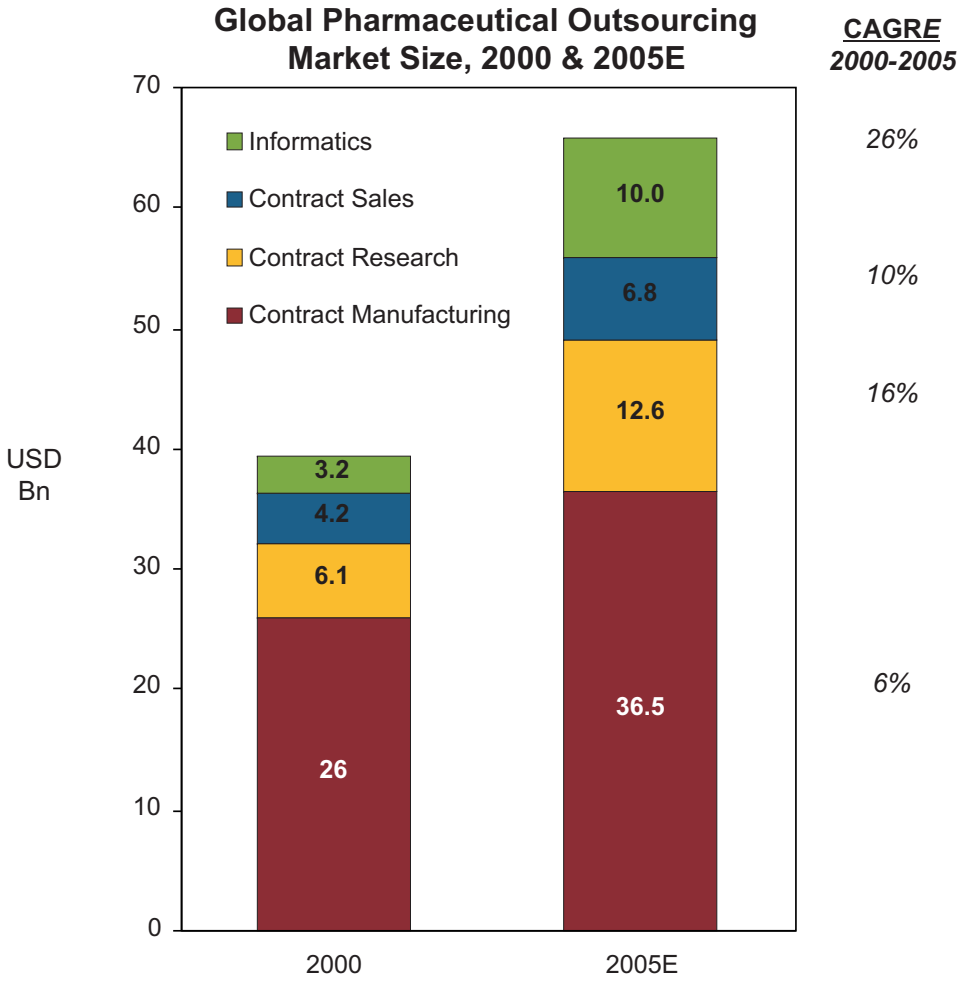
Source: Interviews with global pharma majors; Monitor analysis

Outsourcing opportunities exist across all stages of the value chain



Source: Monitor analysis

Contract manufacturing accounts for the majority of the global outsourcing market



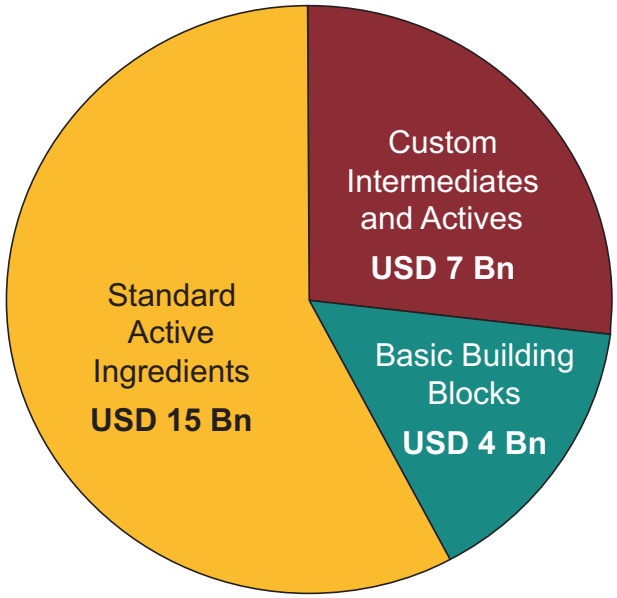
- **Contract Manufacturing** - development and supply of intermediates, active ingredients, custom solutions for drug substance and dosage-form production.
- **Contract Research** - providing both contract research and development products and services to the pharmaceutical, biotech, and medical device industries
- **Contract Sales** - providing commercialization and post-approval support services to drug sponsors
- **Pharma Informatics** - providing information-based technology solutions and systems tool kits aimed at deriving value from the massive quantities of data generated throughout the drug development continuum. Spans the entire healthcare domain (e.g., clinical trials data and healthcare claims data)

Source: Monitor analysis

Active ingredients account for the largest proportion of chemicals used in the manufacturing process

CMO

Purchased Chemicals Used in the Pharmaceutical Industry, 2001



Total = USD 26 Bn

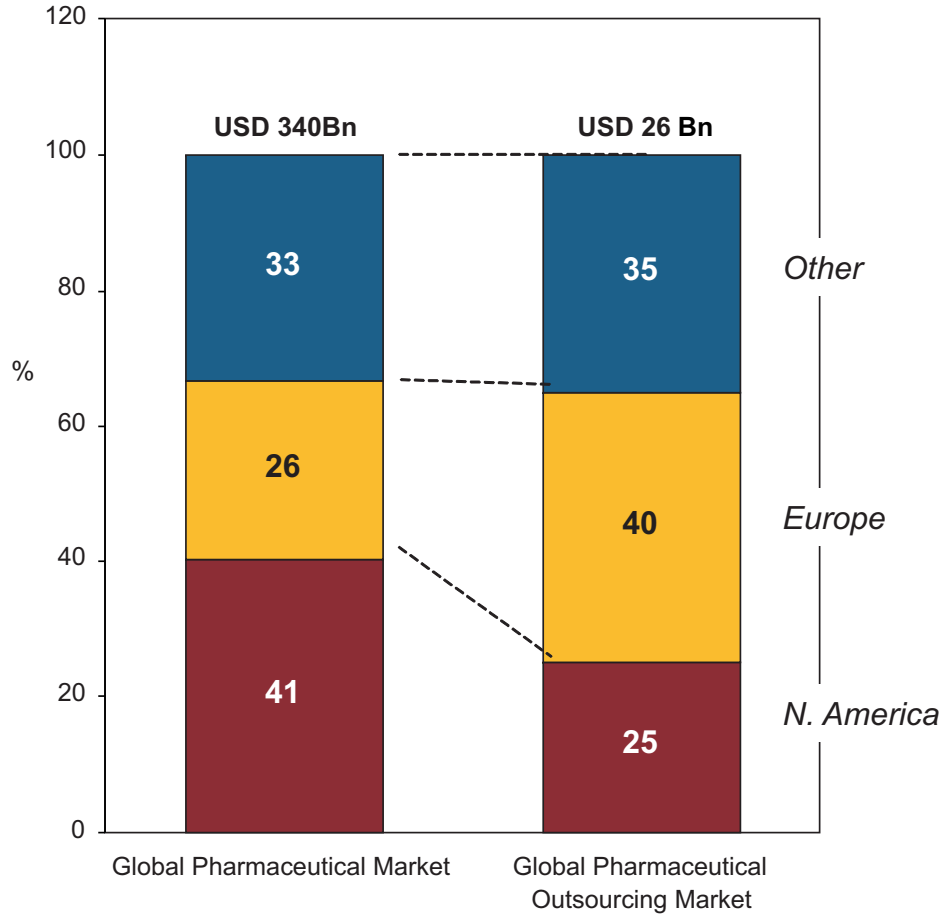
- **Basic Building Blocks**
  - USD 4 Bn market, constitutes the smallest portion of COGS
  - Not a key focus for outsourcing as these can easily be procured from the open market
- **Custom Intermediates and Actives**
  - With USD 7 Bn total market market, this market is smaller than API's but is of key interest for outsourcing
    - Depth of outsourcing relationship as important as other factors like technology, reliability, scale etc.
  - Expected to show the fastest growth rate going forward
- **Standard Active Ingredients**
  - USD15 Bn market size, the largest share of COGS
  - Growth rate expected to be in line with overall pharma growth

Source: Merrill Lynch; Monitor analysis

Europe is the largest originator for contract manufacturing

CMO

Regional Breakdown of the Global Pharmaceutical and Outsourcing Markets, 2000



- Europe is the largest outsourcing market, one of the reasons driving this is the greater cost pressure that European pharma companies operate under

  "In Europe, government has strict cost control over prescription drugs"

- Contract manufacturing in US is also expected to grow as North American pharma companies also come under increasing price pressures

  "US pharmaceutical companies are starting to feel significant pressure from market, government and managed care to lower drug costs"

Source: IMS Health; Chemical Market Reporter; Interviews with global pharma majors; Monitor analysis

Contract manufacturing is expected to grow at slightly higher than overall pharma growth rate

CMO

Strong Growth in Pharma Volume

- Most analysts expect global pharmaceuticals industry to grow at 8-10% in volume terms
  - Expectations based on ageing population, increased prevalence of diseases requiring chronic care and increasing penetration in developing countries

Increased Outsourcing by Large Pharma Companies

- Severe pressure to prices from HMO′s, governments and generics players will force companies to look at outsourcing to keep costs under check
- Outsourcing estimated at between 30%–50% of primary COGS
- Wide range of opinions with regard to future outsourcing. Pharma companies expect outsourcing to grow at a rate of 8%–10% (in line with pharma growth) vs. 15% claimed by some experts, analysts and chemical companies

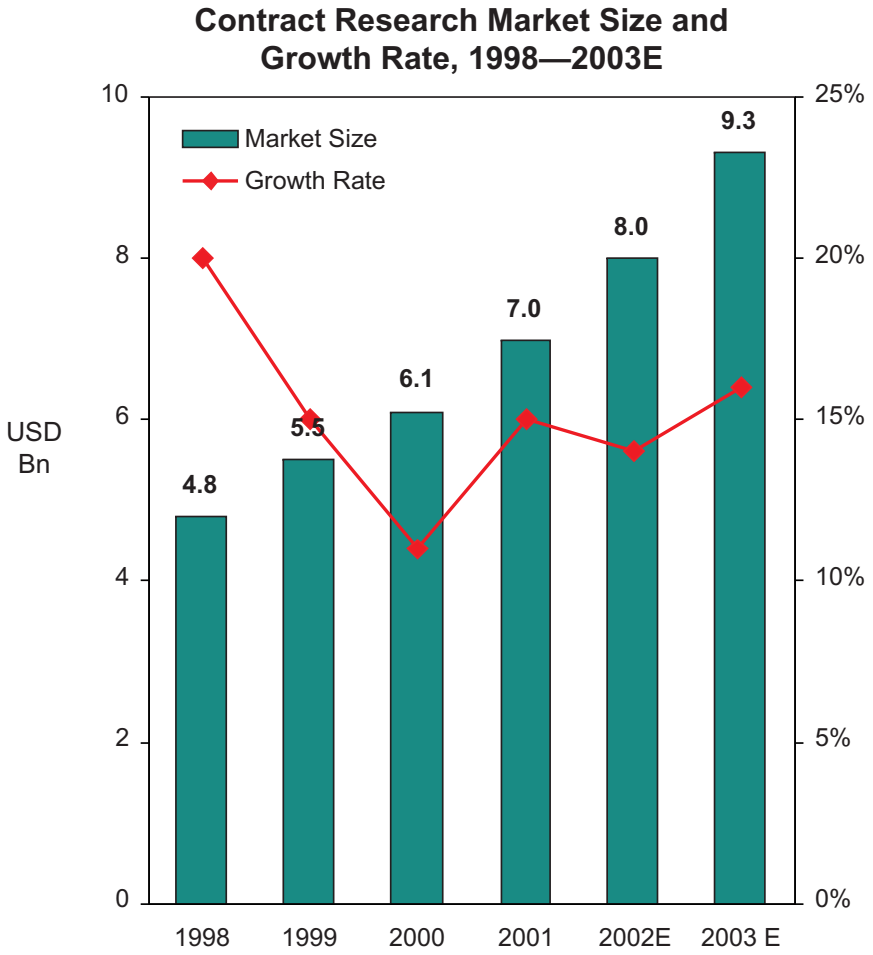
Biotechnology Expansion

- Outsourcing by biotech companies expected to grow at a fast clip
  - Although only 7 biotech products were launched in 1999, an estimated 900+ biotech products were in pre-clinical development
  - Many biotech companies have little or no process development / manufacturing capabilities indicating an opportunity for contract manufacturers to help bring these molecules to market

Source: Merrill Lynch; Monitor analysis

Contract research plays an increasingly important role in many large pharmaceutical firms

CRO



- Contract research took off in the early '90s and achieved explosive growth (35%-45% p.a.) as:
  - The business model was widely accepted by large pharma companies
  - CRO's widened their basket of products and services
- The growth rate has since slowed due structural changes in the industry
  - Industry consolidation has forced many firms to revaluate drug development pipelines
  - Many previously viable products in the pipeline had to be killed due to increasing sales potential thresholds (resulting from higher commercialization expenses)

Source: PhRMA; Parexel; Monitor analysis

Current industry environment suggests that contract research will continue to grow

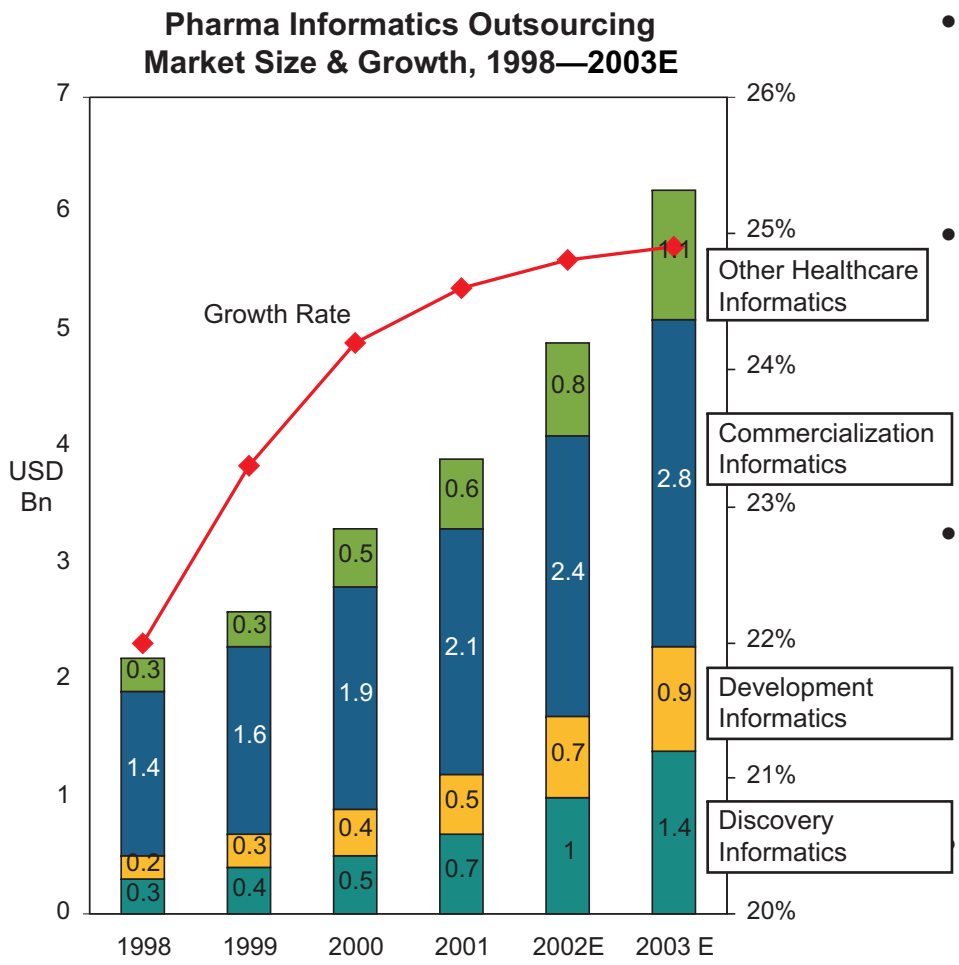
CRO

- R&D expenditure continues to balloon while suffering from declining productivity and increasing complexity of management
  - According to an estimate, it costs a company about US$ 800 MM to get a drug from the laboratory to the patients in the US
- Periods of exclusivity for innovators are getting shorter thus increasing pressure on speed to market
  - For a blockbuster, each day's delay could potentially result in lost sales running into millions of dollars
- Unprecedented wave of patent expirations are creating new discovery challenges
  - About 24 drugs with annual sales over US$ 500 MM will go off-patent in the first half of this decade (2000-2005)
- Intention to capitalize on the "molecule bulge", driven by biotechnology, genomics, and other discovery technologies
  - "Molecule bulge" will be key to meeting the challenges of developing the required number of NCEs in order to continue historic pace of revenue and earnings growth
- Cost containment in the face of the increasing size and complexity of clinical trials
  - Average number of clinical trials required for drug approval have more than doubled from 30 in1980 to 80 today

Source: Advest; National Bank Financial "Canadian CMO for Pharmaceutical Industry" 2001; Tufts Center for the Study of Drug Development; Monitor analysis

Pharmaceutical informatics is a fast growing market

Informatics



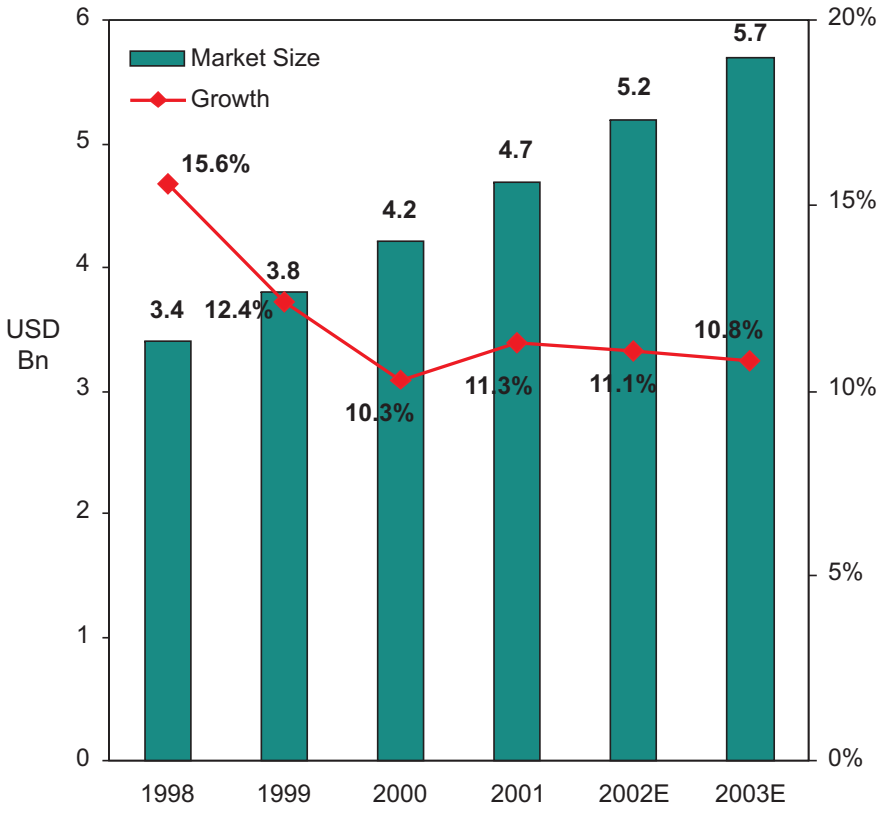
- **Discovery informatics** (or Bioinformatics) is the area witnessing the most activity
  - Mining massive databases and turning the information into knowledge and eventually innovative discoveries has the direct impact on the top line
- **Development informatics** has good potential
  - The drug development process remains highly inefficient, with 85-90% of clinical trial information in paper-based form
  - There are needs to improve clinical patient recruiting, currently a major bottleneck and area of inefficiency in the development process
- **Commercialization informatics** expected to continue its growth
  - Increasing competition from “me to” drugs makes sales and marketing execution critical
  - High competition for doctor’s time
  - The ability to tailor drugs to more specific populations can act as a differentiator
- **Other healthcare related informatics** appears promising
  - There are few integrated systems to capture and mine data generated by healthcare businesses
  - Data mining and integration with the drug development continuum key to unlocking its value

Source: Advest; Interviews with global pharma majors; Monitor analysis

Contract sales is a relatively small but fast growing outsourcing activity

CSO

Global Contract Sales Market Size and Growth, 1998—2003E



- Contract sales organizations (CSO's) began in the United States in the mid '90s by providing sales force training and recruitment services
- Over the years, CSO's have expanded their suite to include sales force management, product launch management, marketing strategy, medical communications, educational events & symposiums and other related services
- Growth is expected to continue due to pressure on ethical manufacturers to:
  - Increase flexibility and reduce fixed overheads
  - Reduce costs
  - Focus (on blockbusters with own specialized sales force while the CSO services the older molecules)

Source: Scott-Levin; IMS Health; Advest; Monitor analysis

Conclusions

- The global pharmaceutical outsourcing industry has shown rapid growth in the recent past and all indicators portend a similar growth going forward. The attractiveness of outsourcing lies in its ability to:
  - Reduce costs
  - Share risks
  - Improve time to market, etc.

- Opportunities for outsourcing exist across the entire pharma value chain
  - Contract manufacturing is the traditional outsourcing activity and accounts for the bulk of outsourcing today
  - Other activities like contract research, contract sales and informatics are small but expected to grow at a fast pace

Contents

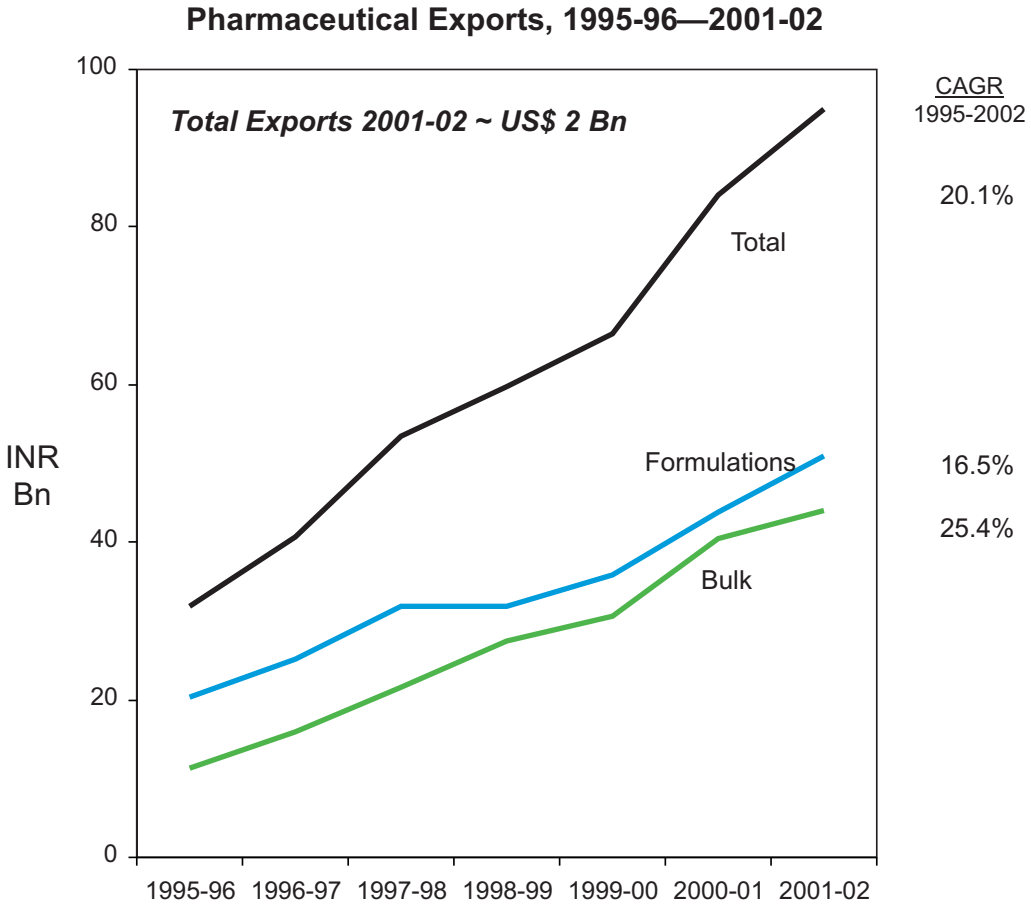
Overview

- Manufactured exports (API and formulations) account for the bulk of the current outsourcing activity in India

- Contract research and informatics are nascent activities that have taken root only in the past few years. Contract sales is non-existent

- India's advantage in outsourcing stems from:
  - Cost advantage in FDA approved manufacturing facilities: for all factor inputs including labour (at all levels), raw materials, equipment
  - Technical skills: in chemistry, biotechnology, process engineering, API technology and IT
  - Availability of abundant English speaking skilled manpower
  - Large patient population: providing a diverse pool for clinical trials

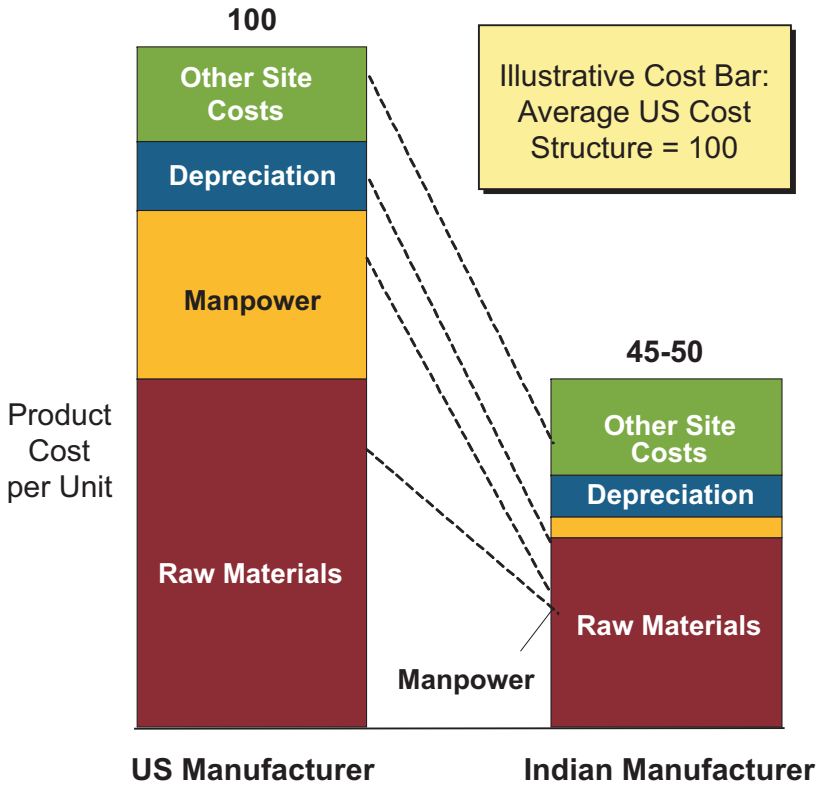
Pharmaceutical exports from India have been growing fast



- Most formulations are exported to developing countries:
  - Many of these countries do not recognize product patents
  - Also, a number of these countries do not have a well developed domestic pharmaceutical manufacturing industry
- In the past decade, many Indian manufacturers have focused on growing exports of generic formulations to developed countries like the US
  - Some companies have entered into distribution arrangements with existing pharmaceutical players in countries like the US while others have set up their own operations
- Bulk drugs are primarily exported to North America and Western Europe

Source: OPPI; Press reports; Monitor analysis

Exports have been aided by India's significant cost advantage…



Basic production costs in India up to 50% lower than in the US

30-50% lower depreciation

- FDA approved plant can be constructed in India for 30-50% lower cost
- Higher utilisation of equipment due to improved processes (not quantified)

85-90% manpower cost savings

- Labour costs in India typically 10-15% of the cost in the USA
- Savings applicable across all personnel (e.g., operators, research scientists, etc.)
- Improved, more efficient processes contribute to lower labour costs per unit (not quantified)

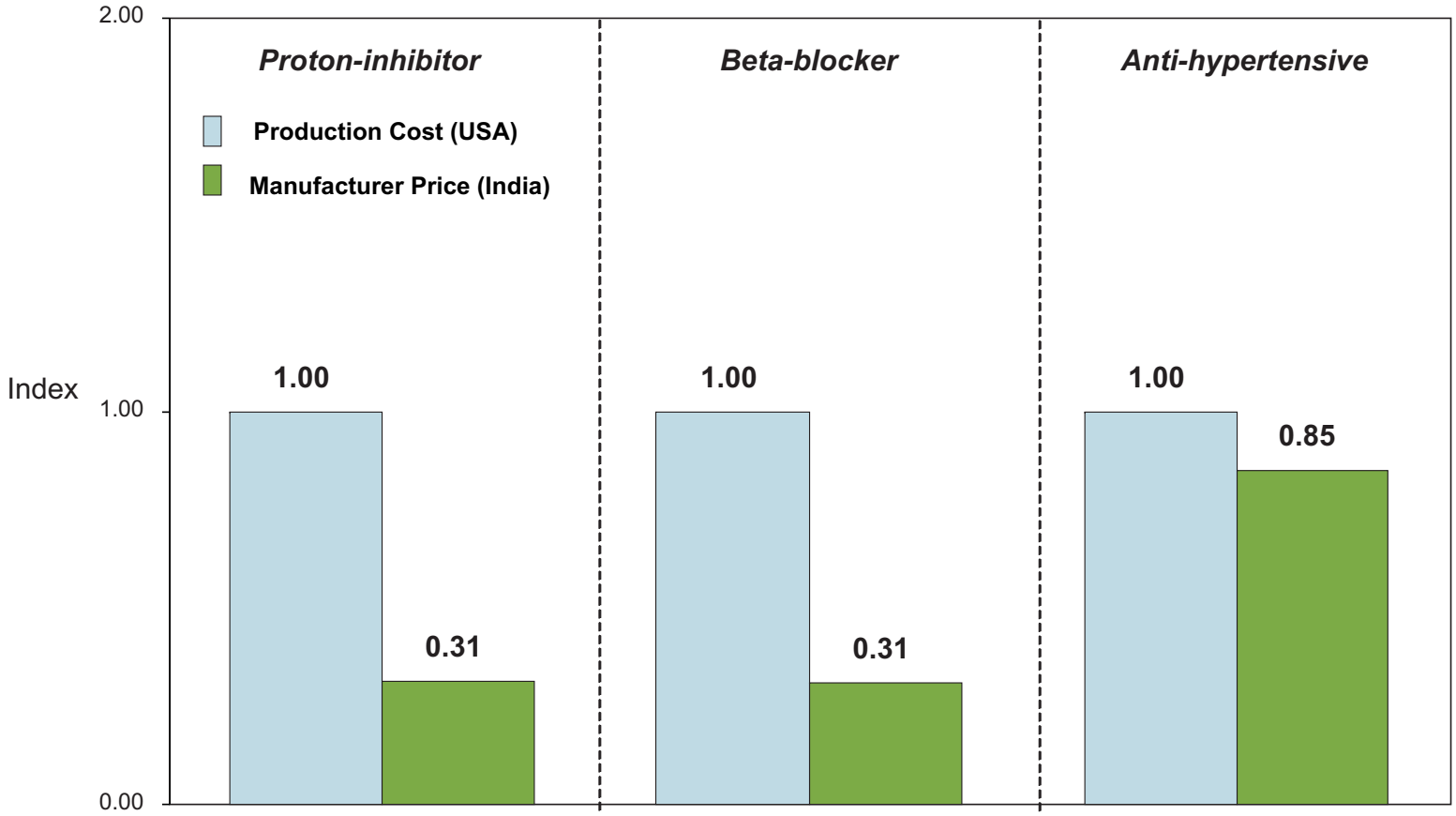
40-50% savings in raw materials

- Bulk drug can be manufactured in-house at 40-50% of ethicals' cost (due to similar sources of advantage to full tablet manufacturing)
- Excipients and intermediates sourced locally at 20-30% lower cost
- Most other raw materials can be sourced locally

Note: Estimates. The illustrative cost advantage does not include potential gains from lower overheads and process efficiencies
Source: Interviews with industry participants; Monitor analysis

…and it is not uncommon to find the manufacturer selling price in India to be lower than the production cost in the US

***Illustrative*: Current Production Costs in USA vs. Indian Manufacturer Selling Price**



Note: US production cost includes raw material, labor, overheads etc., but does not include R&D expense amortization. Indian manufacturer price includes all costs including labor, raw material, overheads, sales and distribution cost, depreciation etc.
Source: IndiaInfoline; CVS; Price comparisons for pharmaceuticals: A review of U.S. and cross-national studies, Wharton; Monitor analysis

Indian manufacturers have also demonstrated their skills in process engineering and technology

Rapid Reverse Engineering

- Indian companies have mastered the art of reverse engineering and are usually able to reverse engineer a molecule within months of its introduction
  - Due to the current patent regime, many Indian manufacturers launch reverse engineered versions of ethicals within a few months of global launch e.g. amlodipine, ciprofloxacin etc.
  - However, this loophole in the patent laws will be plugged post 2005

Process Improvement and Synthesis of Complex Molecules

- Many Indian manufacturers also have the capability to synthesize complex molecules and improve on the manufacturing process
  - Wockhardt is one of the few companies in the world that manufactures human recombinant insulin, the company believes that its yeast technology is superior to Novo Nordisk's yeast technology and Eli Lilly's e-coli technology used to manufacture insulin
  - Ranbaxy has developed and are marketing once-a-day ciprofloxacin dosage form
  - Lupin has launched once-a-day cephalexin dosage form

Adept at Latest Technology

- Indian manufacturers are also adept at using the latest manufacturing techniques, e.g.
  - Wockhardt uses hydrogenation for molecule transformation for anti-asthma, anti-ulcerants and other therapeutic segments
  - Manufacturers like Wockhardt, Biocon, Dr Reddy's etc. are increasingly focusing on biotechnology for synthesizing enzymes, hormones etc.
  - Many of these manufacturers are also adept at technologies like chiral synthesis, peptide synthesis etc.

Source: Company websites; News reports; Analyst reports

The range of drugs sourced is a testimony to the quality and cost advantage of Indian manufacturers

Examples of Global Pharmaceutical Companies Sourcing From Indian Manufacturers

Buyer	Country	Product	Example of Indian Supplier
Eli Lilly	US	Range of APIs	Ranbaxy
Bristol Myers Squibb	US	Doxycyline, amoxycillin API	Ranbaxy
Ferring	Netherlands	Range of APIs	Wockhardt
Cyanamid	US	D2aminobutanol (intermediate)	Lupin
American Pharmaceutical Partners	US	Cephalosporins	Lupin
Wyeth	US	Intermediates	Lupin
Merck Generics	UK	Cephalosporins	Lupin
Aventis	Europe	Glibenclamide	Aventis India

Source: Company websites; Newspaper reports; Analyst reports

Indian subsidiaries of MNC's recognize this opportunity and are increasingly looking to act as sourcing bases for their global operations

"We have set up an entity called the Healthcare Development Center (HDC) that is a global center for the sourcing of generics that are sold by our own generics companies such as Geneva Pharma … today there is an impressive list of molecules that is sourced from India"

— Ranjit Shahani, CEO, Novartis India Ltd

"We have set up a formulations plant with world-class GMP standards in Goa … we are looking at using it as a sourcing base for mature formulations"

— Ranga Iyer, MD, Wyeth Ltd

"We are in talks with Bayer affiliates in Latin America and Eastern Europe for supply of generics…we would get most of the drugs manufactured through local US FDA approved sub-contractors"

— Raghu Kumar, Former CEO, Bayer India

"*We are setting up a new plant in Goa that manufacture older products for supply to Western Europe"*

— Ramesh Subramaniam, CEO, Aventis India

Source: Interviews with OPPI members

India also offers competitive advantages in research and informatics

Availability of Healthcare Infrastructure

- Existing healthcare infrastructure can be leveraged for clinical trials

  "Hospitals in India treat a vast range of diseases…its convenient to work with a single hospital to get access to a range of therapeutic areas. In the US, many hospitals are TA specific, which makes recruitment slower and tedious. In addition, doctors in India are easily available and willing to become investigators for clinical trials"

  – S. Ramakrishna, VP, Pfizer

Large & Diverse Patient Pool

- Large patient population provides a good pool for recruitment
  - Diverse range of diseases and a significant population of patients with a combination of diseases provides a good sample base
  - Relative underexposure to drugs provides a sample with little cross effects

Skilled Manpower & Technical Skills

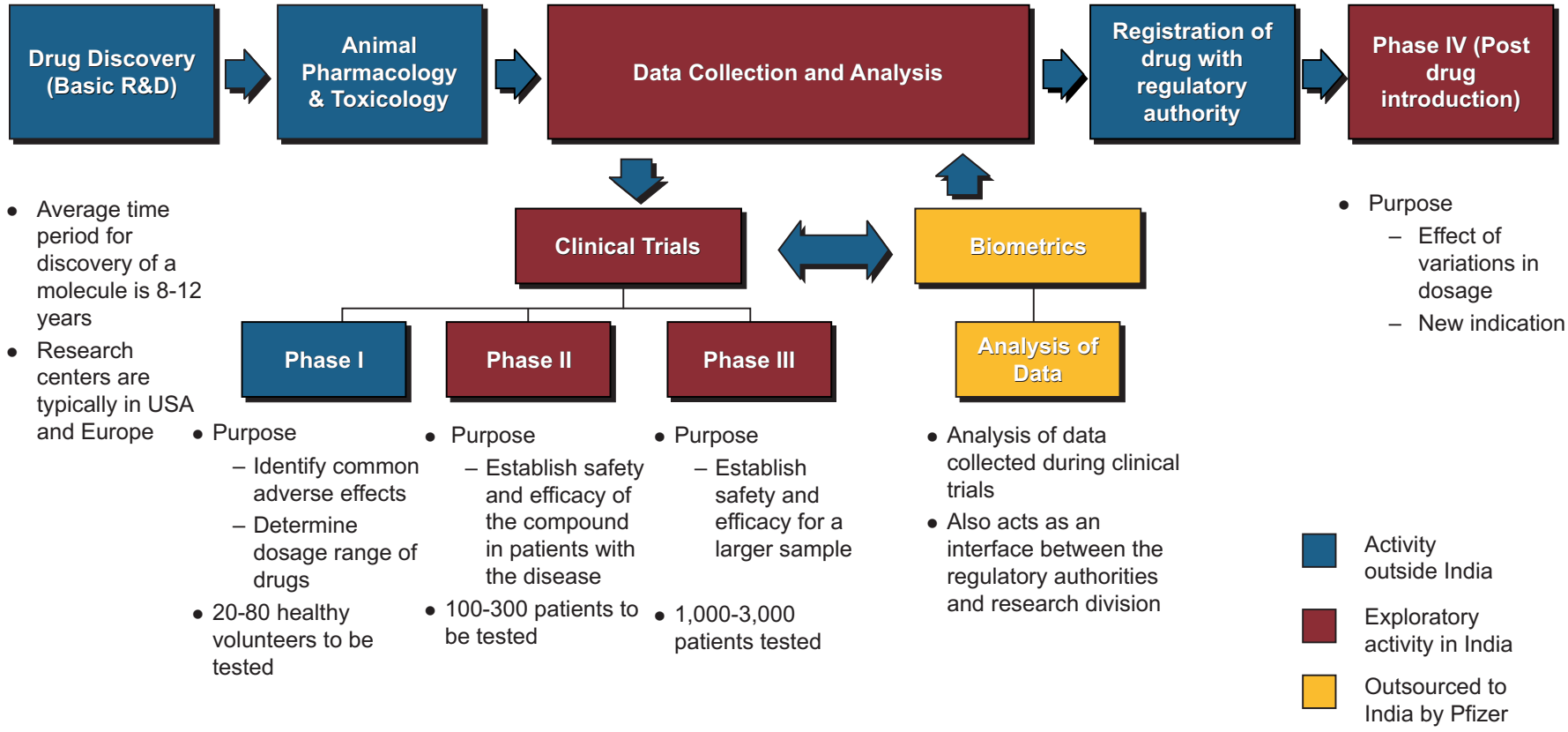
- Strong educational system yields skilled pool of doctors, chemists, statisticians and computer engineers
  - Cost of labour significantly lower in India (compared to the developed world) across professions
- Well established IT industry in the country provides an edge in data mining and software development

Source: Interviews with OPPI members; Monitor analysis

Indian experience in informatics and contract research is recent and has been pioneered by Pfizer

Case Study

The Drug Discovery and Development Process



"The drug development process, right from the drug discovery stage to the full development of the drug may take 12 to 24 years and costs about US$ 500MM"

— Pfizer

Source: Interviews with OPPI members; News articles

Pfizer set up a biometric center in India to leverage the Indian cost advantage

Case Study

- Biometric activities include data entry, data management and statistical analysis of global clinical trials data
- Pfizer determined that biometrics would leverage the key advantages of India
  - Competitive labor cost
  - Large pool of technically qualified workforce (statisticians and doctors)
  - English language ability
- In 1997, the first Pfizer biometric center in Asia was set up in India
  - Investment of US$ 3 MM
  - 18 months set up time

Pfizer Global Biometric Centers — 2002

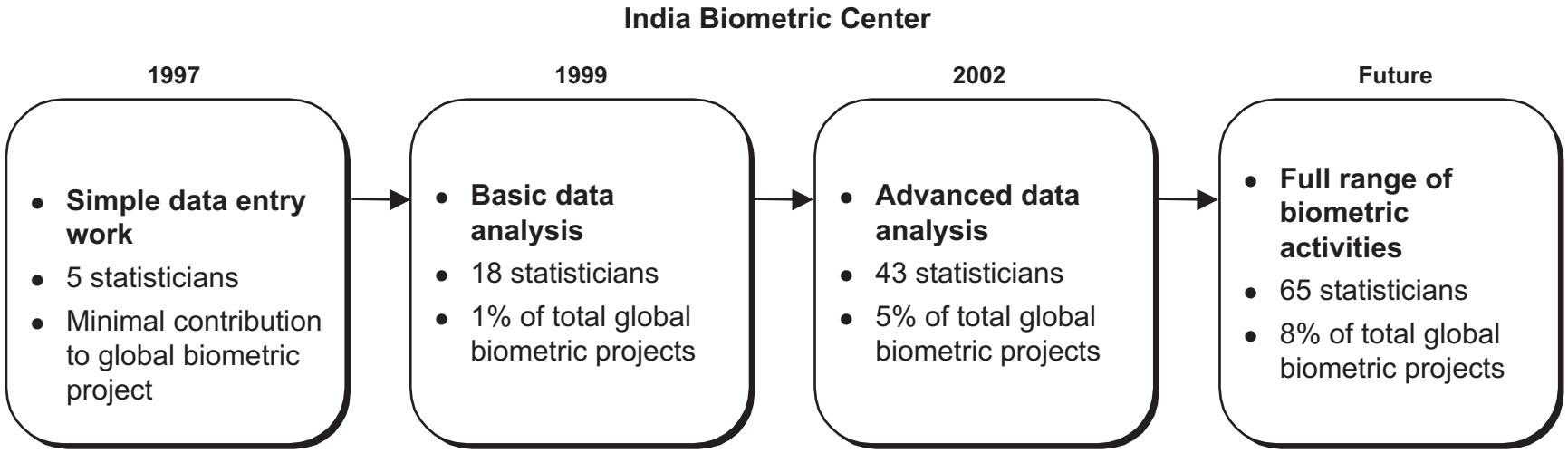
"India ranked high on availability and quality of qualified personnel … and at a competitive cost"

— Dr. Potkar,
Director R&D, Pfizer India

Source: Interviews with OPPI members; News articles

Over the last 5 years, the Indian Biometric Center has grown dramatically

Case Study



"Pfizer has already invested US$ 10 MM in the biometric unit in India and plans to increase this multifold over the next few years"

— Business Standard

"I would not be surprised if eventually India did the bulk of Pfizer's global biometric activity"

— Dr. Potkar, Director R&D, Pfizer India

Source: Interviews with OPPI members; News articles

Pfizer considers the India Biometrics Center superior to international benchmarks

Case Study

- Based on a global internal audit conducted by Pfizer, the India biometric center has been graded as "beyond international benchmarks"

- The India unit was ranked highest on the following parameters
  - Productivity
  - Quality
  - Response Time
  - Cost Competitiveness

"… has demonstrated outstanding performance on all parameters … setting up the unit in India was a wise decision"

— Dr. Potkar, Director R&D, Pfizer India

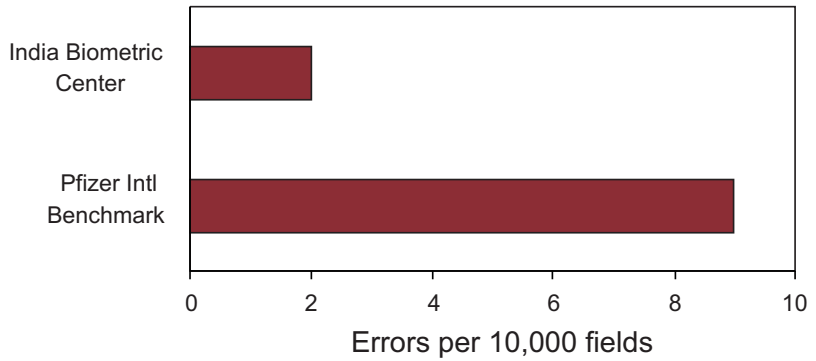
"There are a few such centers around the world, but the Indian one has the gold standard - error rate is close to zero"

– S. Ramakrishna, VP, Pfizer

Source: Interviews with OPPI members; News articles

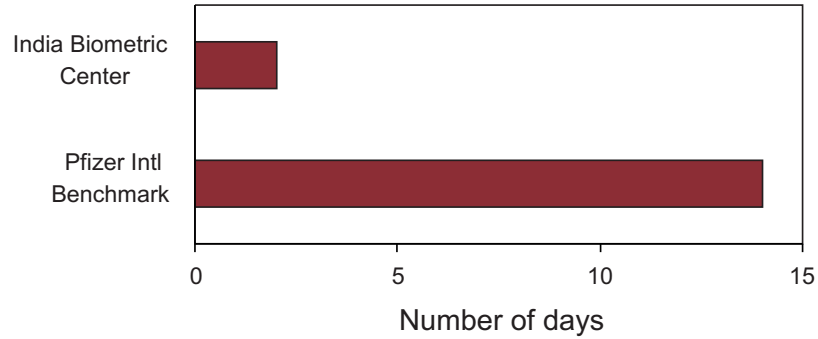
Pfizer India Relative to International Benchmarks

Data Error Rates



Note: the wage arbitrage allows Pfizer to hire better qualified personnel and a larger quality check team

Query Response Time



Note: the wage arbitrage allows Pfizer to increase capacity and reduce backlog

Source: Interview with Director, R&D, Pfizer, India

Moving forward, Pfizer has ambitious plans for India

Case Study

- Pfizer plans to extend their R&D outsourcing activities in India and leverage for the clinical trials opportunity in India post 2005 (the year in which the product patent law is expected to become effective)
  - Has already conducted 15 - 18 exploratory studies (Phase II and III) in India
  - Is conducting a study of the existing CRO (clinical research organizations) in India
  - Entered into an alliance with Bombay College of Pharmacy to set up the Academy for Clinical Excellence to train people to become clinical trial researchers

- The company also plans to leverage India for non R&D activities
  - Is considering setting up an IT-enabled unit call center and back office processing unit in India
  - Plans to move data management functions such as human resources, accounting, etc to India
  - Establish a call/email communication center in India to respond to doctor and customer queries

'"Pfizer Global is excited about India … and plans to leverage the availability of high quality personnel and the competitive costing to a greater extent in the future"

— Business Standard

Source: Interviews with OPPI members; News articles

J&J's experience with their international stability center has been very positive

Case Study

- J&J established the Janssen international stability center in 1999 to meet the global requirements of analytical services for Janssen. Services provided include stability and shelf life studies, method development and validation etc.

- Based on the quality and cost advantages, the center has expanded in both scope of activities and range of countries that it serves
  - The quality of output from the center meets J&J's international norms which are typically more stringent that the European regulatory norms
  - Depending on the study, the Indian center can do the study at 15-25% the cost of a similar center in Europe

"The Indian center meets all time and quality standards that J&J follows internationally at a fraction of the cost"

– Dr Uday Shetty, Janssen Stability Center Mumbai

Source: Interview with company management

Novartis has also set up a center in India to support the statistical needs of their global research team

Case Study

- Novartis evaluated various sites in North America, Europe and Asia before settling on India for setting up a statistical center to support drug development. India chosen due to:
  - Ready availability of low cost, skilled English speaking manpower
  - Existing Novartis infrastructure

- Novartis International Clinical Development Center India (NICCI) set up in 2002. This is the fourth such center for Novartis (the other 3 are in Switzerland, UK and US)
  - NICCI completed over 40 studies in the first year and initial feedback has been very positive

- Like Pfizer, Novartis also has ambitious plans for India

"Though we've started with statistical work, we'd like to move on to design work later. Our target is to have 15-20 studies running at any time. We have discovered a lot of talent to do this safety work, and I'm sure there are other capabilities too that are available here"

– Dr. Lira Parvez, Head, NICCI

Source: Interviews with OPPI members; News articles

Conclusions

Despite significant cost advantages, current outsourcing activities in India have only scratched the surface of the outsourcing opportunity

- India accounts for an insignificant share of the global pharmaceutical trade
  - Of the estimated USD 7 Bn pharmaceuticals purchased materials market in the US, Indian manufacturers supply only USD 149 MM including formulations — a share of under 2%

- More than 30 pharmaceutical MNC's operate in India but only a handful outsource to their Indian subsidiaries
  - Even those that outsource, typically use Indian manufacturing sites to supply to other South Asian countries
  - Amongst those who supply to the parent, it constitutes a miniscule share in their parent's total outsourcing requirements
    - For example, Sanofi Synthelabo's Indian subsidiary contributes 1% to its parent's total pharmaceutical imports

- Current outsourcing activity in non-manufacturing areas — contract research, clinical trials, process chemistry, turnkey projects, capital equipment is limited. However, these offer significant potential for growth
  - Despite unique advantages offered by India, relatively few MNCs are actively outsourcing clinical trials
  - Outsourcing in other areas is virtually non existent

Contents

Manufacturing will likely remain the largest outsourcing area in the medium term

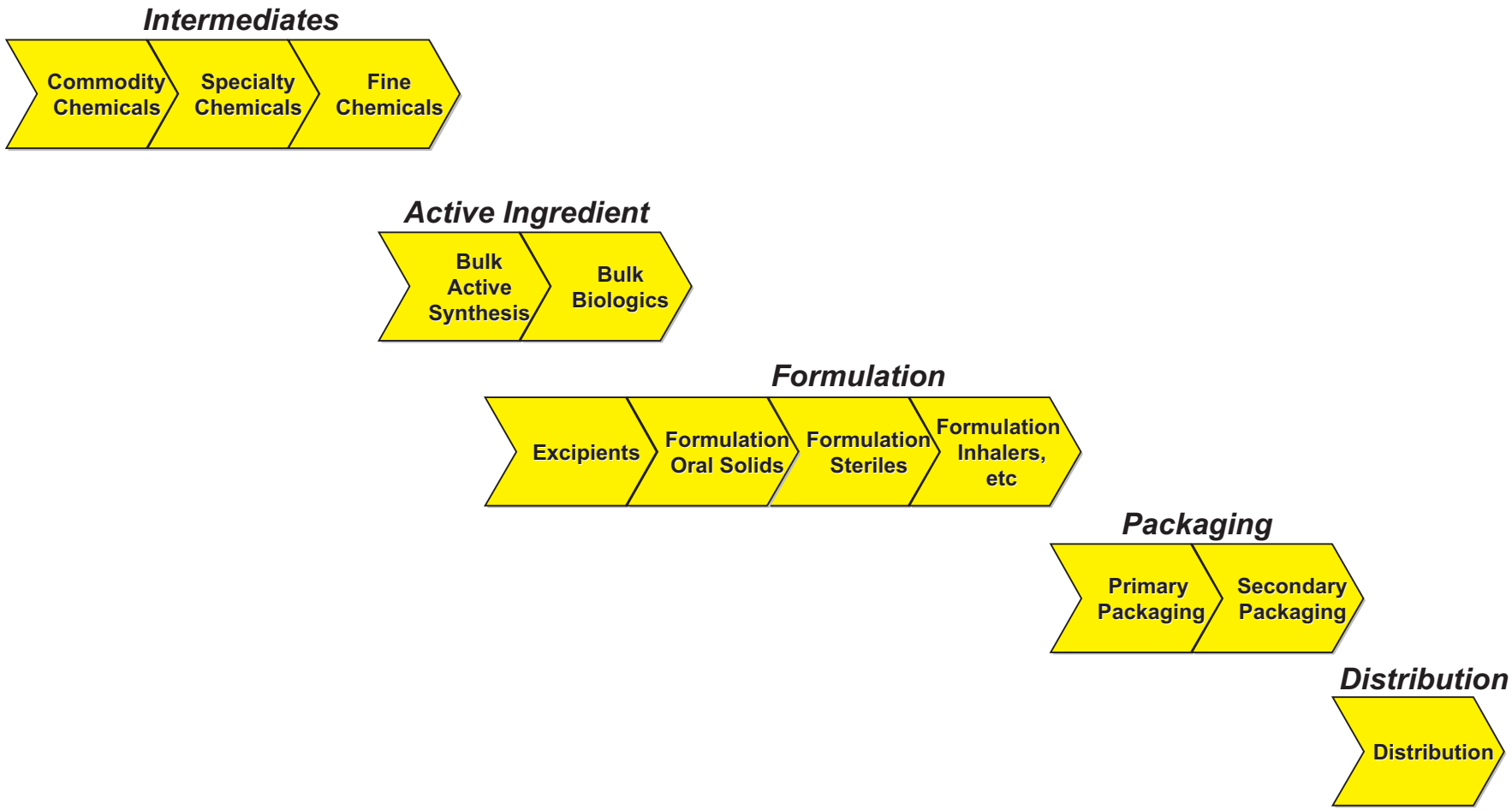
- Contract manufacturing is the largest outsourcing activity globally
  - Indian manufacturers have demonstrated capability of producing quality drugs at a fraction of developed market cost
  - Manufactured exports almost entirely account for India's participation in the outsourcing space

- Contract research and informatics though currently small, are expected to be fast growing outsourcing activities. India offers unique advantages to potential outsourcers in these activities, but current activity on this front is insignificant
  - Other than the obvious cost advantages, availability of abundant skilled manpower and a diverse patient pool uniquely position India as an attractive destination for outsourcing
  - Most OPPI members we spoke with believe that these areas are promising. The positive experience of Pfizer and Novartis should spur other companies to explore these further

- Contract sales does not offer immediate opportunities due to its very nature (requirement of on-the-ground sales team, current focus on US markets)

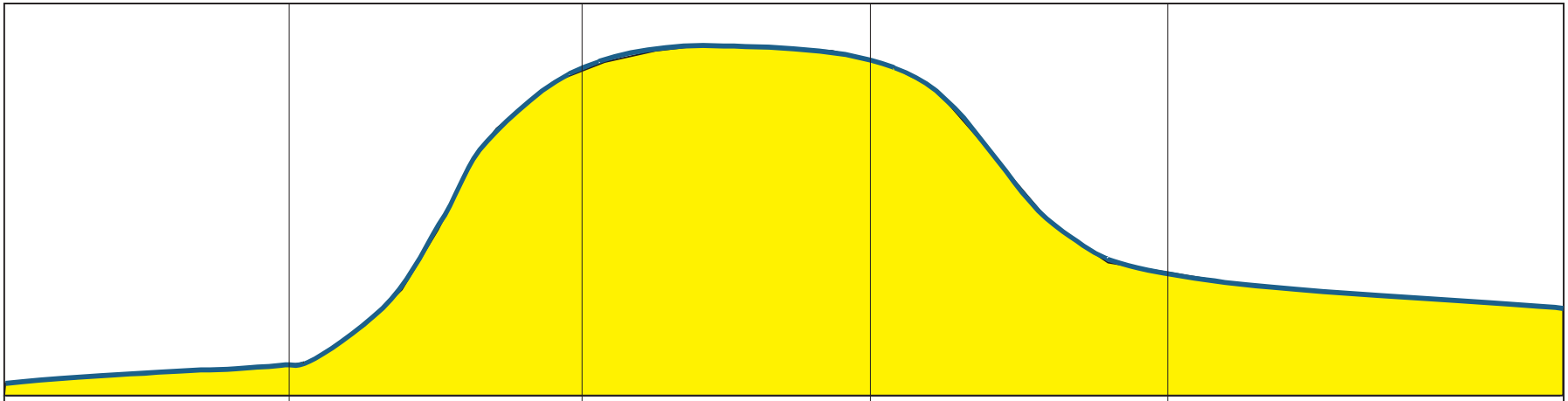
- Given the market potential and established track record, manufacturing will continue to remain the largest outsourcing activity out of India

There are outsourcing opportunities available across the manufacturing value chain



The major ethical MNCs view sourcing decisions differently across the lifecycle of a product

Product Life Cycle



Pre-Launch	Launch	Maturity phase	Decline	Product 'tail'
Outsource if . . . • Use of 3rd party allows rapid TTM – New technology type • High investments needed	Outsource if . . . • Want to create ramp-up *option* • Cannot increase in-house production fast enough	Outsource if . . . • There is a step function capacity investment needed just below peak sales • Technology has become 'routine' • Assets could be redeployed elsewhere • Prepare for end-of-life patent strategy	Outsource if . . . • Assets can be re-used for new drug	Outsource if . . . • Cost savings protect product margin
			• Low cost 3rd party produces the drug in standard portfolio, instead of demanding custom synthesis premium	

Outsource partner that offers **new** technology and **rapid** turnaround

Outsource partner that offers **quality and reliability**

Outsource partner that offers quality, reliability and **low cost**

The outsourcing criteria depend on the product life stage …hence local companies will have to tailor their value proposition to meet specific needs

	Price	Capacity	Technology	Capital Avoidance	Complexity
New Product	• Lower operating costs	• Time to market • Provision of increased capacity for defined periods of time • Rapid access to capacity in specialized areas	• High uncertainty on the product • Technology not available • Non-proprietary	• Major investment required	• Utilise external management resources where insufficient experience exists
Mature Product	• Lower operating costs • Off-Patent products remain competitive with generics producers	• Outsource mature products to Leverage own capacity and competence for strategic products • Non-proprietary	• Reliable and cheaper technical capability • Non-proprietary	• Re-utilization of production capacity for new products	• Utilize external management resources to free up own resources for new products

Source: Monitor analysis

To compete effectively, Indian companies should be ready to address a range of questions that potential outsourcers might have

About Capabilities

- What ranges of technologies do you have?
- Are you FDA cGMP certified? How many warning letters have you received?
- What is your capacity? How quickly can you scale up or down?
- Are you able to do process optimization to lower cost and improve manufacturability?
- What is your ramp-up time? What is the lead-time in each step of your supply chain?
- &and more

About Competitiveness

- Who do you compete with? Who do you see as your peers?
- What is your cost position for a range of technologies?
- Which of our competitors are you doing business with? Would you enter into an exclusive supply agreement?
- &and more

About Regulations

- What tax incentive can I enjoy from the local government?
- What is the Intellectual Protection record?
- How can you ensure the protection of our technology and process know-how?
- &and more

About Partnership

- What is your long-term strategy?
- What can you offer to the partnership?
- How much are you willing to invest to meet our ongoing needs?
- Are you prepared to accept contracts with annual cost decreases built-in?
- What is the exit strategy if the partnership does not work?
- &and more

Conclusions

- India's potential as an outsourcing destination has been tapped to a very limited extent
  - Contract manufacturing to India is a very small proportion of the total global market
  - With a few exceptions, contract research and informatics are virtually non-existent

- There is immense potential to grow the outsourcing market to India. A conservative 5% share of global contract manufacturing will more than double India's pharmaceuticals exports

- Indian subsidiaries of MNC's will have a crucial role to play in convincing their parents to outsource to India

- While highlighting the potential advantages of outsourcing to India is important, Indian companies should also be prepared to address concerns of potential outsourcers. These concerns could include:
  - Quality and reliability track record
  - Technological skills
  - IP protection