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India Pharmaceutical Summit 2012

12-13 July, 2012, Hilton Mumbai International Airport, India

Indian Pharmaceutical Industry has witnessed a robust growth from US$ 11.4 billion in 2010 to US$ 13 billion in 2011 with a scorching pace of growth of 15%. The industry ranks 3rd in terms of volume and is 14th in terms of value globally. Showing tremendous progress in terms of infrastructure development, technology base creation and a wide range of products, the Indian pharmaceutical industry has established its presence and determination to flourish in the changing environment.

Projects worth more than 1.2 billion dollars are currently under implementation on various products, suggesting massive investments by Indian pharmaceutical companies.

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Dr Monir Islam
Director, Health Systems Development
WHO - Regional Office for South East Asia (SEARO)

Dr Quazi Monirul Islam is the Director of the Health System and Development since March 2012 and before that the Director of Family Health and Research Department in WHO Regional Office for South-East Asia.
Dr Islam is a public health specialist from Bangladesh. He received his medical degree (MBBS) from Mymensigh Medical College, Dhaka University in 1979 and received MPH from Amsterdam University and the Royal Tropical Institute in the Netherlands in 1989.
Dr Islam visited and provided policy and strategic support to 75 countries in Asia, Africa, Meddle East, Eastern Europe, Pacific and in Latin America.
He has number of scientific articles published in peered reviewed journals including the Lancet and authored chapters in various globally reputed Medical and Public Health Text books.
He has extensive working experience and networks with Multi-Lateral Organizations e.g. UNICEF, UNFPA, FAO, ILO, UNHCR, World Bank, Asia and African Development Bank, various donors (USA, UK, Canada, Japan, Australia, Netherlands, Sweden, Denmark, Norway, Finland, Spain, Portugal, Germany, Austria), Institutions, NGOs and professional bodies and well know personality globally in public health.
In August 2010 Dr Islam took up the post as Director, Family Health and Research Department in WHO SEARO, in August 2010. In March 2012 he was reassigned as Director, Health System and Development to organize WHO's support to countries in strengthening Health System.

Mr. N R Munjal
Chairman
Pharmaceuticals Export Promotion Council of India (Pharmexcil)

Mr. N R Munjal is the Chairman of Pharmaceuticals Export Promotion Council, (Pharmexcil) a statutory body set up by Ministry of Commerce & Industry, Govt. of India, for promoting the Exports of Indian Pharmaceutical Industries.

He is also the Vice-Chairman and Managing Director of the Ind-Swift Group. Since the very inception of his career starting a small Pharma Unit - Ind-Swift Ltd. in 1984, with an annual turnover of Rs. 2 Lac and later incorporated Ind-Swift Laboratories Ltd., with Punjab State Industrial Development Corporation (PSIDC) in the year 1995 and steady growth of the Group across the globe establishing the subsidiaries in USA, Singapore, Dubai, Iran (Joint Venture Manufacturing) and marketing offices in UK (London) and China in a span of 15 years with its manufacturing facilities having international quality accreditations such as USFDA, MHRA, PMDA and TGA, has now grown up becoming a group with turnover of Rs. 2000 Cr.

Mr. Munjal's involvement in steering and leading the activities of key industry organizations includes Indian Drug Manufacturers' Association (IDMA) as President for the last 3 consecutive years (2009 to 2011) and still involvement as Immediate Past President and also with Pharmexcil as Vice-Chairman for the last 2 years (from 2009 to 2011) and now started (2011-2013) functioning as Chairman for the next 2 years.

Mr. Rahul Padhye
Head, Corporate Development
Reliance Life Sciences Private Limited
(RLS)

Rahul has been working in Reliance Group since 1994 in various business divisions such as petroleum marketing, infrastructure and alternative energy.

In early 2000, he joined Reliance's life sciences initiative and is today part of the core management team involved in the development of Life Sciences initiative.

Besides, heading corporate development group, Rahul also heads pharmaceutical business unit of RLS.

He has been involved in development of strategy and business plans for all the initiatives in Life Sciences Business.

He is responsible for setting up strategic alliances with academia, biotech and pharma companies, investment companies and licensing deals with technology providers and pharmaceutical companies.

His work also involves identification of opportunities for M&A across life sciences domains and participation in the entire process .

Dr. Sriram Akundi
Associate Vice President
Quality and Regulatory Affairs
Biocon Limited

Head of quality assurance, quality control and Regulatory affairs at Biocon.

Biopharmaceutical scientist with extensive background in the fields of regulatory affairs, quality control and quality assurance aspects.

Successfully faced major international regulatory audits for manufacturing facility compliance.

Led the cross functional teams for successful development and commercialization of multiple biopharmaceuticals.

Invited speaker at various international meeting in US, EU and Asia.

Over 13 years of demonstrated expertise in downstream process, protein formulation and lyophilization of new biological entities and Biosimilars.

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Mr. Daara B. Patel
Secretary-General
Indian Drug Manufacturers' Association (IDMA)

Mr. Daara B Patel is the Secretary General of Indian Drug Manufacturers' Association, an apex body of pharmaceutical and bulk drug manufacturers.

He is responsible for the smooth functioning of the association as per the constitution and By-Laws. He provides prompt response to members' queries and problems, organizes industry specific seminars, training programs & workshops, makes presentations, chairs technical sessions at various industry events, efficient handling of pricing related issues, EXIM policy and regulatory & technical affairs, Industry Trade related issues. He also coordinates activities / issues with other Associations.

His role involves supporting small & medium scale manufacturers in up-gradation of skills & obtaining government funding, liaison with various Ministries, DCG (I), state FDA's etc, overseeing the smooth administration of various state board offices, conducting monthly Executive Committee meetings, coordinating activities with consulates viz. facilitating trade delegations, seminars and exhibitions, P.R. activities and close liaison with media, coordinating activities with other associations etc.

He has excellent leadership qualities and is an able administrator. He is responsible for the Association's P.R. activities. He leads the association's CSR initiatives.

Dr. T.V.Narayana
Vice President
India Pharmaceutical Association

Dr. T.V.Narayana is Vice-President of the Indian Pharmaceutical Association, Mumbai and Chairman of IPA Education Division. He has been bestowed the honor of IPA fellowship in 2004 for his outstanding contribution.

He initiated the IPA Student forum and organized 4 National Level Student Congresses and 125 workshops throughout the country for the benefit of pharmacy students. Responsible for creating the largest network of Indian pharmacy students throughout the country, he has organized 45 QIP Programmes to pharmacy teachers and 25 Continuing Education Programmes for Community and Hospital Pharmacists throughout the country.

He is Core Committee Member of the Indian Host Committee of the recently held FIP world Congress at Hyderabad in 2011 and Joint Secretary of the 63rd Indian Pharmaceutical Congress. He is member of Pharmacy Council of India (PCI), a statutory body which regulates the pharmacy profession in India. He is active member of professional pharmacy and pharmacy Ethics Committee of PCI, New Delhi.

He is member of FIP since 2004 and has been attending the world congress of FIP since 2002. He has motivated and lead the Indian pharmacists to FIP Congresses held at Egypt, China, Basel, Istanbul and Lisbon. He has attended the Global Pharma Education Task Force meetings as official representative of IPA and promoted the ongoing projects of FIP in India.

Dr. Ravisekhar Kasibhatta
Vice President
Lupin Bioresearch Center

With over 25 years experience in clinical research and development, Dr. Ravisekhar Kasibhatta is currently Vice President, Clinical Research, Pharm. R&D at Lupin Bioresearch Center. He is heading Lupin Bioresearch Center to conduct Bioavailability / Bioequivalence and Clinical Equivalence Studies for generic products.

Dr. Ravisekhar Kasibhatta is a Ph.D. degree holder in pharmacology, at the Dept. of Clinical Pharmacology and Therapeutics of the Nizam's Institute of Medical Sciences, Hyderabad.

His vast experience in pharmaceutical R&D includes: Senior Manager - R&D at Dr.Reddy's Laboratories, Generics Hyderabad, India, Senior Scientist at APL Research Centre (A division of Aurobindo Pharma Ltd) Hyderabad, India, Sr. Research Scientist with Lambda Therapeutic Research Ahmedabad, India, and Chief Analyst in Dept. of Clinical Pharmacology and Therapeutics, Nizam's Institute of Medical Science (NIMS) at Hyderabad, India

Dr. Ravisekhar Kasibhatta has participated in different scientific conferences, seminars and workshops and delivered lectures at different CROs, Pharmacy Colleges and national and international conferences. His publications cover more than 25 papers in both national and international scientific journals)

Dr. P.M. Naik
Project *Director*
Zydus Cadila.
Ex-President
Indian Pharmaceutical Associatio

Dr. P M Naik as a Masters Degree in Pharmacy from Banaras Hindu University PhD, PGDIM and Master of Financial Management from Bombay University, He is fellow of Royal Society of Chemistry UK and Institute of Chemist Kolkatta. Dr. P. M. Naik, past President of the Indian Pharmaceutical Association as well as Indian Pharmaceutical congress association, has 50 years wide experience in the pharmaceutical industry covering API,Pharma & Biological products Manufacturing, PPC, Purchase, Distribution, Engg.Services, R&D & Projects. He was Technical Director at German Remedies Ltd, Senior.Vice President/SBU Chief at Zydus Cadila, and Managing Director at Zydus Byk. Currently he is retained as Project Director, Zydus Cadila.

He has delivered more than 60 lecture in prestiges National Forum and Chaired many technical sessions including IPCA. He has been awarded and recognised in many occasion which include, Special Award as Pharma Times Editor during, Eminent Pharmacist Award 2005, Excellence in Pharma Profession, 2009, and IPA -Ramanbhai Foundation – Lifetime Achievement Award in 2010.

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Confirmed Keynote Speakers

Mr. Manish U. Doshi
President
Indian Drug Manufacturers' Association (IDMA)

Mr. Manish Doshi, 50 years, Managing Director of Amoli Organics Private Limited.

He is a graduate in pharmacy and Post Graduate in Financial Management from Jamnanalal Bajaj Institute of Management Mumbai. He is managing his family business for last 28 years. Amoli Group of companies manufactures API and Formulations. The group exports to more than 80 countries. He was appointed as the Vice-President of IDMA in 2007. He is currently the President of Indian Drugs Manufacturers Association (IDMA).

Mr. Nirmalya Banerjee
Business Head
BMGI India

Nirmalya is Business Head and Senior Principal Consultant with BMGI India. He has over 12 years of experience in Business Strategy, Process Improvement and Innovation.

A Gold Medallist Mechanical Engineer as well as a Business Graduate, Nirmalya has worked across industries before embarking on a career in consulting.

Nirmalya has proven successes in Organizational Transformation in terms of business results as well as in change management. He has lend his expertise for business turnaround using varied tools and methodologies at different client sites spanning countries that include South Africa, Singapore, Thailand, Philippines, Vietnam, Sri Lanka apart from India. Nirmalya has extensively supported the Pharma behemoth Johnson and Johnson in their 'Journey of Excellence. He also anchored 'Business Process Reengineering' exercise at Torrent Pharmaceuticals. He has also supported several other clients that include ThyssenKrupp, ITC, RIL, Daimler, Hitachi, Volkswagen, Siemens, SKF, Apollo Tyres, Reliance Infocom, Idea, Asian Paints, Marico, Infosys, Oracle, HCL, HP to name a few in their journey to excellence and growth.

An experienced thought leader for industries like Process Industry, Automotive, Construction, IT and Healthcare, Nirmalya has acted as a keynote Speaker at many seminars and conferences across industries. He is widely recognized as a prolific speaker for his oratory skills and business acumen across the globe.

Dr. H.G. Koshia
Commissioner , Food & Drug Control Administration , Gujarat,
Chairman Regulatory Affairs,
Indian Pharmaceutical Association (IPA)

Dr. H.G. Koshia is the Commissioner of Food & Drug Control Administration in the state of Gujarat.

His key responsibilities under this capacity include:
1. Enforcement of "Drugs & Cosmetics Act, 1940 and rules there under"
2. Enforcement of "Food Safety & Standard Act, 2006" and rules there under,
3. Heading apex licensing authority for manufacturing of Allopathic Drugs, Homeopathic Drugs & Cosmetics
4. Ensure strict quality adherence of food and pharmaceutical products moving across Gujarat State (and exported from Gujarat not limited to but including regulatory markets like USA, Europe, Japan, etc)
5. Managing a team of over 1250 people, across 26 district offices in Gujarat

Apart from the above, Dr. Koshia's main achievements include:

1. Actively representing nine national & state level regulatory committees in India
2. Played a pivotal role in transformation of Pharma sector in Gujarat to emerge as a favourable investment destination with introduction of proactive policy framework
3. Spearheaded implementation of e-governance in the State of Gujarat (first state in India to introduce e-governance in this sector)
4. Regular interaction with officials of US FDA, Health Canada, DCGI, GoI, technocrats, Indian Drug Manufacturing Association, Druggists and Chemists forum at State and District levels, etc to ensure a consultative approach towards inclusive development and growth

Dr. Koshia is also the Vice President and Chairman – Regulatory Affairs Division at the Indian Pharmaceutical Association and he has Memberships/additional responsibilities at various Gujarat/India level regulatory bodies.

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Keynote Speakers

Dr. Monir Islam
Director, Health Systems Development
WHO - Regional Office for South East Asia (SEARO)

Mr. Manish U. Doshi
President
Indian Drug Manufacturers' Association (IDMA)

Mr. Daara B. Patel
Secretary-General
Indian Drug Manufacturers' Association (IDMA)

Dr. T.V.Narayana
Vice President
Chairman Education Division
India Pharmaceutical Association (IPA)

Dr. H.G. Koshia
Commissioner , Food & Drug Control Administration , Gujarat,
Chairman Regulatory Affairs, Indian Pharmaceutical Association (IPA)

Mr. N R Munjal
Chairman
Pharmaceuticals Export Promotion Council of India (Pharmexcil)

Dr. Ruchi Tiwari
Deputy Controller of Patents and Designs
Patent Office, Mumbai

Dr. P.M. Naik
Project Director
Zydus Cadila
Ex-President
Indian Pharmaceutical Association

Dr. Sriram Akundi
Associate Vice President, Quality and Regulatory Affairs
Biocon Limited

Mr. Rahul Padhye
Head, Corporate Development
Reliance Life Sciences Private Limited (RLS)

Dr. Ravisekhar Kasibhatta
Vice President – CR
Lupin Bioresearch Center

Dr. Ashok Srivastava
Medical Oncologist, Hematologist
CEO, Chief Medical Officer and Chief Safety Officer
Global Pharma Tek, USA

Mr. Nirmalya Banerjee
Business Head
BMGI India

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DAY 1

08:00	**Registration and Morning Tea**
08:35	Welcoming Address from Noppen
08:40	Opening Speech from the Chairman Mr. Naresh T Raisinghani - Chief Executive Officer, Breakthrough Management Group India Pvt Ltd
09:00	Overview of the Pharmaceutical Sector in South Asia – Issues, Challenges & Solutions •The status quo of the pharmaceutical industry in South Asia •WHO's view on patent and public health
09:30	Overview of the Pharmaceutical Sector in India – Issues, Challenges & Solutions •The status quo of India's pharmaceutical industry •Challenges facing the industry and solutions
10:00	India's Role in New Drug Discovery and the Importance of Investing on R&D •Transition of the Indian pharmaceutical industry into a discovery-driven industry •Restructuring R&D to maximise productivity and innovation
10:30	**Networking Tea Break**
11:00	Creation of World Class GMP Compliant Pharma Facilities for API and Doses Forms
11:30	Best Practice of Pharmaceutical Manufacturing (1)
12:00	Best Practice of Pharmaceutical Manufacturing (2)
12:30	**Luncheon and Networking**
14:00	Elixir for Transforming Indian Pharmaceutical Industry
14:30	Biotech Sector in India •Overview of Indian biosimilars sector •India's advantages & limitations and emerging landscape
15:00	India's Bio-pharmaceutical Industry Discussion •Building and upgrading India's bio-tech facilities •Identifying scientific, technical and operational challenges in biosimilar compounds development •Animal studies and clinical trial in biosimilar munufacturing
15:30	Policies and Initiatives by the Government in the Pharmaceutical and Biotech Industry •Overview towards the future of FDI (foreign direct investment) in India's pharmaceutical industry •Price control of the API sector •Policy updates on regulatory measures regarding similar biologics
16:00	**Networking Tea Break**
16:30	Discussion Panel Session: India's Advantages in R&D to Improve Innovation and Reduce Cost
17:30	**Closing Remarks at the End of Day One**

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DAY 2

08:00	**Registration and Morning Tea**
08:50	**Opening Speech from the Chairman and his presentation (Title TBC)** Mr. Daara B. Patel - Secretary-General, Indian Drug Manufacturers' Association (IDMA)
09:30	India's Pharmaceutical Export •Overview of India's pharmaceutical export and government support and initiatives •Regulation updates to US and EU markets •Finding opportunities in emerging markets
10:00	Pharmaceutical Partnering and Investment •Expansion through strategic investments and partnerships globally •Synergies between Indian biotechs for successful commercialization of technology with global players •Positioning and preparing your company for merger and acquisition to optimise value
10:30	**Networking Tea Break (Sponsorship Available)**
11:00	Drug Safety and Pharmacovigilance •Safety management during early drug development program •Safety management during clinical trials through medical monitoring •Latest pharmacovigilance regulation updates •Challenges in Global Drug Safety and Pharmacovigilance of Cancer Drugs in India and the US
11:30	Development of India's Pharmaceutical Machinery Industry •Overview of India's pharmaceutical machinery industry •Increasing investment in R/D and industry scale-up •Promoting international collaboration by encouraging joint ventures and technology transfer
12:00	Pharmacy Education in India : Prospects and Perspectives
12:30	**Luncheon and Networking (Sponsorship Available)**
14:00	Pharmaceutical Supply Chain Challenges and Best Practices •Benefits and challenges of implementing an adaptive supply chain •Speed, flexibility, visibility, responsiveness, costs and safety -- key drivers for the pharmaceutical supply chain •Customising cold chain strategies for the Indian market
14:30	Pharmaceutical Patenting and Licensing in India •Introduction and updates to India's patent system •Striking a balance in protecting patents and patients •Pros and cons of compulsory license (CL)
15:30	**Networking Tea Break (Sponsorship Available)**
16:00	**Discussion Panel Session: India's Leading Role in Generics and Pharmaceutical Patenting in India**
17:00	**Closing Remarks at the End of Day Two**

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NETWORKING TEA BREAKS
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Biosensors International Ltd.

"Very good event indeed"
PerkinElmer

"Inspiring and had a good combination of officials, professionals and experts"
Shanghai Clinical Research Center (SCRC)

"I'm impressed by the rich content of the event and it is very useful to my future work."
Eli Lily

"Good to have representatives from industry, academia & government sit together to discuss topics."
Bristol Myers Squibb

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