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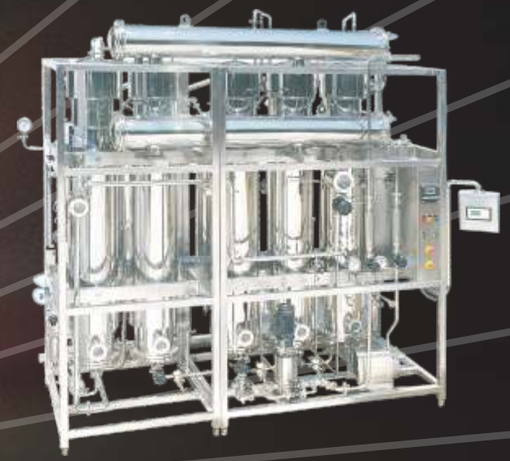

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PHARMA PRO&PACK

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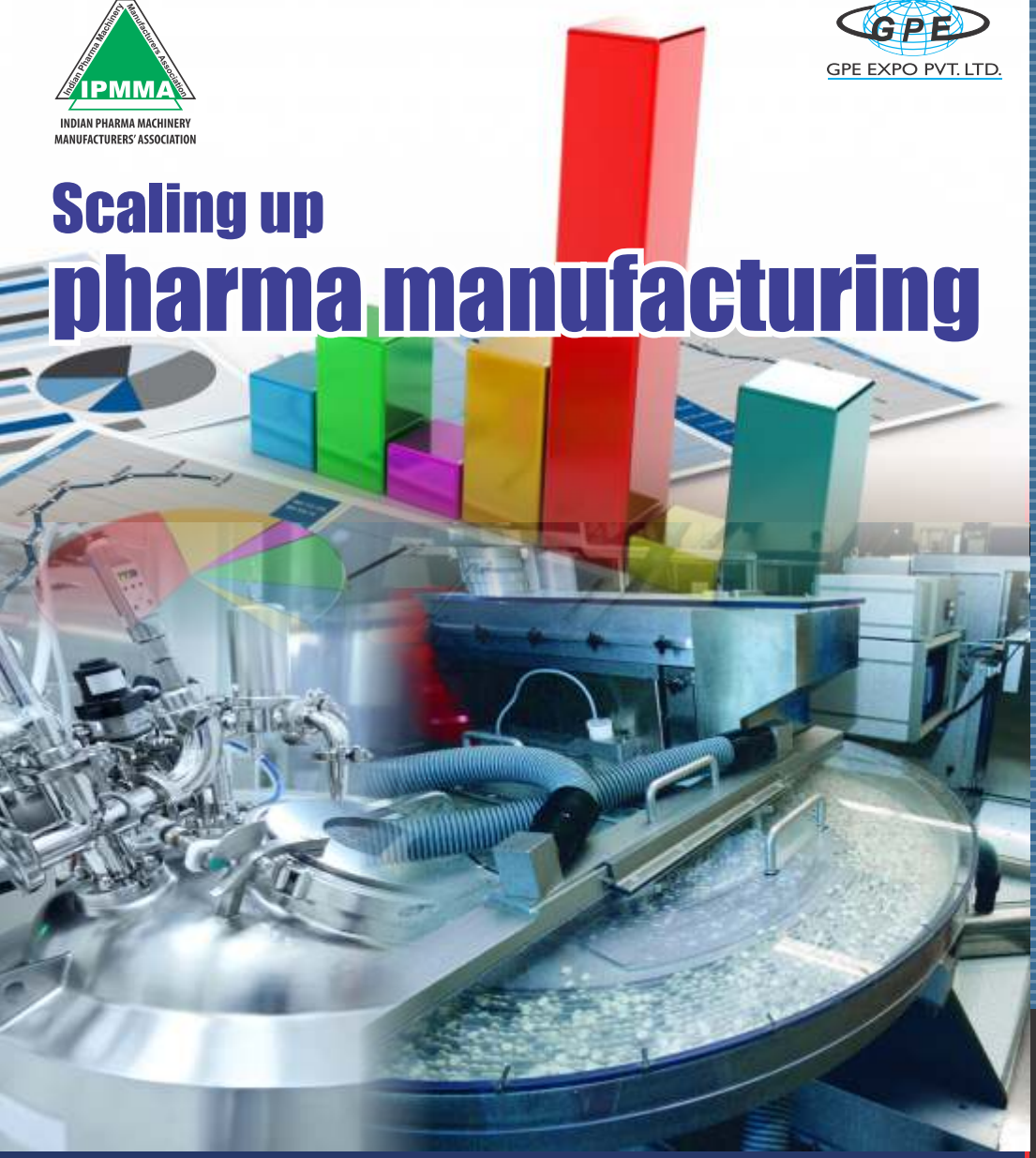

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Editorial

Rajesh Shah
Editor-in-Chief
PHARMA Pro&Pack

Amidst all the news of gloom and doom on different fronts both in India and at the world level, finally there appears to be a ray of hope just like the light at the end of the tunnel. In the first week of July, India's top notch rating agency ICRA came out with a report which says the Indian pharmaceutical industry would continue to experience strong growth in the near future. Much of this growth is attributed mainly to the generic opportunities in the United States which will continue to fuel and drive revenue growth for Indian pharma companies.

Fiscal 2012-13 was a year of strong operating performance for the Indian pharmaceutical industry as it benefitted from patent expiration wave in the US, strong growth from the emerging markets and favourable foreign exchange scenario. During the year, Indian pharma companies also managed to gain traction in their European businesses despite the challenging environment. But back home the growth momentum showed signs of moderation owing to relatively weak seasonal demand, adverse impact of inflationary pressures on disposable incomes coupled with uncertainties surrounding the implementation of the new pricing policy in the second half the financial year.

Opting for scale-up and strengthening R&D has more relevance for the Indian industry than ever before. It is now of paramount importance for the Indian pharmaceutical industry to scale up their R&D intensity to strengthen their position in the global market place. As the ICRA report points out candidly -- Growth opportunities are intact. But the key to fructifying these growth openings and prospects lie in how the Indian industry manages the challenges confronting it at the ground level.

I also take this opportunity to draw your attention to the resounding success seen by PHARMA Pro&Pack Expo 2013, the first ever international exhibition on total pharma manufacturing technologies jointly organised by Indian Pharma Machinery Manufacturers' Association (IPMMA) and GPE EXPO PVT. LTD.) at Mumbai during April 24 to 26. The unprecedented success of the show has indeed propelled all of us at IPMMA to run the extra mile and burn the midnight oil for a much larger and grander gathering at the 2014 edition of PPPE.

From the Desk of the Publisher

Paresh Jhurmurwala
Publisher

Success it is said is like a train. It has It has several coaches – Hard work, Focus, Luck, Attitude, Vision but leading all those is the "Engine of Confidence." How true these words are! As I relax and sit back to analyse the resounding success of the Pharma Pro&Pack Expo 2013 (PPPE 2013), the first ever exhibition of its kind jointly organised by none other but by IPMMA (Indian Pharma Machinery Manufacturers Association) and GPE Expo Pvt. Ltd., I indeed realise that success is not solitary. But is a sum total of all these attributes which I have mentioned above.

Over the years, there was a growing demand from the Indian pharma machinery manufacturers to host and organise a world level event. And finally this has come true. Here I can also say that it is simple to be successful -- You have to know what you are doing - Love what you are doing & believe in what you are doing!! It was this belief in the abilities and capabilities of the industry as a whole that not only resulted in the success of the first ever world level exhibition of its kind but it is also this confidence that has propelled us to look forward to a much greater 2014 edition of the Pharma Pro&Pack Expo.

I also take this opportunity to extend my sense of gratitude and heartfelt thanks to all the people of made a success of PPPE2013. Almost all the stakeholders preferred to walk that extra mile which eventually made the PPPE2013 a grand success. Right from the top echelons of the organising committee to the workers on the ground everybody believed in the maxim that success & excuses do not talk together. If you want excuses, forget about success. If you want success don't give excuses...

At IPMMA and GPE Expo we are have worked and toiled hard to develop the habit of success and in the process I am sure all of us are going to make success a habit. Throughout the year leading to April 2013, problems cropped up at each and every turn. But we had a combination of Patience, Persistence & Perspiration. This makes an unbeatable combination for Success..!

Also we have all the regular features in this latest issue.

Please do write to us with your comments, views, news and ideas so that Pharma Pro&Pack, the official mouthpiece of IPMMA continues its journey towards excellence.

Wishing all of you a very happy reading..!

PHARMA Pro&Pack Expo 2013 and iPHEX 2013 established global benchmark of Brand INDIA for Indian pharma industry

19,500 buyers from 104 countries visit 227 exhibitors from 16 countries at PHARMA Pro&Pack Expo 2013 and 400 exhibitors at iPHEX 2013 exhibitions

The maiden launch show of PHARMA Pro&Pack Expo2013 – an international exhibition on TOTAL pharmaceutical manufacturing technologies organized during April 24 to 26, 2013 at the Mumbai Exhibition Center, Mumbai, India (organized by the Indian Pharma Machinery Manufacturers' Association (IPMMA) and GPE EXPO PVT LTD) and co-located with iPHEX 2013 – an international exhibition for pharmaceutical & healthcare (organized by PHARMEXCIL) and supported by more than 14 national & international pharma & trade associations had a exciting and flying start with the Hon'ble Chief Minister of Maharashtra, Mr. Prithviraj Chauhan declaring it open.

PHARMA PRO&PACK EXPO 2013
24 - 25 - 26 April 2013
Mumbai Exhibition Center, Goregaon (East), Mumbai INDIA

The successful exhibition has left a strong footprint in the Indian pharma-economy and has given and provided the best opportunity and the ideal platform to the industry to promote the Brand INDIA concept. With the show being initiated, promoted and organized by industry itself, it helped in providing a common platform to one and all with a micro scaled entrepreneur sharing and exhibiting alongside the industry giants and promoting their skills and services.

While the Chief Guest – Mr. Prithviraj Chauhan, Hon. Chief Minister – Maharashtra state inaugurated the twin exhibitions, PHARMA Pro&Pack Expo 2013 and iPHEX 2013, the Special Guest – Mr. Rajeev Kher, IAS, Additional Secretary, Department of Commerce & Industry, Government of India and Guest of Honour – Dr. G. N. Singh, Drug Controller General (India) – [DCGI – India] inaugurated the event. All the dignitaries took a round of the exhibition, visiting the exhibiting companies and took a deep interest in the growth story and growth prospects of the Indian pharma machinery sector across the world.

The overall feedback from the industry for the PHARMA Pro&Pack Expo 2013 exhibition comes across as very promising and encouraging. This gains added significance as this was for the first that a global and international scale exhibition was taking place. Mr. Kenji Maeda of Freund Corporation, Japan (manufacturers of Roll Compactor, Lab scale FBD, Granulators, etc.) said, "PPPE 2013 is a very good show. We will surely participate at PHARMA Pro&Pack Expo 2014 exhibition..!"

Mr. Yuji Matsunga from another Japanese exhibiting company Daiichi Jitsugyo Viswill Co. Ltd. (manufacturers of Vision Inspection Systems offering machines used for the tabletting section) said: "Yes. We had a wide range of customers to see the machines and there was a good acceptance. We are already in India since the past five to six years. But this exhibition offered good chance to display the technologies and to meet customers with ease."

iPHEX 2013
International Exhibition for Pharma and Healthcare
www.iphex-india.com

Mr. Rajesh Shah – Chairman, Maharshi Udyog and President – IPMMA informed; "Since 2001, the year IPMMA was launched there was a demand to have the industry's own exhibition on pharma machineries. And with PHARMA Pro&Pack Expo 2013 exhibition, all the members of the association feel proud of having ownership of the show..! The inaugural show was a resounding success and the way the show was planned out the performance was seamless. There

was also an overpowering feeling of the exhibition belonging to all of us. I am extremely hopeful that PHARMA Pro&Pack Expo 2014 will also be a resounding success on a much bigger scale."

Mr. Rattan Singhania, Director - Pharmachine India and Vice President – IPMMA said, "With IPMMA organising this show, it was indeed a wonderful feeling. All the exhibiting members were feeling the ownership of the show. In terms of visitors the show achieved moderate to good success but whatever visitors were there were serious trade professionals. From what I hear is that lot many companies will participate not only in the 2014 show but also in the 2015 show as well."

Mr. Ross Townshend Executive Director RML Engineering Ltd. New Zealand said, "It was a very nice and smooth show. The quality of visitors was very good." Mr. Vishesh Parekh, Director INCOME Marketing Pvt. Ltd: "IPMMA has shown its mettle by taking this step successfully."

The overall response across the industry to PHARMA Pro&Pack Expo 2013 exhibition was remarkable. Though, the exhibition was organized for the first time, the quality and number of the attendees were very much noticeable and indicating the serious interests of the visitors. Over 227 exhibitors from 16 countries of PHARMA Pro&Pack Expo 2013 and 400 exhibitors of iPHEX 2013 exhibition took part. Over 19,500 pharma professionals from 104 countries visited the show. More than 87% companies have already re-confirmed their participation at the 2nd edition of PHARMA Pro&Pack Expo 2014, Mumbai exhibition.

- 88% of the Exhibitors appreciated the Quality of Visitors
- 76% of the Exhibitors appreciated the Number of Visitors
- 83% of the Exhibitors satisfied with Return on Investment (ROI)
- 94% of the Exhibitors admired the Infrastructural Facilities at the Venue like Registration, Electric Power, Compressed Air, House Keeping, Exhibition Material & Services, Security, Parking, Exhibit Material Loading/Unloading, etc.)

Kevin Process Technologies Pvt. Ltd. – a group company of CADMACH, one of the leading manufacturers for granulation line equipments of India was one of the exhibitors. Dr. Parag Shah, GM (Sales – Global Markets), Kevin Process Technologies Pvt. Ltd. was delighted to share his experience about the participation; "PHARMA Pro&Pack Expo 2013 was a good experience. Visitors' quality was also good. We had a lot of decision makers visiting our stall with their genuine requirements.

According to Ms. Susan Fowlke, Charles Ischi AG, Switzerland (Manufacturers of Online and Offline Tab Cap Testing Equipments), and "The PHARMA Pro&Pack Expo 2013 was a very busy event. It was indeed such a pleasant surprise to have such first-class attendance of buyers and decision makers. Echoing similar sentiments, Mr. Raul March of BOSSAR Packaging, S.A., Spain said, "This exhibition was very profitable for us as most of the top pharma companies attended the show."

Elizabeth Carbide Die Co., USA (manufacturers of Tablet Press Machines and spares for tablet presses at six different manufacturing plants worldwide) was one of the international exhibiting companies at the exhibition. Mr. Dave Keefer, President was excited with the successful attendance of high quality buyers who attended the show as the show provided a unique platform to meet Indian customers directly.

According to Mr. Alexander, ROTA Verpackungstechnik GmbH & Co KG, Germany – the manufacturers of complete line of machines for injectible section, "Though it was being organised for the first time, the show had a lot of genuine decision makers visiting us at our booth." Mr. Luke Song and Mr Jason Kim of Sky Softel Company, Korea felt that the exhibition was poised for much growth in its launch year itself.

The exhibition was made more interesting and proved its worth to the participants because of two vital and essential elements. First was the visit of serious and genuine buyers from the industry and second was the exhibition of wide range of different upgraded technologies for pharma manufacturing. The show was beneficial to all stake holders from the technology providers to the trade professionals to the business visitors as everyone could spend extended time span to understand the new technologies on display and fruitful discussions.

Mr. Roberto Belicchi MBS Srl – Italy said the show would go a long way in improving business prospects. "We found this exhibition as very useful platform to update new technologies," Mr. Anil Kumar, GM – Engineering, Alkem Laboratories Ltd. said.

"The quality was quite good and we are very happy to introduce our new products. We would be exhibiting again in 2014," said Mr. Bassler Hans Jurgen Skan AG, Switzerland. "The show will become the premier industry show in the years to come," Mr. Karnik Parikh, Director Pharmalab India Pvt Ltd said.

For more information on PHARMA Pro&Pack Expo 2014 scheduled during April 24 to 26, 2014 at Mumbai Exhibition Center, Mumbai, India, please email: contact@pharmapropack.com or CALL: +91 80004 81114/+91 79 4000 8233 / 53 / 2687 1390 or visit the website: www.PharmaProPack.com.

Explore untapped potential of Central & West African pharma markets at Nigeria Pharma Manufacturers Expo 2013

Nigeria Pharma Manufacturers Expo 2013 (NPME 2013), an international exhibition on pharmaceutical industry is happening for the second time during October 17 to 19, 2013 at Blue Roof TV Complex, Ikeja, Lagos, Nigeria. NPME 2013 is hailed as one of the biggest international pharma manufacturing exhibition of the Central & West Africa region attracting more than 110 exhibiting companies and nearly 3,500 pharma trade professionals from across the region including Nigeria, Ghana, Mali, Chad, Cameroon, EQ Guinea, Central African Republic, Senegal, The Gambia, Ivory Coast, Niger, Burkina Faso, Benin amongst others.

NPME 2013 is being jointly organized by the Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN) and GPE Expo Pvt. Ltd. and Endorsed by Federal Ministry of Health (Nigeria), National Agency for Food & Drug Administration & Control (NAFDAC - Nigeria), West African Pharmaceutical Manufacturers Association, Economic Community of West African States (ECOWAS), Pharmaceutical Society of Nigeria, and Supported by the Pharmaceutical Export Promotion Council (PHARMEXCIL - India) and Indian Pharma Machinery Manufacturers' Association (IPMMA). The official media is PHARMA Pro&Pack magazine and official website of NPME 2013 is www.nigeriapharmaexpo.com.

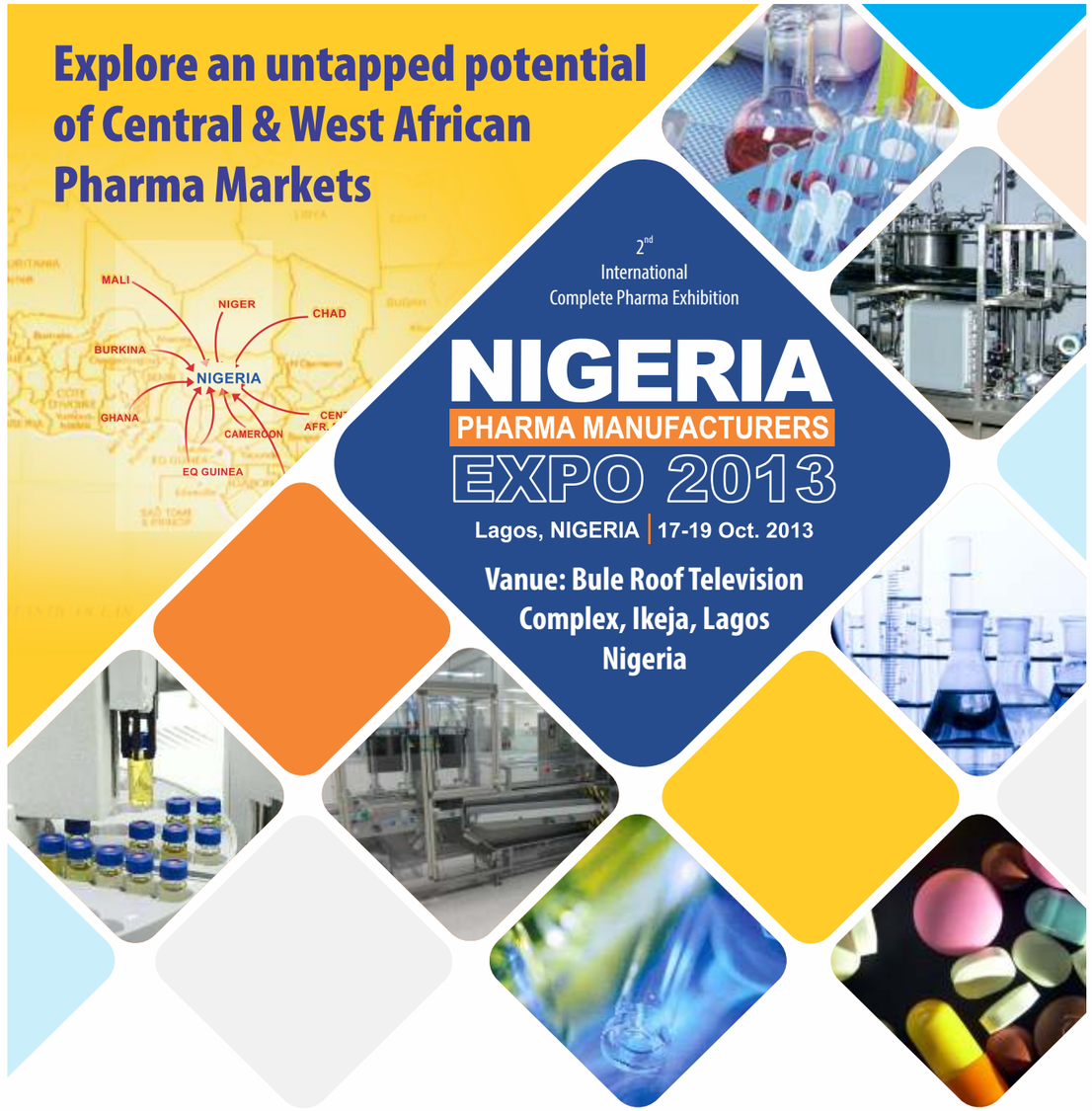
The NPME 2013 will be held at Blue Roof TV Complex, Ikeja, Lagos, Nigeria – the most suitable venue for such important international business gathering. Importantly the venue is located in the prime industrial corridor of Lagos.

Nigeria is one of the most promising and rapidly growing pharmaceutical markets in West Africa with more than 120 pharma formulation manufacturing facilities. The Nigerian pharma industry is growing at 12 percent annually. The estimated market size would be USD million 717 (2011) (USD 740 million in 2009). About 60 per cent of drug manufacturing in the ECOWAS (Economic Community of West African States) sub-region takes place in Nigeria, underlining the huge sub regional market.

The three-day long international exhibition, NPME 2013 will be an excellent opportunity to meet one to one ensures focused promotions and meaningful interaction for business. The show will be catalyst to develop new business opportunities, technology and trade sources, new tie up and technology transfer. Moreover, during this three-day show, OEM will have great opening to meet the existing vendors and identify the new ones, too.

NPME 2013, an international exhibition will provide an unique platform to showcase Pharma Processing & Packaging Machineries and Materials, API & Bulk Actives, Analytical Lab Instruments & Supplies, Environment Control Systems, Utilities Products & Services, Water Management, Research, Consultants, Turnkey Contractors, Formulations & Contract Manufacturing, Trade Association & Promotion Organizations, Trade Associations, etc.

The leading companies from Nigeria, India, and China will be exhibiting their latest products/services and pharma manufacturing technologies at NPME 2013, Lagos exhibition. Some of the exhibiting companies are; Pradipkumar Pharma Pvt. Ltd., S S Packaging Industries Pvt. Ltd., Airtel Nigeria Ltd., Rapid Pack Engineering Pvt. Ltd., Skye Bank Nigeria Plc, Worldwide Technologies Ltd., NPM Machinery Pvt. Ltd., Promp+Tech Pharma Industries, Karnavati Engineering Ltd., Affy Group Of Companies, Contec Airflow (E) Pvt. Ltd., Lovisa Speciality Products Ltd., Sinochem Ningbo Ltd., Sushen Medicamentos Pvt. Ltd., Pmg Man, Md Logistics, Ambica Pharma Machines Pvt. Ltd., Gmp Technical Solutions Pvt. Ltd., Anchor Mark Pvt. Ltd., S.R.P. Group (Jagat Industries, Rotofil Industries), Pacific Tools Pvt. Ltd., CMC Machinery / Cadmanch Machinery Pvt. Ltd., Bectochem Consultants & Engineers Pvt. Ltd., BASF - Germany, Strides Vital Nigeria Ltd., Bry Air (Asia) Pvt. Ltd., ACG Worldwide, Adept Engineers, Chinese Chamber, Syncom Formulations (I) Ltd., Jawa International Ltd., Neimeth International Pharma Plc., Sam Pharmaceuticals Ltd., Dana Pharmaceutical Ltd., S K Pharma Machinery Pvt. Ltd., TSA Process Equipments Pvt. Ltd., Pharmalab India Pvt. Ltd., Novo Excipients Pvt. Ltd., Jiangsu Guotai, Shandong Pharma Glass., Austar Ltd., Shree Bhagwati Machtech India Pvt. Ltd., SSPM Systems & Engineers, Parle Elizabeth Tools Pvt. Ltd., Natural Capsules Ltd., Hulian Pharma Machinery., Bentos Pharma Products, Evans Medical Plc., Drugfield Pharma Ltd., Skg-Pharma Ltd., Vitabiotics Nig Ltd., Fabtech Technologies Africa Ltd., Maharshi International, Daily Need Industries Ltd., Fidson Healthcare Plc., N. K. P. Pharma Pvt. Ltd., Fluidpack India, Accurate Machines, Tapasya Engineering Works Pvt. Ltd., Impact Labs Pvt. Ltd., Neelam Global Pvt. Ltd., The Bombay Engineering Works, Narendra Packaging Pvt. Ltd., Clean Coats Pvt. Ltd., Emzor Pharma Ind. Ltd., Precikot Pharma Pvt. Ltd., Konark Machine Tools Pvt. Ltd., Anish Pharma Equipments Pvt. Ltd., Parth Engineers, Prism Pharma Machinery, Bharat Rubber Works Pvt. Ltd., Newtronic Lifecare Equipment Pvt. Ltd., Rahul Ferromet & Engineering Pvt. Ltd., Gansons Ltd., Nomagbo



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The NPME 2013 will be highly resourceful, informative and meaningful for the entire segment of the pharma trade professionals to acquire vital information required in day to day operations of pharma manufacturing facilities. NPME 2013 will be attended by Biotechnology Specialists, CEO's Engineers, Technocrats and Scientists, Compliance, Corporate Management, Custom Manufacturing / Marketing Services, Equipment Suppliers & Distributors, Maintenance Engineering, Manufacturing / Production Engineering, Operations Management, Packaging Engineering, Pharmacists, Plant Management, Policy Makers, Diplomats and Foreign Commercial Corp., Process Engineering, Procurement Dept., Purchase, Purchase Officers, Quality Assurance / Quality Control, R & D Professionals, Regulatory Officers, Validation, Vendor Development, etc.

Brief about the Organizers:

Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN):

PMG-MAN is the umbrella body of the local manufacturers of the medicines and healthcare products in Nigeria with over one hundred members having established factories that manufacturing life-saving medicines to support the Healthcare Delivery System. The major target of the PMG-MAN is to realize Government objective of making Nigeria self sufficient in essential medicines through local manufacturing of Drugs. The Group also focuses on the exports drive of locally manufactured quality medicines to the West African region.

PMG MAN
Pharmaceutical Manufacturers Group of Manufacturers Ass. of Nig. (PMG-MAN)

The pharmaceutical manufacturing sector of Nigeria contributes to nation building with aggregate investments in excess of N300 billion, paying taxes and other tariffs and employing over 600,000 persons.

In collaboration with relevant stakeholders, PMG-MAN established the 1st special Exhibition / Expo starting in June 2008 in Abuja, which sensitized and showcased the resources, contributions and breakthrough pharmaceutical products – Proudly Made – in – Nigeria to Nigerian citizenry, policy makers and the international community.

The Nigeria Pharma Manufacturers Expo 2013 coming up in October 2013 is an opportunity for stakeholders in the health sector to exchange information, products, services and ideas towards achieving the Health related Millennium Development Goals and other developmental initiatives in Nigeria and West African region.

GPE Expo Pvt. Ltd. (GPEEPL):

Established in 1997, GPEEPL has attained an international recognition worldwide including, India, Malaysia, Syria, Bangladesh, Pakistan, Nepal, and have become specialized in providing event planning and consultation services, event marketing & management for country specific international Exhibitions, along with for corporations, associations and individual organizations of pharmaceutical and healthcare sectors.

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The core strength is in the logistical details of organizing and executing large events involving multiple players, while integrating diverse services. Based on the experience in the industry, GPEEPL has established an expertise, which enables to produce a top rated event in all areas including decor, food and beverage, entertainment, and timely execution. We pride ourselves on having a professional commitment to each aspect of a client's project.

GPEEPL enjoys the credits of highly successful organization (marketing, management, and execution) of several country specific international exhibitions for pharmaceutical industry, includes; PHARMA Pro&Pack Expo (India), Asia Pharma Expo (Malaysia & Bangladesh), Pak Pharma Expo (Pakistan), Nepal Pharma Expo (Nepal), Global Pharma Expo (India), and many more to emphasize the significance of the local pharma industry on the global platform. GPEEPL is having co-ordeal relationship with various national trade associations of pharma industry, like, Bangladesh, Pakistan, Malaysia, Nepal, etc.

Besides servicing pharmaceutical industry, GPEEPL has been also associated with Healthacre and Chemical segments, including Association of Surgeons of India, Society of Gastroenterology (India), Society of Gastrointestinal Endoscopy of India, Association of Colon and Rectum Surgeons of India, Research Society for the Study of Diabetes in India, Indian Society of Knee and Hip Surgeons, Association of Physicians of India, Urologist Society of India, etc.

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Indian pharma machinery manufacturers need to leverage position through scale-up

Indian pharmaceutical machinery manufacturers have made a rather strong headway in the world markets. No wonder India's increasing clout in the pharmaceutical domain is a universally acknowledged fact. But just a couple of decades ago, the conditions and the circumstances were totally different. India in the 50s, 60s and 70s mostly depended on imports for practically all its needs of pharma machinery. Most of the imports were from European countries to cater to India's growing needs in processing and packaging requirements. The pharma machinery industry was almost non-existent till early 70s. But today the Indian pharmaceutical machinery industry is a flourishing one; currently, growing at the rate of 15-20% annually.

Developments in the mid seventies came like a blessing in disguise for the ultimate development of pharma machinery manufacturers in India. A severe shortage of foreign funds forced the Government of India to introduce high import duties on imported machineries amongst other things. Alongwith the stiff duties, strict import licensing policies were also introduced. A net fall out of this action was that the fast growing Indian pharmaceutical industry was compelled to look for local alternatives and Made-in-India options. Unfortunately with hardly any presence of any Indian engineering company into manufacturing of pharma machinery, the Indian pharma industry was left scratching its head. The only way ahead was to persuade, push and support Indian engineering companies to diversify into manufacturing of pharma machineries.

With a golden opportunity knocking on their doors, the small scale engineering companies in India grabbed this golden break with both hands and in practically no time at all hundreds of Indian machinery manufacturers set up shops to cater to the growing machinery requirements of the burgeoning pharma companies. And it was like the proverbial no looking back. Providing value for money machinery, the Indian pharma machinery manufacturers have played a key role in the development of the Indian pharma industry as a whole and also in India being recognised the world over as a low cost manufacturing hub.

Within no time, the Indian capabilities in the pharma domain were a talk of the world and many machine manufacturers from across the world were enthusiastically looking towards India for good business prospects. A win-win situation was emerging for all the prospective stake holders because in return, the Indian machinery manufacturers got the advantage and benefit of the technology and expertise of the foreign companies. Not only did the Indian companies cash in on the foreign expertise and technology on offer by improvising on the existing machineries but also forged a deep and strong bond with most of these global players. Today, pharma machineries manufactured in India cost just one third or one fourth as compared to machines brought from overseas. With costs playing an important role in selection of a machine, all eyes are now turning to India when it comes to buying high-quality-low-cost pharma machinery.

Most of the industry analysts predict a good, sunny and rosy future for the Indian pharma machinery manufacturers. But there are conditions attached for this bright and luminous future. And one of the important aspects is that the pharma machinery manufacturers will have to opt for scale-up of their operations.

In the scale-up process, the pharma machinery manufactures will have to ensure that the industry gets equipped with latest technology. There should be no cutting of corners to introduce world quality pharma machineries and equipments right from production to packaging. Fortunately a bulk of the industry is waking up to this reality. Also the time is right for Indian pharma machinery manufacturers to understand the importance of thorough and proper research and development and implement it across the board. The industry needs to get together and curb tendencies of copying out European machines. This has to stop. Also the penchant for adopting a 'herd mentality' needs to be given a goodbye in the overall

Regulatory aspects of scale-up and the post approval changes that need to be addressed

Mr. Mohit Kumar, Head Engineering Projects (Pharma)
Ranbaxy Laboratories Ltd.

Any significant change in a process of making a pharmaceutical dosage form is a regulatory concern. Scale-Up and Post approval Changes (SUPAC) are of special interest to the regulators.

Scale-up problems may require post approval changes that affect formulation composition, site, and manufacturing process or equipment. In a typical drug development cycle, once a set of clinical studies has been completed or an NDA / ANDA has been approved, it becomes very difficult to change the product or the process to accommodate specific production needs. Such needs may include changes in batch size and manufacturing equipment or process. Manufacturing changes may require new stability, dissolution, and in vivo bioequivalence testing. This is especially true for Level 2 equipment changes (change in equipment to a different design and different operating principles) and the process changes of Level 2 (process changes, e.g., in mixing times and operating speeds within application / validation ranges) and Level 3 (change in the type of process used in the manufacture of the product, such as from wet granulation to direct compression of dry powder).

interests of the industry. Such policies may give results in the short run but in the long run, one has to understand that if the Indian machinery manufacturers need to carve out a niche on the global levels then there is no alternative of giving a push to R&D so that innovation is nurtured and innovation flourishes in the long run on consistent basis. Also of importance is that this R&D has to be an all encompassing one which needs to be across all models, all sizes and all capacities. This will be of great help in scale-up for formulation developers. And once this is achieved then there cannot be in barrier or obstruction to continuous growth. The only pre-condition is to have the mindset and the attitude needed to opt for the path of R&D.

Global demand for Indian pharma machinery is surging because the industry is embracing with open arms several measures, policies and regulations. The Indian machinery manufacturers have started practicing cGMP, US FDA, MCA standards. To enhance, improve and increase the global appeal of Indian machinery quality systems like ISO-9000, standardization, services, innovation and continuous improvement of design are now being followed. Because of the GMP compliance by the Indian pharma machinery manufacturers, the 'Made in India' machines are in demand in the regulated markets of developed countries. Orders are pouring into India from Australia, New Zealand, Spain, Norway, Sweden and Finland amongst others and also from semi-regulated markets like Latin America, Malaysia, Thailand and Indonesia.

In the coming five years, world pharmaceutical market alone will predictably grow at a rate of 8 per cent plus with business opportunity expanding like never before. Countries like USA, Japan and those of Europe will be in control of over 80 per cent of the trade. Asian countries like South Korea, Taiwan and India are estimated to register growth rates ranging in between 12 to 15 per cent annually. Also developing economies are triggering growth.

In addition, the new product patent regime and increased export of Indian pharmaceutical products to global markets have pushed Indian pharma machinery industry to enhance GMP and to go for technological adaptation. In keeping with the international standards, Indian machinery manufacturers practice proper documentation for every manufacturing and maintenance procedure. Also, Indian machinery manufacturers are constantly upgrading themselves, to remain relevant in these evolving times. Today, Indian machines are far better in quality, than it used to be 15 years ago. Indian manufacturers practice the ISO 14000 and 9001 series of quality certification.

In India, the technological up gradation of pharmaceutical machineries is also taking place at a fast pace. From low-cost technological offerings to offering value-added engineering with integration of new-technologies, the Indian pharmaceutical machinery manufacturers have indeed traveled and traversed a long way. Several global companies have already set up shop in India forging joint ventures with local partners. Many other such companies are scouting for partners and opportunities. India still has much to offer in terms of cost-effective solutions. The numerous joint ventures taking place between Indian and foreign companies is a proof that India produces world-class machineries at reasonable prices.

The growth in advancement and up-gradation of technology in machinery has been faster in India. But now the time has come for the industry to scale-up operations. With almost low technology offerings in the initial stage, the Indian machinery today is considered as one that can offer value added engineering with integration of new technologies. Various international companies found it cost effective to work with Indian partners in the form of collaborative ventures. The number of joint ventures between foreign and Indian machinery manufacturers is a testimony to the fact that the Indian machinery industry understands the stringent need of pharmaceutical industry and that it can produce international quality at affordable prices. PPP

"Scale-up will reduce overall development costs & time. It would also lead to better understanding of process variables"

Cipla Vice-President Shri Anjani Kumar talks to Pharma Pro & Pack on the growing importance of scale-up in the Indian pharma machinery manufacturing industry.

Cipla was established in 1935 with the vision of making India self-reliant and self-sufficient in healthcare. Today, Cipla is one of the world's largest generic pharmaceutical companies with a presence in over 170 countries and a work force of over 20,000 working in as many as 34 state-of-the-art manufacturing facilities approved by major international regulatory agencies. Cipla today manufacturers over 2,000 products, 65 therapeutic categories and over 40 dosage forms with continuous and path breaking innovations in R&D. No wonder than Cipla also has over 20 world firsts.

Cipla is renowned for making affordable, world-class medicines that meet the needs of patients across therapies. Cipla also offers services like consulting, commissioning, plant engineering, technical know-how transfer and support amongst other services.

Cipla also has approvals from the US FDA, WHO-Geneva, MHRA-UK, TGA-Australia, SUKL-Slovak Republic, APVMA-Australia, MCC-South Africa, PIC-Germany, Danish Medical Agency, ANVISA-Brazil, INVIMA-Colombia, NDA-Uganda, Department of Health-Canada and MOH-Saudi Arabia, amongst others.

PPP: Has the Indian pharma machinery sector opened up to the importance of scale-up?

Shri Anjani Kumar: Only recently Indian pharma machinery sector was approached by pharmaceutical manufacturing sector to gear-up for scale up activities. Leading machinery manufacturers of India have adopted a very positive and open approach and have shown their willingness to opt for scale-up by working out an agreement.

PPP: How does scale-up helps the Indian pharma machinery manufacturing industry?

Shri Anjani Kumar: Scale-up helps in many ways. Scale-up will help the Indian industry to develop and upgrade the entire process control system. Manufacturers can identify a mathematical model to predict and correlate process parameters to ensure that the process remains within defined manufacturing space. Scale-up will also lead to development and up-gradation of relevant software for recipe and process trending to improve product and process parameters. In scale-up the Indian pharma machinery manufacturing industry can find a tool to modify, upgrade design, control and may be working principle of the machine & technology. It would also help the industry at large to develop and supply machines with identical design with different capacities as per scale up requirements.

PPP: What sort of an approach should be followed in scale-up?

Shri Anjani Kumar: Talking about approach, I think scale-up batch/s should be manufactured prior to exhibit batch/s to optimize process parameters. Concept of Fraude Number, Reynolds Number, Tip Speed, Peripheral velocity, Thixotropy etc used along with statistical model to generate , compare and evaluate process parameters

PPP: What processes should be followed for a scale-up?

Shri Anjani Kumar: Adequate number of scale-up batches should be manufactured to challenge and assess process parameters to define Critical Process Parameters (CPP). Data generated should be compared and evaluated to measure its impact on the Critical Quality Attributes. One should remember that the selection of batch size for scale-up batch is important and should be as close to exhibit or commercial batch size. Machine and technology used for scale up batches should be equivalent in design with machines used in exhibit or commercial batches. Also machines should be congruent.

PPP: Is scale up limited to a particular segment or can be implemented across the board?

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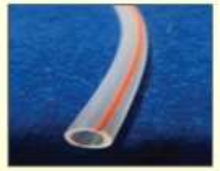

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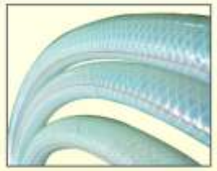

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Shri Anjani Kumar: Scale up and process optimization are tools which are widely used in all industries and recommended in pharmaceuticals industry for all products, dosage forms and processes.

PPP: What are the combinations one has to keep in mind while opting for scale-up of any pharmaceutical machinery manufacturing process?

Shri Anjani Kumar: Machine Design, Construction Material, Occupancy, Critical Process Parameters, Category of Product , Safety Aspects, cGMP requirements, QbD compliances, Expected level of process Containment, Cost, Physiochemical Properties of Material, Risk Assessment are some of the different factors. But most of these factors are interlinked and a combination of these factors drives scale up activities.

PPP: Do you think traditional methods of process scale up in the Indian pharma machinery sector have given way to newer tools and methods for scale-up?

Shri Anjani Kumar: New and better process controls will ensure and increase level of confidence to adhere and meet predefined quality parameters. New mathematical models can be identified and developed for better for process control. PAT tools can be incorporated for inline, online and offline monitoring and evaluation of process.

PPP: What according to you are the most effective methods and tools for a scale-up?

Shri Anjani Kumar: Tabulation, comparison and evaluation of data for process and quality attributes to define manufacturing space for registration, validation and commercial batches. New PAT tools would always be welcome by the industry.

PPP: What are the factors which determine the success of a scale-up in Indian pharma machinery manufacturing process?

Shri Anjani Kumar: Adequate number of laboratory scale up batches along with robustness of process will determine the success for scale up batches. Evaluation of product and process risk assessment and implementation of concept QbD will also increase success rating and post approval changes.

PPP: What are the costs involved in scale-up?

Shri Anjani Kumar: Initial cost incurred in scale up activities, will be paid off subsequently as it may reduce cost incurred in post approval changes, deviations, rejection and failure of batches.

PPP: What are the problems a unit may face while opting for a scale up?

Shri Anjani Kumar: Since it is new concept all machine manufacturers and pharmaceutical manufacturers may not have separate classified facility and machines available for proposed scale up and process optimization activities. Most of these activities are carried out in commercial set up with constraints in resources. PAT tools are still dream rather than reality. Statistical tools are too complicated to adopt. The pharma industry is highly regulated and implementation of new technology and tools are always a challenge. Compliance, Cost, Time and Resources are other hurdles in these new tools in development activities.

PPP: How important are aspects of engineering support and maintenance for proper scale-up of any process?

Shri Anjani Kumar: Most of Indian machine manufacturers do not adhere to design when supplying machines with higher capacities leading to non linear curve in scale up activities. Geometric, Dynamic and Kinematic similarity of machines are important and major contributory factors in successful scale up activities.

PPP: How important are plant design and machinery maintenance issues?

Shri Anjani Kumar: Product category, process details, expected level of containment, cross contamination, availability of required utilities, environmental controls, cleaning process, man- material flow, safety and other factors govern by plant design and maintenance can have impact scale up activities.

PPP: What are the regulatory aspects of scale-up and what are the post approval changes that need to be addressed?

Shri Anjani Kumar: As per ICH guidelines and new USFDA guidelines for process validation it is required to generate sufficient data to define critical process parameters and limits for critical process parameters. This data can further be used to support post approval changes if it is out of manufacturing but within design space.

PPP: Would a proper scale-up help the Indian pharma machinery industry gain a competitive and efficient edge in the years to come?

Shri Anjani Kumar: This will reduce overall development cost and time and it would also lead to better understanding of process variables. Besides it will reduce overall time to respond CMC, Bio and Labelling query. Timeline for product launch can be scheduled and adhered. It would also lead to better compliances of cGMP, Occupational, Safety and other regulatory requirements

PPP: What would your message be to the industry for a proper scale-up?

Shri Anjani Kumar: Every product manufactured will consistently meet preset standards of quality, purity, efficacy and safety with assured and timely supply at competitive price. PPP

Adopting scientific methods & work-cultures like scale-up is now mandatory

ACG Worldwide has been serving the pharmaceutical industry for five decades and is the second largest manufacturer of empty hard capsules in the world. The group comprises of 13 companies, including subsidiaries in China, USA, Indonesia, Brazil and Europe.

ACG Worldwide has a presence in over 100 countries with its products and services, employing approximately 3,200 members that strive to provide world-class technology across multiple domains. ACG offers a complete range of solutions beginning with empty capsules; granulation and coating; capsule filling; tabletting; packaging films; blister packing and carton packing to the end-of-line solutions. With over 20,000 machine installations worldwide, it speaks lengths of the high quality standards followed at ACG as well as complying with major international quality certifications or legislations.

ACG Worldwide is committed to a core corporate competence. ACG research teams strive to develop innovative technology in order to continually give its customers the benefit of a cost competitive edge plus world-class technology. 'SciTech Centre', the group's 50,000 sq. ft. R & D centre located in the heart of Mumbai, is a government-recognized research institution. Especially in the last 25 years, it has witnessed breakthroughs in dosage form development-including controlled-release-pharmaceutical engineering, veterinary and agricultural research, emphasizing on delivery systems.

ACG Worldwide Chairman Shri Ajit Singh speaks to **Pharma Pro&Pack** about the growing importance of scale-up in the Indian pharma industry.

Scaling-up Pharmaceutical Manufacturing

PPP: Has the Indian pharma machinery sector opened up to the importance of scale-up?

Shri Ajit Singh: The Indian pharmaceutical industry has been exposed to regulated markets such as the US and Europe for quite some time now. In fact, the extent of exposure to these global regulatory requirements has increased considerably in the last decade or so. In lieu with these mandatory requirements, the Indian pharma industry is required to provide all necessary assurance in terms of quality of its finished products. Hence, adopting scientific methods and work-cultures like scale-up has become mandatory.

PPP: How does scale-up help the Indian pharma machinery manufacturing industry?

Shri Ajit Singh: Scale-up requires conducting thorough studies on new formulations and processes during the development-phase to pilot-phase. Getting to know the process well leads to understanding of variables that can be controlled and monitored to achieve reproducibility. Extensive studies made on a small-scale help in minimizing optimization of the products on a commercial-scale. Equipment manufacturers like ACG Worldwide which specialises in both lab scale machine models and commercial equipment support the industry with technical & development support for scale-up.

PPP: What sort of an approach should be followed in scale-up?

Shri Ajit Singh: It is necessary for the Indian pharmaceutical industry to realise that there has been a major change in regulatory requirements as well as the work culture for assessing quality during processing. The shift is from measurement of finished product quality attributes to measurement of process parameters and Critical Quality Attributes (CQAs). The following steps detail a strategic planning and approach for a successful scale-up operation:

- Define the target product profile in terms of quality, safety and efficacy
- Identify critical quality attributes of the drug product, so that the product characteristics that have an impact on the product quality can be studied and controlled
- Determine the quality attributes of the drug substance and excipients, and select the type and amount of excipients to deliver drug product of the desired quality and efficacy

- Select appropriate manufacturing processes (and equipments)
- Identify a control strategy, wherever possible

A complete understanding of these process variables during small-scale trials in the lab and a system to monitor & control all variables determines the success.

PPP: Is scale up limited to a particular segment or can be implemented across the board?

Shri Ajit Singh: No, scale-up is not limited to any particular segment

and is applicable to all. Right from granulation to capsule filling, from tabletting to tablet coating, scale-up expertise is required across the manufacturing cycle. This requires technical expertise and an experience of working with a wide range of formulations and excipients. With over 50 years of experience and technology backup from global pharma giants, companies like ACG have helped hundreds of formulation scale-ups.

PPP: What are the combinations one has to keep in mind while opting for scale-up of any pharmaceutical process?

Shri Ajit Singh: The factors that need to be considered during scale-up are:

- Consider whether the principle of operation of in lab-scale pharmaceutical machinery or equipments is the same as the commercial-scale equipment.
- Evaluate efficient material handling options for large volumes with closed transfers
- Conduct studies on the effect of long process times on the materials & their subsequent stability as processing times may increase in scaled-up batches
- Also consider CONSUMPTION of utilities and the necessary capacities in commercial

PPP: Do you think traditional methods of process scale up in the Indian pharma machinery sector have given way to newer tools and methods for scale-up?

Shri Ajit Singh: The only traditional methods in practice were by trial and error, or on the basis of one's experience. Earlier, scientific methods were not used to make an estimate of the situation in the processing of scaled-up batches. This has changed drastically as the exposure to global regulated markets has made the industry aware of the methodology to be adopted for a proper scale-up. Hi-tech process monitoring systems incorporated on both lab scale and commercial equipment help in making a 'Science' out of a 'Practice'.

PPP: What according to you are the most effective methods and tools for a scale-up?

Shri Ajit Singh: Various techniques and processes such as Design of Experiments (DOE), QbD Design Space, Process Analytical Technology (PAT), Multivariate Analysis and Risk Analysis are often employed for a scale-up to be effective. A lot of these programs are brought to India by ISPE, the International Society of Pharmaceutical Engineering. We pioneered the entry of the ISPE into India by setting up the ISPE India affiliate. Associations like the ISPE help in bringing global experts and international knowledge on new pharmaceutical technologies into India.

PPP: What are the costs involved in scale-up?

Shri Ajit Singh: As a rule of thumb, the number of trials required to be performed for any new product would be more or less the same. The differentiating factors between various products, in terms of costs, would be the cost of materials, cost of equipments & processing, and cost of utilities. However, companies need to realize that such costs incurred are much less as compared to costs of rework or recalls.

A major unforeseen cost that may arise is the lack of adequate studies made in lab-scale trials, attributed to either lack of proper data compilation and analysis, or worse, lack of necessary action on findings from lab trials. Although such costs of rework and failures are difficult to estimate, one could say that these ultimately reflect in the ROI calculation of scale-up. Add to this, the cost of losing business opportunities due to reworking, or the loss of business due to recalls in case the product was launched without adequate studies.

PPP: What are the problems a unit may face while opting for a scale-up?

Shri Ajit Singh: The major problems encountered during scale-up are:

- Considerable time is required for scale-up studies, and the company should be willing to invest time in planning and implementing scale-up
- Considerable expense in terms of materials, skilled &

competent manpower and investment in infrastructure
- Lack of linearity in the equipments & utilities used in the lab-scale, pilot-scale and commercial-scale
- Marketing pressures and perceived loss of business opportunity

PPP: How important are aspects of engineering support and maintenance for proper scale-up of any process?

Shri Ajit Singh: Support from engineering and maintenance are very much essential. During optimization of any process, it is necessary to have minimum variables. The raw materials, themselves and their behaviour during processing, are the major source of variables. It is desirable to have the equipments function as per their design and not contribute to the plethora of variables that will make analysis of any process difficult.
Engineering considerations are important in defining equipment specifications and utility consumptions in scale-up calculations. Any error in such calculations could lead to serious failures in processing.

After procuring the correct equipments, it is expected that they perform correctly each time they are used in order to remove any room for doubt in process studies.

PPP: Would a proper scale-up help the Indian pharma industry gain a competitive and efficient edge in the years to come?

Shri Ajit Singh: Yes, absolutely. As the global pharmaceutical market is gearing up for cost-effective ways of producing drugs while creating a new pipeline for future growth, scale-up plays a significantly important role – and particularly so for the Indian pharmaceutical industry. According to Pharmexcil, the industry registered exports of US$ 14.5 billion for the year 2012-13, rising nearly 25% compared to the previous year figures. With the commerce ministry announcing Indian pharma sector's exports to touch US$ 25 billion by 2016, processes like scale-up will prove to be effective tools for helping the industry build a robust product, reduce - preferably eliminate - avoidable costs, and continue to deliver cost-effective drugs.

PPP: What would your message be to the industry for a proper scale-up?

Shri Ajit Singh: Adopting scale-up as a regular tool in optimizing processes to commercial-scale is not a matter of choice. Carrying out scale-up in a scientific manner is the only way to establish processes that deliver products to the market that meet QbD requirements and Quality, Safety & Efficacy standards. PPP

Scale-up can add much needed competitive edge to the Indian industry

Shri Bharat Kumar Doshi has more than 30 years of experience in facility design for API, Bulk Drug, pharmaceutical & biotechnology industry as per the WHO, GMP, USFDA, MHRA and other International Regulatory Requirements.

Shri Bharat Kumar Doshi, Managing Director of Doshi Consultants Pvt. Ltd. delivered many seminars nationally and internationally in various country on cGMP facility design, HVAC, Water Systems design, validation, qualification, Risk Assessment and Analysis. He is also on Panel of WAHO (West Africa Health Organization).

Shri Doshi is also an active member of the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), USA, the International Society of Pharmaceutical Engineering (ISPE), USA, the Institution of Validation Technologies (IVT), USA, Drug Information Association (DIA), USA, Institute of Engineers (IEI), India, Life member, National Safety Council (NSC), India, Life member, Solar Energy Society of India (SESI), India and Honorary Faculty Member, DAVV University of Indore, India.
He is in his credit design of more than 150 Pharmaceutical, Biotech, API facility in various countries like USA, Europe, Saudi Arabia, African CIS countries etc apart from India.

PPP: Has the Indian pharma machinery sector opened up to the importance of scale-up? How does scale-up helps the Indian pharma machinery manufacturing industry?

Shri B.K. Doshi: The Indian pharma machinery industry has come a long way from being an import-dependent sector in the sixties and seventies, to an industry with an annual growth rate of 17 per cent to 20 per cent. But I think the Indian pharma machinery manufacturers have as yet not warmed up to the importance of scale-up. The Indian pharma machinery manufacturers still need to put in a lot of efforts in this regard and catch up with the rest of the world. We need to advance at a fast pace and opt for the innovations taking place at the global level. Scale-up will definitely help the Indian pharma machinery manufacturing industry. Scale-up will open up global opportunities and also add the much needed competitive edge to the Indian industry.

PPP: What sort of an approach should be followed in scale-up?

Shri B.K. Doshi: For effective scale-up in the context of the Indian industry, I think the best option available to us is to opt for joint ventures with big international players. Till recently we could were not successful in attracting international manufacturers for high value, high tech products to have joint ventures, for technology transfers. For this, the industry at large needs to continuously work on improving the brand image of our products and industry. Fortunately in the engineering space, we have been able to overcome this perception to some extent. There are positive fallouts for all the stakeholders. If an Indian company ties up with a European company for engineering design then the Indian company gets technical support from the European company and the European company by doing the engineering design here in India also gains as it works out far more cheaper than as compared to Europe. This works out well for everybody. Indian companies have the support of a European brand name.

PPP: What processes should be followed for a scale-up?

Shri B.K. Doshi: Again my answer is going to be very simple. The time has come for the Indian pharma machinery manufacturers to understand the importance of automation in the manufacturing process. So the first step for scale-up is to opt for more automation in manufacturing facility. By scaling up we also should aim at reversing the situation prevalent in the industry today. Look at the export-import segment. In value terms, there are more machines being imported today than exported, but in terms of quantity, it is reverse. This is because imported machines are more than seven to eight times the value of the Indian machines. By opting for scale-up, the Indian industry needs to make a cut in the high tech segment. The Indian industry will need to make machines requiring high technology and also lab equipment required for R&D labs.

PPP: Is scale up limited to a particular segment or can be implemented across the board?

Shri B.K. Doshi: Scale-up cannot be implemented in a compartmentalized manner. It can only be successful if it is across the board for all segments of pharma machinery. I

suppose the biggest issue that scale-up can confront it the low investment by the Indian industry in the R&D sector. There should also be a lot of knowledge and information sharing for scale-up. Unfortunately the manufacturers do not work together and there is a lot of fragmentation in the industry with participation of a large number of small scale manufacturers. IPMMA has initiated efforts to unite the industry. But I suppose more needs to be done. We have to scale up economically and invest in R&D in a bigger way. If we were to cooperate in marketing and R&D efforts, this could become a reality. Also demanding urgent attention is the issue of trained manpower. Salaries and pay packets have been on the rise and this makes all the more difficult for small scale manufacturers to attract and afford skilled and trained manpower.

PPP: What are the combinations one has to keep in mind while opting for scale-up of any pharmaceutical machinery manufacturing process?

Shri B.K. Doshi: There are several combinations one has to keep in mind while opting for scale-up of any pharmaceutical machinery manufacturing process. But according to me the focus should be on more and complete automation with GMP aspects. One also has to understand that given the fact that the pharma industry is set to grow, the Indian pharma machinery manufacturers also need to understand and work out steps to match this pace of growth. I don't foresee any demand supply gap, in terms of volumes. The pharma machinery manufacturers have been able to meet the needs of the industry. With orders almost pouring almost all the machinery manufacturers have increased their capacities. What we need to do is to keep pace with the rapidly changing technology on the international scene. For that we have to invest in R&D and initiated process to build our brand. We also need to enter into technology transfers. We need to have marketing tie-ups internationally so that we can increase our volumes and scale up. These efforts are on, but we need to do much more.

PPP: Do you think traditional methods of process scale up in the Indian pharma machinery sector have given way to newer tools and methods for scale-up?

Shri B.K. Doshi: Yes indeed. With dynamic changes taking place at a fast speed the days of the traditional methods are over since long. Traditional methods may just not work. We need to look towards newer tools and methods for scale-up. In fact the new and latest tools, techniques, processes and systems are indeed making their way into the industry. If the machinery manufactures want to truly partner the pharma and life science sector of this country then they need to evolve in terms of technology and put in investments needed for this technology. The industry needs to upgrade to newer technologies, to increase levels of automation. The industry also needs to improve documentation. I also learnt that IPMMA was requesting personnel from pharmacy colleges to train industry professionals in better documentation techniques.

PPP: What according to you are the most effective methods and tools for a scale-up?

Shri B.K. Doshi: I suppose the joint venture approach is the right and efficient approach to scale-up. Over the years, Indian pharmaceutical machinery manufacturers have earned the reputation of being the hub for low-cost manufacturing of machines. The reasons behind this is the availability of cost-efficient man power, highly skilled and experienced engineers and low capital investment on plant and machinery. Also India has shown remarkable progress in growth in up-gradation and advancement of technology in machinery. Today, India is in the forefront to offer value added engineering with integration of new technologies. Many foreign companies find it cost effective to work in the form of collaborative ventures with Indian partners. The number of joint ventures (JVs) between international and Indian machinery manufacturers is a proof of the fact that the Indian manufactures of machineries understands the stringent needs of pharma industry. Indian manufacturers can now produce international quality at affordable prices. It is significant to note that India is making machines which are 10-20 times less expensive than machines produced in the US and Europe.

PPP: What are the factors which determine the success of a scale-up in Indian pharma machinery manufacturing process? What are the costs involved in scale-up? Also what are the problems a unit may face while opting for a scale-up? How important are plant design and machinery maintenance issues?

Shri B.K. Doshi: Success of scale-up hinges on several factors. But I suppose the success primarily rests on the quality course the industry opts for. Also one has to factor in the cost competitiveness and delivery schedules. Costs would depend upon what sort of scale-up does a unit opts for. It is the way and the manner in which the approach is made to scale-up that would determine the costs. All the risks associated with the market are associated with scale-up. This is the reason why scale-up has to be properly and adequately thought out process. Also plant design and machinery maintenance issues are very important as any loss of time will have a major bearing on the overall costing. Faulty designs and maintenance issues may well pull down the overall productivity.

PPP: What are the regulatory aspects of scale-up and what are the post approval changes that need to be addressed? Also would a proper scale-up help the Indian pharma machinery industry gain a competitive and efficient edge in the years to come?

Shri B.K. Doshi: The regulatory aspects have to be factored in while opting for a scale-up. Yes very much. The Indian industry will be in a position to check the Chinese invasion only if it opts for the right scale-up at the right time.

PPP: What would your message be to the industry for a proper scale-up?

Shri B.K. Doshi: With global exposure Indian machine manufacturers have the potential of capturing the global markets. If they improve quality, accuracy and time line with a proper scale-up in place, they can very well get a better price, more turn over and a larger chunk of the world market. The time has come to leverage the strengths of the Indian pharma engineering and machinery players. The USP of the Indian machinery sector is value for money. Different machineries manufactured in India are extremely competitive and have a good price: performance ratio. Secondly, Indian pharma machinery manufacturers have not yet got into the culture of strictly adhering to contracts. This is the reason why Indian machinery manufacturers give better after sales service, going beyond the Annual Maintenance Contracts (AMCs). Also the Indian manufacturers and suppliers are very flexible for customers in terms of deliveries and other contractual terms. Foreign manufacturers do not give such support to pharma manufacturers. We need to leverage on some of these strong points. PPP

Indian pharmaceutical industry update

Growth opportunities intact but managing industry challenges remains key, says ICRA

Overview

Fiscal 2012-13 was a year of strong operating performance for the Indian pharmaceutical industry as it benefitted from patent expiration wave in the US, strong growth from the emerging markets and favourable foreign exchange scenario. During the year, Indian pharma companies also managed to gain traction in their European businesses despite the challenging environment. However, back home in India, the growth momentum showed signs of moderation owing to relatively weak seasonal demand, adverse impact of inflationary pressures on disposable incomes coupled with uncertainties surrounding the implementation of the new pricing policy in the second half the financial year says India's leading credit rating agency ICRA in its July2013 pharmaceutical industry update report.

US Generics: Patent expirations will continue to underpin growth; focus on complex generics and attempts to diversify positive for long-run

Despite the high-base of the previous year, we believe that the industry would continue to experience strong growth in the near-term however there would some moderation in the growth trajectory. Principally, the generic opportunities in US will continue to drive revenue growth for Indian pharma companies. This would be an outcome of a) the sizeable generic opportunity (drugs with brand value of US$ 80 billion are expected to face generic competition) over the next 4-5 years, b) strong product pipeline of pending ANDAs with high increasing proportion of complex generics and c) market share improvement given the relatively small base (share of leading Indian companies is less than 10% in the U.S. generics space). In addition, acquisitions by Indian companies to add technical capabilities and focus on strengthening branded business (albeit on a small scale) are also likely to drive growth going forward as companies feel the need to diversify.

Domestic Formulations: Growth momentum likely to improve as pricing policy related concrns subside

While growth momentum in the domestic formulation industry slowed down in 2012-13 owing to a confluence of reasons (discussed above), we believe that the industry would revert to its long-term growth trajectory in the medium-term as structural growth drivers continue to remain impervious. The growth momentum has picked-up over the past few months and with pricing policy related matters behind us, we expect the industry to revert to a growth of 10-12% in 2013-14. The impact of new DPCO though expected to be limited, could also get offset by volume expansion and efforts of industry participants to take price hike in rest of the portfolio.

Europe: Growth opportunities marred by pricing pressure and changing market dynamics

In Europe, the performance of Indian companies improved in 2012-13 in comparison to the prior year led by primarily new product launches which helped to offset the impact of pricing pressure. However, given the pace of healthcare reforms and the way competitive landscape is changing in Europe, we believe that the performance of generic companies would remain contingent on new product introductions. As many of the European markets are gradually shifting character from being 'branded generic' to 'un-branded generic' and from being 'physician-influenced' to 'pay or-influenced', a relook at business plans also appears to be a common theme across companies. Generics companies are increasingly focusing on expanding presence in relatively underpenetrated markets (i.e. France, Spain & Italy), branded generic markets of East Europe and niche areas like complex generics, OTCs etc. In general, Indian pharma companies generate a relatively lower share of revenues from Europe with profitability also subdued compared to other markets.

Emerging Markets: Offer promising growth opportunities but with caveats

In addition US generics, emerging markets present one of the most promising growth opportunities for Indian pharmaceutical companies. As growth prospects normalize in developed markets, companies are increasingly focusing on emerging markets through portfolio expansion, alliances or JVs and acquisitions. Given the distinct nature of some the markets being tapped, managing regulatory hurdles (i.e. delays in receiving approvals in Brazil, healthcare reforms in Russia) and execution however remains the key. Indian companies though have an inherent advantage given their experience with 'branded generics' in India. Amongst new frontiers, evolving generic market in Japan (world's second largest pharmaceutical market with only 23% generic penetration) and biosimilars provide alternative growth prospects for Indian

companies. While product filings and approvals will be gradual in Japan, hurdles in biosimilars could be multi-fold, stemming from higher R&D outlay for clinical trials and uncertainties related to pathway for regulatory approvals.

Profitability indicators remained stable in 2012-13 but some headwinds persist in the near-term

In 2012-13, operating profitability indicators of the pharma companies remained fairly stable in comparison to the prior year led by strong scale-up in the US generics business on back of high margin FTF opportunities and favourable foreign exchange environment. Steady growth momentum in some of the branded generic emerging markets also aided to the earnings profiles. Overall, margin pressures were limited to few companies and lack of new product introductions in the US, higher expenditure on R&D, one-time charges related to the implementation of GDUFA and increase in manpower costs were the most common factors. We believe that the margins of Indian pharma companies are currently sensitive to broadly four key factors – a) the implementation of the new pricing policy in India, b) relatively lower proportion of blockbuster generic opportunities in the US in CY 2013 compared to CY 2011 and CY 2012, c) expectation of increasing R&D spending and d) evolving regulatory reforms across many of the emerging markets which may impact margins. The sharp volatility in foreign exchange and the recent depreciation of INR vis-à-vis US$ will also have influencing role to play given the dependence on international markets. That said, company specific factors would however continue to impact earnings profile and quality of product pipeline with higher share of limited competition launches will be the single most differentiating factor. Earnings of companies with debt profile skewed in favor of foreign exchange borrowings would be exposed to MTM losses.

Investments in R&D and acquisitions expected to gain momentum

Over the years, Indian pharma companies have developed capabilities to target complex segments like injectables, inhalers, ophthalmics and even biosimilars. Given the increasing focus on these segments, pharma companies have been investing a higher proportion of their sales in R&D activities over the past few years and have guided to spend even higher amounts as they continue to broaden their product portfolio of complex compounds. We believe that there three key drivers for higher R&D spending by Indian companies – a) increased pace of product filings in US and Europe, b) focus on complex generics, some of which require clinical trials to demonstrate basic safety and efficacy and c) investments in developing biosimilars for emerging markets and eventually for developed markets. In addition, we expect in-organic investments to also gain momentum in the medium-term as companies plan to create stronger presence in emerging markets and build expertise in select therapy areas. In particular, fast-growing branded generics markets in South-East Asia, Latin America and even some of the markets in East Europe will be of interest to Indian companies. Besides, market-entry driven acquisitions, we also expect investments to add technical capabilities in selected therapy areas or delivery systems to also continue going forward in view of increasing focus on complex generics. PPP

Central & West African regions emerge as pharma focus regions

India still remains the largest source of pharmaceutical products to Nigeria

Central & West Africa is growing into one big focus region for the global pharma industry. Comprising almost a third of the whole continent, especially the West African region has a population of approximately 250 million. Imports of finished products account for over 60% of the African pharmaceutical industry. Just Nigeria's pharma business is worth USD 2.5 billion serving 150 million Nigerians. The pharmaceutical market in West Africa has been growing 5% - 7% annually. With over 200 active manufacturers of pharmaceuticals in West Africa, there are great opportunities for investment and development.

It is that potential for the African continent to act as a hedge against slowing long-term growth in established emerging markets that appeal to pharma companies. Pharma companies are thinking hard about what happens when those emerging markets start to slow because they are not going to continue growing at the rate that they're growing forever – and a place where pharma companies are putting a lot of our attention is Africa in general and in the Central and West African region in particular.

Most of the growth will be fuelled by increasing economic wealth and demand for treatments for chronic diseases in a more urban, middle-class population. Non-communicable diseases – like heart disease, lung disorders, diabetes and cancer – are expected to account for 46% of all deaths in sub-Saharan Africa by 2030, up from 28% in 2008, according to the World Bank.

Also news is coming in on how western diseases' are driving a pharma boom in these regions. No wonder then drug makers are eyeing central and West Africa's potential. Overall Africa's growing urban middle class is attracting pharmaceutical firms and analysts say pharmaceutical spending will rise to USD 30 billion by 2016 in the African continent as the continent is expected to experience a rise in demand for chronic disease treatments.

Major pharmaceutical companies are increasingly looking to harness central and West Africa's growing pharma opportunities, lured by an emerging middle class in the growing urban centers. Although the total size of the region's market is still small compared to other global regions, analysts say that the growing urbanisation hold the key to unlocking the industry's lucrative potential. Increasing individual wealth, coupled with a developing health system infrastructure and a rising demand for drugs treating chronic diseases, are driving demand for pharmaceuticals.

According to the World Health Organization (WHO), Africa is home to 11% of the world's population, yet accounts for 24% of the global disease burden. And as urban populations are becoming wealthier they are going to suffer the kind of chronic diseases that western individuals suffer. But while infectious illnesses such as HIV/AIDS and tuberculosis still remain a major problem, the continent is also expected to experience a surge in demand for treatment of non-communicable diseases (NCD), such as cardiovascular and respiratory disorders as well as cancer and diabetes, in the coming years. The WHO estimates that by 2020 the biggest increases in NCD deaths will occur in Africa. A 2011 report by the African Development Bank said that Africa's middle class -- defined as people spending between USD 2 and USD 20 a day at 2005 prices -- increased to 34% of the continent's population in 2010 -- nearly 313 million people. The continent's urban population is also projected to exceed that of China and India by 2050, according to U.N. figures.

Next to major market-leading multinationals such as Sanofi and GlaxoSmithKline, which traditionally have had a strong presence in the continent, a diverse mix of drug manufacturers have made significant inroads in recent years. Indian and Chinese companies have more than doubled their imports to Africa over the last decade. India still remains the largest source of pharmaceutical products to Nigeria with pharmaceutical exports to the West African country standing at USD 307 million a year by the end of March 2012, having gone up by 35 per cent and 37 per cent annually during the previous two years.

It's not surprising, then, that major cities of Central & West Africa are expected to be at the forefront of the industry's growth. There is a rapidly growing opportunity across Africa, not just in the markets that are well established but growth is strong and the macroeconomic indicators are that growth will continue to remain strong over the next 10 years and probably beyond.

Yet companies keen to tap Central and West Africa's pharmaceutical opportunity must overcome several challenges whilst operating in a diverse and heterogeneous market, different languages, varied regulations and unequal levels of infrastructure development. Amid such challenges, the industry is also keeping an eye on the substantial threat posed by counterfeit drug makers, who are also trying to benefit from Africa's expanding demand for modern medicines. Still, despite these challenges, insiders say the industry's future is bright. There is a boom and it's going to get even stronger as the middle class grows. Pharma companies have to be on the ground now to be able to win in this segment. Nigeria is the one country that pharma companies can't ignore. Within a decade Nigeria could be one of the world's 20 largest economies. Its population of 160 million means it is already larger than Morocco in terms of market size.

Industry experts also point out that Central and West Africa isn't just an opportunity for pharma. At its very heart it is a macro economic opportunity. Next year, the African continent will have seven of the 10 fastest growing economies in the world. But as far as pharma is concerned the pharma companies will have to look at rise of the African middle class consumer, the ability to pay for more drugs, and the willingness to spend money on healthcare. Indeed, 10 major African cities are expected to represent between 20 and 30 % of the total pharmaceutical market opportunity by 2016. Since 2000, healthcare spending has grown at a 9.6 % pace (CAGR) across many African countries.

As such Africa is a vast continent of 53 countries. But different regions are chalking out their own plans of actions. Central and West Africa are seeing increase in public healthcare spending, countries are moving towards national health insurance schemes and investing in public healthcare and looking forward to introducing new healthcare schemes. Growth is coming from the central and the western parts. Africa is a long-term growth opportunity that will probably be going strong when some of the current big 'pharmerging' markets will be starting to moderate their growth levels. The only challenge that companies have is deciding which of Africa's countries to invest in.

Not only is the continent's economic growth grabbing attention in boardrooms but the shifting nature of its disease burden is luring Big Pharma, as new opportunities open up for treating chronic diseases afflicting the middle classes, rather than just fire-fighting infection. Global pharma companies hope to reap rewards by investing early in a region where many of them already have historic commercial ties. Recent violence in Mali and Algeria may have put Africa in the headlines but Sanofi of France – the international drug company with the biggest sales in Africa – is still pushing ahead with a third factory in Algeria.

Over the past couple of years, Africa has become an extremely interesting market and many pharma companies want to continue to expand their commercial presence there. By 2016 pharmaceutical spending on the continent is expected to reach USD 30 billion, driven by a 10.6% annual growth rate that is second only to Asia and in line with Latin America. Presently the spending stands at USD 18billion. By 2020 the market will have more than doubled from current levels to USD 45-billion with the emergence of large cities of well-off middle classes that can increasingly afford to pay for western medicines. The market presents this opportunity for drug makers, spurred in part by robust economic growth and demographic changes.

Although it is likely to remain a niche market, the promise of Africa is that it will continue to grow in the next decade as Asia and Latin America start to reach maturity. Secondly drug manufacturing does not happen in a void. And the expertise needed, such as training, the links between universities and industry, regulatory framework needs to be established. The market is promising but hurdles need to be cleared. The potential for continued revenue growth in Central & West Africa is very significant. The region may be still very challenging and there are still all sorts of issues, but gradually Central and West Africa is coming. The pharmaceutical business is growing and it will grow. It is the next big thing in Africa. PPP

EDI progress ahead on Pharma Machinery Manufacturing Cluster in Ahmedabad

Monthly Progress Report
May-2013
Name of Project : Pharma Machinery Manufacturing Cluster
Location : Ahmedabad
Association : Indian Pharma Machinery Manufacturers' Association (IPMMA)

The following activities have been completed / in progress:-

(1) Training has been given to BDS provider in following aspects of technology:

- Electro-polishing process on stainless steel
- Design of machineries with tolerances , open tolerance
- Establishing Common Facility Centre (CFC)
- Technology of electro less nickel plating
- Seam welding , projection welding, stud welding

(2) The BDS providers along with the CDE visited the following units for the purpose of counselling:-

SR NO.	NAME OF THE UNIT	CONTECT PERSON	ADDRESS
1.	N.K.P. Pharma Pvt. Ltd.	Mr. Darshanbhai	Vatva, GIDC
2.	Prism Pharma Machinery	Mr. Bharat bhai	Vatva GIDC
3.	Ashish Engineering	Mr. Ajay Joshi	Vatva, GIDC
4.	Laxmi Pharma Machinery	Mr. Kiritbhai	Kathwada, GIDC
5.	Powerpac Engineering	Mr. ManaharGajjar	Vatva, GIDC
6.	Parth Engineering & Consultant	Mr. Arvindbhai	Vatva, GIDC
7.	Aryan Engineers	Mr. SagarPatva	Gota, Ahmedabad
8.	Shree Shakti Krupa Boring Works	Mr. Jigneshbhai	Vatva, GIDC
9.	Proton Engineers	Mr. Hiren Patel	Kathwada, GIDC
10.	Chitra Machineries Pvt. Ltd.	Mr. Vasantbhai	Kathwada, GIDC

(3) Counselling was offered on:-

- Backward forward linkages
- Electropolishing on SS components
- Tolerance Analysis
- Establishing Common Facility Centre, GOG & GOI Scheme
- Business opportunity for profitable business venture
- Welding Technology And Quality Improvement

(4) The following activities and programmes of the project are on progress:-

- Improvement in productivity and quality
- Export marketing
- Backward / Forward Linkages
- Business development service and enterprise linkages
- Exposure to International and National Standards
- Domestic marketing

(5) In company program on Tolerance Analysis and its application was conducted at N.K.P. Pharma Pvt. Ltd., Vatva GIDC on 03-05-2013 :-

EDI organised incompany program at N.K.P. Pharma Pvt. Ltd. on 03-05-2013. A group of intrapreneurs/ professionals are participated in the program. The company has requested for repetition of such programs. EDI has given partial exposure of Indian Standards, IS-2102 part-1: General tolerance for linear and angular dimensions without individual tolerance indications.

Mr. Riken Shah, EDI, conducted in company programme at N.K.P. Pharma Pvt. Ltd.

(6) In company program on Tolerance Analysis and its application was conducted at Prism Pharma Machinery at Vatva GIDC on 30-05-2013

As per the need of the cluster units, they want to do standardisation in their products and it is possible by following Indian Standards on design of machineries. Therefore, EDI organised in company program at Prism Pharma Machinery on 30-05-2013. This was the first phase of the program, in which the participants have been informed on the need of standardisation of the machines they are manufacturing and the ways to follow the same.

A group of professionals participated in the program.

By
Sandip Gediya | Assistant Cluster Development Manager
EDI OF INDIA

Entrepreneurship Development Institute of India (EDI) is implementing Cluster Development Project at Pharma Machinery Manufacturing Cluster-Ahmedabad in association with IPMMA. Three years Cluster Project is sponsored by Industries Commissionerate, Government of Gujarat. As per the findings of the Diagnostic Study conducted by EDI, implementation of the action plan has been started since January 2013. EDI is doing R&D work, incompany programs, counselling to units & inter-linkages amongst the cluster stakeholders. During the Cluster Development Co-ordination Committee (CDCC) meeting held on 28-06-2013 at prism Pharma Machinery, Vatva, EDI has presented the different activities carried out in last six months. This includes completion of R&D for development of Electropolishing on stainless steel components as per the international standard ASTM –B 912.

Shri H D Shrimali, AddlnInd Commissioner, Govt. of Gujarat chaired the CDCC meeting. About 16 proactive members of the cluster attended the meeting. EDI presented the list of machinery required for the proposed CFC. These machines are inline with the diagnostic study findings. Shri H D Shrimali gave the detailed information on the CFC schemes of GoI and GoG. He guided to the members on step by step roadmap for establishment of CFC. He answered the queries raised by the members during the meeting and ensures to give full support to establish a CFC. The entrepreneurs committed that they will form an internal committee for commencing the activities of the proposed CFC. EDI will facilitate for SPV (Special Purpose Vehicle) formation and DPR (Detail Project Report) preparation as a part of CFC establishment.

Shri H D Shrimali, Additional Industries Commissioner, Govt of Gujarat is guiding the entrepreneurs on CFC establishment in the Pharma Machinery Manufacturing Cluster at Ahmedabad during the CDCC meeting held on 28-06-2013 at Vatva, Ahmedabad.

Part-lll (Continue from Apr - June 2013 issue)

VDMA Documents
Food Processing Machinery and Packaging Machinery

Integration of intelligent components in packaging and processing machinery in a GxP environment

VDMA
Food Processing and Packaging Machinery

VDMA-guideline on integration of intelligent components in packaging and processing machinery in a GxP environment
Frankfurt am Main, January 10, 2013 – This guideline outlines the requirements arising from 21 CFR 11 and structures the data interchange to take account of these requirements.
Furthermore it specifies the communication protocol VDMAXML version 2.0 to facilitate communication in a GxP environment. Examples of the implementation of GxP-specific services are given in the appendix of the guideline.
The guideline published as VDMA Document Food Processing Machinery and Packaging Machinery No. 9, revised edition 2012, is downloadable free of charge from the VDMA publications database at www.vdma.org/nuv.

Contact: Dr. Peter Golz, VDMA Food Processing and Packaging Machinery

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+49 69 66 03-2656
peter.golz@vdma.org

Example of data:

```
<VDMAXML_P>
    <PUT v="SysEventMessage" s="cur">
        <SysEvent>
            <UserID>ADMIN</UserID>
            <UserFullName>Hans Maier</UserFullName
            <ComponentID>Panel1</ComponentID>
            <MsgID>661</MsgID>
            <MsgType>UserLogin</MsgType>
            <ClientTime>4294967321</ClientTime>
            <Text>
```

Integration of intelligent components in packaging and processing machinery in a GxP environment

```
                <TextID>ID_LOGIN</TextID>
                <Lang>en</Lang>
                <Entry>User G. Miller logged in successfully</Entry>
            </Text>
        </SysEvent>
    </PUT>
</VDMAXML_P>
```

Integration of intelligent components in packaging and processing machinery in a GxP environment

BatchControl service

In order to carry out a change of batch consistently for the whole machine it may be necessary to control or interrogate connected devices in a defined sequence (e.g. counter counts).
This purpose is served by three control variables which are to be operated by each connected device producing batch-relevant data. Since the variables are related to devices, their global names start with the respective ComponentID.

Agreed PVs

Memory class (s)	Name (v)	Data	Meaning
cmd	*ComponentID*_BatchCmd		Batch-related command to the component
cur	*ComponentID*_BatchStatus		Message back from the component about the status of the batch-relevant data
cur	*ComponentID*_BatchCmdProgress	0-100	Progress of execution of BatchCmd (in percent)

Commands and status values have yet to be laid down. Typical commands are BatchEnd, BatchReset, BatchRestart.

Integration of intelligent components in packaging and processing machinery in a GxP environment

Appendix IV (informative) Variable names

The following list is a compilation of the variables defined in this document

Variable	Meaning	Described in Section ...
*ComponentID*_Start Server	Variable for controlling the DataServer	6.6.2
*ComponentID*_StartScan	Variable for interrogating the current setting values	6.6.2
*ComponentID*_ServerStatus	Variable for transmitting DataServer status messages	6.6.2
*ComponentID*_ServerMessage	Message from a DataServer	6.6.2
LoginRequest	Variable containing data required for registering on the log-on server	Appendix III
LogoutRequest	Variable for logging off on the log-on server	Appendix III
PublicKey	Variable for transmitting the public key in the RSA 1024 bit encryption system	Appendix III
*ComponentID*_UserPerm	Variable containing the log-on result, the userID, the user role and the remaining period of validity of the password	Appendix III
*ComponentID*_UserName	Variable for inquiring about the user currently logged onto a component	Appendix III
SetFormat	Variable containing statement of desired value for format/formulation	Appendix III
CurrentFormat	Variable containing data of the format or formulation currently set	Appendix III
Save Format	Variable for storing the current process values as format	Appendix III
Formats	Variable for reading out all known formats	Appendix III
*ComponentID*_SetSubFormat	Variable containing statement of desired value for format/formulation on the component	Appendix III
*ComponentID*_CurrentSubFormat	Variable containing data of the format or formulation currently set	Appendix III
*ComponentID*_SaveSubFormat	Variable for storing the current process values of a component as format	Appendix III
*ComponentID*_SubFormats	Variable for reading out all known formats of a component	Appendix III
ChangePasswordRequest	Variable containing data needed for a password change	Appendix III
*ComponentID*_ChangePasswordStatus	Variable containing data needed for presenting the result of a password change request	Appendix III
AuditTrailMessage	Variable containing a message to the audit trail server	Appendix III
AuditTrailCmd	Command to the AuditTrail server	Appendix III
*ComponentID*_AuditTrailAck	Acknowledge variable for confirming receipt of an AuditTrail message	Appendix III
SysEventMessage	Variable with content of a message to the event logger	Appendix III
SysEventCmd	Command to the event logger	Appendix III
*ComponentID*_BatchCmd	Batch-related command to the component	Appendix III
*ComponentID*_BatchStatus	Return message from the component about the status of batch-relevant data	Appendix III
*ComponentID*_BatchCmdProgress	Progress of processing ComponentID_BatchCmd in %	Appendix III

Notes:
The name element „*ComponentID*_“ is the uniquely configured name of a component.

Integration of intelligent components in packaging and processing machinery in a GxP environment

Appendix V (informative)
Notes on the implementation of a broker architecture

In the VDMAXML_P concept, the broker is not only the central switching point for messages, but it also implements functions without which the overall concept would be difficult to understand.
The broker communicates simultaneously with two types of components: clients (e.g. visualization) and DataServers (e.g. an SPS or a connected device). These two types differ in the nature of their responsibilities and the types of messages allowed. The broker presents itself to the clients as a (TCP) server and to the DataServers as a (TCP) client. In the VDMAXML_P concept, there are some rules which contribute to determining the behavior of the broker:

- All communication relates to process variables (PV).
- A client is responsible for establishing and maintaining its network connections.
- Messages have no explicitly nominated recipient.[5]
- All process variables are configured and known to the broker.[6]
- No dynamic change in the properties of a PV in a DataServer is planned.
- Housekeeping of variables in a server is designed and fixed.[7]

Communication with clients:
The broker accepts connection requests from clients to a ServerPort and processes these requests.
The broker optionally requires authentication from the client. (21 CFR 11)[8]
The broker accepts PUT, GET, SUBS and UNSUBS messages from the clients.
PUT, GET and SUBS messages are passed on to the DataServers in question but not to clients.
An UNSUBS message is sent to a DataServer only when there are no more subscribers for the variable addressed.
If a client connection is interrupted, its subscriptions are canceled internally.
Each PUT, GET and SUBS message for a variable which is either unknown or whose source is not available at the time, is replied to by an "invalidate" message.[9]
The process-global names of the variables are converted to internal item names when they are passed on to the servers.

Communication with servers:
The broker automatically establishes connections to all DataServers known in the system.
From servers, the broker accepts only STATE messages. These are passed on to all subscribers to the variable in question.
In PUT, GET and SUBS messages from clients, the DataServers are addressed in accordance with the RWU attribute of the PV description for the server in question.[10]
When communication with a server fails:

- the broker generates an "invalidate" message for each process variable which the lost server would have to have dealt with (subscriptions only);
- the broker makes regular attempts to reestablish communication with the server; and
- it makes an entry in a log file (limited number).

After the connection is reestablished, all pending subscriptions for the DataServer are renewed. During the outage further subscriptions for the PVs in question are accepted. They are, however, met with an initial "invalidate" message.

[5] Clients receive a message when they have subscribed to the addressed variable; servers receive it when the variable is configured in their variable housekeeping. A sender cannot determine to whom the message is to go.
[6] This applies to memory classes "cur", "fmt" and "mem". Other memory classes are served by fixed servers (log-on) or configured servers.
[7] This applies to memory classes "cur", "fmt" and "mem". Other memory classes are served by fixed servers (log-on) or configured servers.
[8] The sequence has yet to be defined. The feature can be implemented in a protocol-compatible way. Implementation could follow the next version of the protocol.
[9] Agreed error codes could be delivered back here.
[10] Each PV must be configured for each DataServer. The minimum necessary are details about the server-internal variable name (item) and the read/write utility (RWU attribute). If a PV is configured for more than one server, only one server may supply the variable (source, readable). It emerges from the protocol that only PUT messages are sent to more than one server; accordingly, "cross-connections" between two servers cannot arise since servers may not send PUT messages. The configuration files should be standardized so that simple interchange is possible.

Integration of intelligent components in packaging and processing machinery in a GxP environment

The device-internal item names of the variables are converted to the process-global names when they are passed on to the clients.

Routing
The standard routing for the memory classes "cur", "fmt" and "mem" is derived from the configuration data of the DataServers.
PVs of memory class "cmd" are passed on to the servers only once. They are not stored.[11][12]
PVs of memory class "login" are passed on only to the configured log-on server.
For all other memory classes a DataServer is explicitly configured. All messages of these classes are then dealt with by only these servers.[13]

Configuration data:
The broker requires the following configuration data:

- its own ServerPort for client inquiries
- the names and IP:Port addresses of all DataServers
- a variable description file for each DataServer specifying name-item relationships and write/read utility[14]
- the names and IP:Port addresses of all DataServers for certain memory classes.

Pharmingredients+ to offer a new response to pharmaceutical industry trends

From 25 to 28 November 2013, Pavilion 75 of Moscow's VVC exhibition centre will host Pharmtech 2013, the 15th anniversary international exhibition of technologies for the pharmaceutical industry.

Pharmtech is the only exhibition in Russia and the CIS to present the full pharmaceutical production process - from developing ingredients, quality control of raw materials, production equipment for medicines and packaging technologies to storage and transportation of medicines and staff recruitment. Pharmtech's high standards are confirmed by the leading industry players from Russia and further afield that have exhibited at the event since its launch.
315 companies from 29 countries exhibited at Pharmtech 2012, taking up exhibition space of over 5,900 sqm. Producers and suppliers of pharmaceutical equipment, ingredients and packaging all regularly exhibit at the event, along with designers and builders of turnkey pharmaceutical production facilities.

This year will see the launch of a new exhibition of raw materials and ingredients for pharmaceutical production – Pharmingredients+. Exhibitors will include Russian and international producers and suppliers of pharmaceutical substances, materials, ingredients and auxiliaries, as well as development, analysis and registration companies. Specialists in medicine, bio-active supplements and veterinary drugs will have an opportunity to network and discuss future partnership.

This new section is a response to the development trends of the pharmaceutical market today, reflecting the growing role of high-quality active pharmaceutical and functional ingredients in modern medicine production. If GMP standards are to be introduced successfully, high standards for the raw materials used in production must be introduced as a priority. The Pharmingredients+ business programme features presentations from leading industry experts dedicated to the latest developments in the active pharmaceutical and functional ingredients market. All these presentations will take place in just one day – 26 November, Pharmingredients+ Day.

According to professionals of the industry, Pharmtech reflects the processes taking place in the pharmaceutical sectors of Russia and the CIS. Pharmtech offers the ability to react quickly to changes in the industry, its problems and the new challenges faced by pharmaceutical market participants. This makes the event an essential platform for communication, finding new partners and sourcing clients.

Business programme
An important part of the exhibition is its extensive business programme. The Pharmtechprom Forum takes place within Pharmtech every year, bringing together Russian and CIS pharmaceutical companies, leading European producers of raw materials, packaging and equipment, and industry experts and analysts. The Pharmtechprom Forum is a main event for discussing the pharmaceutical industry's current issues.

There will be an accent on new technologies on the second day of the Pharmtechprom Forum, 27 November, with presentations of modern technologies and equipment for production of tablets, capsules, and other medicine forms; innovative solutions for primary and secondary packaging; integrated medicine production systems that meet GMP standards; and quality control and production management systems. Delegates will be able to find out more about the leading materials, equipment and services companies from Germany, Italy, France and other countries, as well as expanding their knowledge of advanced medicine production and packaging methods.

Successfully launched in 2012, the Pharmtech Tutor project will return this year. 23 students from higher education institutions specialising in pharmaceuticals will undergo mini-work placements with some of the leading international companies exhibiting at Pharmtech. Students will gain practical experience of working with the equipment, technology and production of their host companies.
Pharmtech and Pharmingredients+ are supported by the Association of Russian Pharmaceutical Manufacturers. The General Partner of the exhibition is Drug Development & Registration magazine.

Pharmtech and Pharmingredients+ are organised by ITE Group.

25 – 28.11.2013

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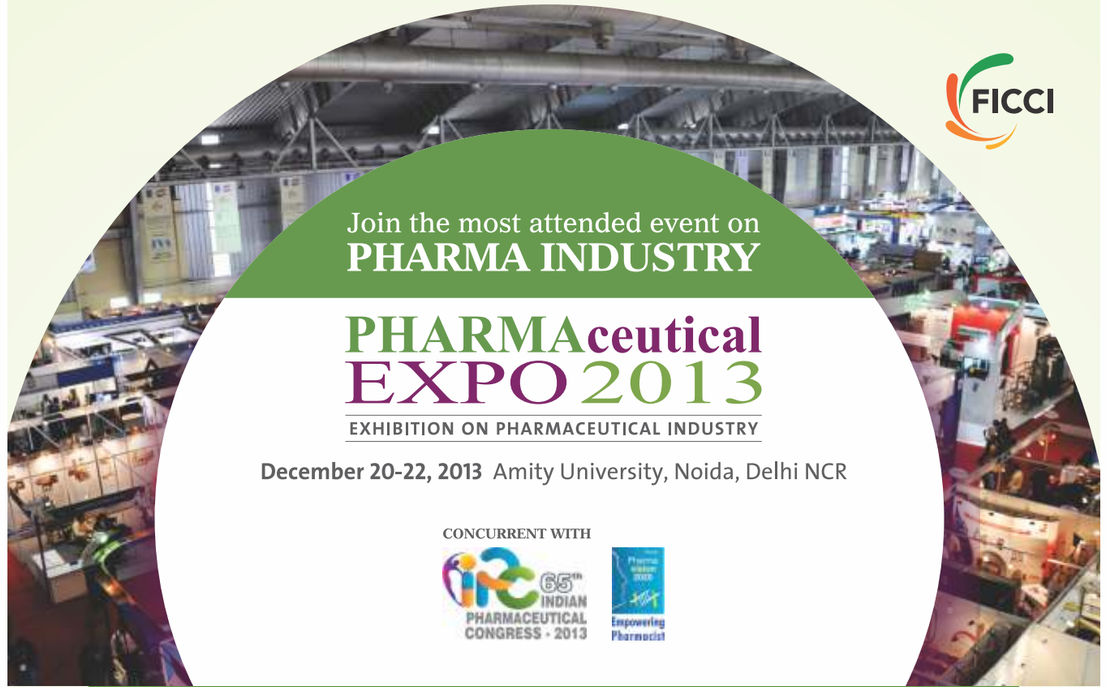

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For more information logon to

www.pharmaexpo.in

Indore to host the 2nd Edition of Central India's largest PharmaTech Expo 2013 from October 6th -8th

PharmaTechnologyIndex.com Pvt. Ltd, a KNS group of company & Indian Drug Manufacturers' Association (IDMA) is delighted to invite you to attend Central India's Largest Pharmaceutical Exhibition, Pharma Tech Expo 2013 from 6th to 8th October at the newly built state of the art Brilliant Convention Centre, centrally Air Conditioned with all modern amenities in Indore, Madhya Pradesh. The previous event PharmaTech Expo 2011 which was held at Indore has showcased the Cutting Edge Technologies in industrial expo in Pharmaceutical industry and has gained so much of interest from pharmaceutical companies and manufacturers all over the India in the Pharmaceutical R&D sector. Now, it is the time for the 2nd edition of PharmaTech Expo 2013 to share about exhibiting the Recent Technologies in Pharmaceutics which will be held at Indore. Last PharmaTech Expo in 2011, bagged visitors from various spheres of industries like CEOs, Purchase officers, Researchers, Academicians, production and R&D professionals of various pharmaceutical organizations. Indore being the hub of large and medium scale Pharmaceutical companies like Ranbaxy, IPCA, Plethico, Piramal, PDPL, Syncom, Lupin, Advance Enzyme, etc. Mylan and Teva are now coming up with their new projects at Indore in a very big way. It will be a great opportunity for Machinery and Equipment suppliers to showcase their products at such a level to these industries.

Indore market scenario for PharmaTech Expo:
Indore, the industrial capital of Madhya Pradesh, represents Central India in the most interesting way. Also known as Ahilya Nagari, this city has a lot to offer in every domain - be it historical, cultural, culinary or commercial. It therefore qualifies as a dynamic destination which adds a holistic dimension to any event. Indore is the Industrial capital of Madhya Pradesh, with a long and chequered history. There are plenty of industries dotted over the city. There are IT companies and many modern pharmaceutical companies. It is centrally located in the country, so that most places in central, western and northern India are within reasonable reach. It is called the "MINI MUMBAI" of India. It is surrounded by Ujjain, Dewas, Dhar, Pithampur, Bhopal which are also having their own industrial areas. The City is becoming the hub of pharma industry with the achievement of being one of the largest producers of pharmaceuticals in Asia. At present about 250 pharmaceutical units in and around Indore are involved in manufacturing of Allopathic, Homeopathic & Ayurvedic formulations. Parenteral Drugs (India) Ltd. has a new pharmaceutical project in Indore. An "Herbal Park" near Betma is also proposed for infrastructure development for Ayurvedic medicines manufacturing units. Two multinational Pharma companies Mylan and Teva have got the land in city and both have started to explore the market of Indore. Connectivity of Indore to other states and wholesale markets is a major advantage for the development of pharmaceutical units .As the city caters the need of almost all the categories of market segments throughout the state, It is becoming the business capital of the state. All these make Indore one of the prime industrial locations for pharmaceutical Industries.

Event Highlights:
- An international Exhibition on Technologies & Trade.
- Expected 5,000 Trade Professionals / Decision Makers.
- More than 150 industry majors will exhibit their products / Technologies / Services.
- Most affordable participation tariff ensures control on unexpected expenses.
- Most affordable exhibition related services / utilities.
- An equal opportunity to all the participants to exhibit their products / services to the Indian and global Pharmaceutical and allied industries.
- A must attend event to share the knowledge, discuss the updates and evolve the new ideas towards the advancements in the Pharmaceutical and allied industries.
- Will cover an Exhibition space of 75000 sq. ft.

Why PharmaTech Expo:
- Ideal platform to showcase new products and advanced technology before buyers, dealers and suppliers.
- Gather new qualified information about emerging market trends, technological innovations, new scientific developments, updates on regulations in pharmaceutical and allied industries
- Point of contact to meet clients & prospective customers at one place.
- Get to know about current and upcoming market needs
- Strengthen cooperation through network with customers
- One to one interface
- Discovering new business opportunities

Exhibitor profile:
Processing Plant and machinery, Packaging materials and machinery, Lab equipments, instruments and lab wares, Water treatment, waste water treatment and waste management, Biotechnology research organization and clinical research organizations, Bulk drugs, intermediates, and formulations, Excipients and additives, R&D, quality control laboratories, Healthcare products -Ayurvedic and neutraceutical manufacturers, Cosmetic and personal care, IPR standards and patent formulations, Environment and pollution control bodies, Trade associations, trade promotion bodies, Safety equipments, Software & data management for Pharma industry and management

Visitor's Profile:
CEOs, Engineers, Technocrats, Pharmacists and scientists, R&D professionals, Academicians, Teachers and students
Equipment suppliers and distributors, Policy makers and decision makers, foreign commercial corporations, Regulatory officers, Purchase officers of pharmaceutical companies, Trade delegates of various countries, Students of pharmacy colleges

Seminar: A seminar on interesting and important topics will be organized by IDMA

For quick access of information on PharmaTech Expo 2013, Please visit our website: **www.pharmatechexpo.com /www.idma-assn.org**

For further inquiries please write in to
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Fifth India Lab Expo at Hyderabad from 21st to 23rd November

"As India's largest laboratory event, India Lab Expo provides the ideal platform to laboratory professionals from around the world to showcase their products & services. After the first year of participation, Optec Instrumentation wants to exhibited, but we have already marked our calendar for next year's event."
Mr. Puneet Jain, Managing Director - Optec Instruments

"Remi has been a part of the India Lab Expo for the past 4 years. We keep coming back because of the one-stop platform the show provides us to meet interested buyers, as well as network with customers and partners across the India's Laboratory Industry. We take this opportunity to showcase our state-of-the-art technology and demonstrate the value that our solutions offer to experts in the field."
Mr. Sunil Saraf, M.D. - Remi Electrotechnik Ltd.

"It has been a very busy India Lab Expo for us this year; the China pavilion has seen huge interest and all Chinese exhibitors made some solid industry leads and orders. We were thinking of moving to a bigger pavilion next year and expecting more Chinese companies will participate."
Mr. Archer Sai, Group Leader, China Pavilion

"India Lab Expo 2012 was amazing to visit, interesting and useful to the visitor. There are no negative comments because everything was organized superbly. I am really glad to see such a huge event in Hyderabad where demand of laboratory instruments is highest among all the major cities in India. I also wish to see this exhibition again in 2013 in Hyderabad."
Dr. Ahmad Kamal, Director of Indian Institute of Chemical Technology (IICT)

INDIA LAB EXPO is the biggest exhibition in South East Asia for Laboratory, Analytical, Biotechnology, Life Science, Material Testing, and Laboratory Consumable Products & Instruments. The purpose of this exhibition and conference is to bring suppliers and buyers of focal industries and institutions face-to-face for three days. In this pursuit we facilitate manufacturers and distributors from all over the world to showcase their latest products and technology to buyers and users on a common platform in India. The exhibition provides an opportunity to the participants to connect with global leaders, learn about cutting edge technology, hear about vital research and appreciate the changes the industry is going to witness in the near future.

India lab Expo has become the biggest platform within a short span of time and continuously growing at the rate of 25% annually in terms of number of exhibitors and visitors. The purpose of shifting the exhibition from New Delhi to Hyderabad was mooted to provide better access to life science, pharmaceutical and biotechnology industries, research institutions and educational sector which has witnessed 19 percent growth in 2013 and is clustered and concentrated in the state of Andhra Pradesh and other nearby states. We have also launched Pharma Mac Pac Expo – A focused Exhibition on Pharmaceutical & Packaging Machineries concurrently with India Lab Expo 2013 at same venue.

The show will be all about laboratory equipments when the Fifth India Lab Expo 2013 will be hosted at the Hitex Exhibition Centre, Hyderabad, India from 21-23 November, 2013. The focus of show is on the latest trends and technology in the area of laboratory and analytical instrumentation, Chromatography & Spectroscopy, Biotechnology and Life Sciences, Process Control & Reactors, Medical & Clinical Diagnostics, Clean Room & Sterilization, Quality Control & Environmental, Educational Labs, Measurement & Testing, Liquid Handling & Filtration, Laboratory Consumables & Allied Products, Laboratory Furniture & Construction. It will offer the exhibiting companies to not only present their innovations, products and services but to meet with the key decision makers and find leads and confirmed orders. Attendees will have a unique opportunity to not only have the entire spectrum of the laboratory industry in one place, at one time, providing them total solutions but an ideal platform to learn industry insights, connect with peers and grow professionally.

Hyderabad as the hosting city for the 5th India Lab Expo provides many obvious advantages. It is the Bio-Pharmaceutical Hub and Pharmaceutical capital of India producing 1/3rd of India's total bulk drugs. It also ranks 2nd in producing value added food & beverages, has very good premier technical and research institutions alongwith a large number of hospitals and diagnostic labs. Hyderabad has also got a vibrant ecosystem for chemical, life science and pharmaceutical industry consisting of large number of companies, institutions, support agencies and services along with a very strong community of professionals serving these industries. This generates regular sourcing of laboratory, analytical & biotechnology equipment and consumables by these labs and creation and dissemination of knowledge and skills specific to the industry.

Companies participating in earlier India Lab Expo are satisfied with the business value that they have received and are excited to participate in the 5th edition of the show. Besides providing the ideal platform to showcase their products and services, the value addition the participating companies get is new business leads and deals, strengthening relationship with key decision makers in buying organisations and networking with professional peers and officials of government and regulatory agencies. We wish to continue to be important factor and significant partner in the success of our exhibitors. This year, more than 50 foreign companies are participating directly and more than 400 foreign principals are participating through their channel partners in India. The foreign companies which are participating are from Germany, USA, UK, Hungary, Switzerland, Italy, Canada, China, South Korea, Russia, Taiwan, Sweden, the Netherlands, etc. We expect 300+ exhibitors and 10,000+ visitors representing diverse industries to participate in 5th India Lab Expo, 2013. The exhibiting space is getting sold out very fast and only few locations are left out to be grabbed.

Also we are committed to remain the leader in the laboratory exhibition in India and provide the best value to our partners and patrons by providing opportunities to grow their business within the country and beyond. We believe we will continue to make a difference to your business.

FIPB clears six investment proposals in pharma sector worth Rs. 855 cr

The Foreign Investment Promotion Board (FIPB) of India cleared six investment proposals in the pharmaceutical sector worth Rs855 crore in the month of July 2013. Earlier in the same month, FIPB had cleared seven proposals related to the sector even as the industry department and local drug makers are demanding clarity on India's foreign direct investment (FDI) policy.

The department of industrial policy and promotion (DIPP) had raised concerns over a spate of acquisitions of local pharma companies by multinationals since few investments were being made in creation of production facilities in India. The proposals approved at the meeting include that of Smith & Nephew Pte Ltd, Globion India Pvt. Ltd, Calyx Chemicals and Pharmaceuticals Ltd, Fresenius Kabi (Singapore) Pte Ltd, Lotus Surgical Specialities Pvt. Ltd and Celon Laboratories Ltd.

Ministries, including health, finance and commerce are deciding on conditions to be imposed on foreign direct investments in the pharmaceutical sector. There is ample evidence to suggest that acquisitions and mergers lead to changes in patterns of productions, even discontinuing certain drugs and vaccines needed in India market analysts said. But the bigger concern for our markets would be pricing of the drugs.

India permits 100% foreign investment in the pharmaceutical sector through the automatic approval route for new projects but foreign investment in existing drug makers are allowed only after FIPB's approval. The DIPP had earlier decided that any multinational firm buying a stake higher than 49% in an Indian pharma company will maintain the same level of investment in research activities and production of essential medicines for five years and is now seeking more riders to be included in the policy fearing adverse impact on the domestic industry.

Pharma packaging units to gain as drugmakers gear up to curb counterfeits

As pharmaceutical companies are keen to take steps to fight counterfeiting, pharma packaging machinery units are expecting a surge in demand as well as higher margins. The National Pharmaceutical Pricing Authority (NPPA) is also mulling whether to allow pharma companies to raise their margins in packaging cost of medicines, which could further boost the packaging industry. Currently, the pharmaceutical packaging sector in India is characterised primarily by blister packaging machinery, small scale blister packaging machinery, de-blistering machines and leak testing machinery. The dedicated production capacities of large players in the packaging sector contribute to nearly 50 per cent of the entire market, while the rest of the packaging is outsourced. Pharma companies are now keen to invest more in packaging technology to fight counterfeit drugs, says Sanjay Gandhi, promoter of Krishna Foils, a Naroda-based packaging unit. "This would mean more margin for packaging units as well," he adds. Gujarat-based pharma packaging units and packaging machinery units have been clocking a 15-18 per cent compounded annual growth rate. Ishika Industries, an Ahmedabad-based packaging unit claimed that orders had grown by 12 times in the last five to eight years.

Many packaging units in the state are also supplying material to the hilly states like Himachal Pradesh and Sikkim as several Gujarat-based pharma units have set up production plants in these hilly states to take advantage of the tax incentives. Krishna Foils too claims that there is huge demand from pharma units in Baddi (Himachal Pradesh), Hyderabad, Maharashtra apart from southern states like Chennai. Interestingly, packaging and conversion cost account for nearly one-third of the price that consumers have to pay for a medicine. "If the NPPA allows more margin to the drugmakers in packaging cost, it would definitely boost the packaging industry at large," said a senior official of the Gujarat State Plastic Manufacturers Association (GSPMA). For that matter, GSPMA points out that while the overall plastic packaging industry in the state has grown by 10-12 per cent last fiscal, the pharma packaging space has managed to do better, clock a 15-18 per cent growth. At the same time, a recent PlastIndia report outlines that currently the share of pharma packaging in the Rs 1,25,000 crore polymer processing industry is around 7 per cent, and therefore, there is huge potential for growth. At present, there would be around 250 pharma packaging units in Gujarat clocking a turnover of close to Rs 1,000 crore, according to a senior official at the GSPMA.

Obituary

Cadmach Machinery's Mr. Anil Shukla is no more

Mr. Anil Shukla, Head - Marketing (Domestic) Cadmach Machinery Co Pvt. Ltd. passed away on May 23, 2013 after brief illness. Since the past 25 years, Mr. Shukla served in different capacities in various organisations in the pharma machinery segment. Mr. Shukla had a deep understanding of the industry and had developed excellent and cordial relations across the pharma industry in general and the pharma machinery industry in particular.

Mr. Shukla was associated with Cadmach Machinery Co. Pvt. Ltd since the past seven years.

In his passing away, the Indian pharma machinery industry has lost one of the most respected and efficient pharma professional. His passing away has created a void which would be difficult to fill in.

We pray to Almighty Lord for ever lasting peace for the departed soul. We also pray to the Lord Almighty to give the strength and the moral courage to his family and his near and dear ones to bear this loss.

Early assessment of event shows satisfactory results

Pharmintech grows both in visitors and quality

Nigeria Pharma Manufacturers Expo 2013 (NPME 2013), an international exhibition on pharmaceutical industry is happening for the second time during October 17 to 19, 2013 at Blue Roof TV Complex, Ikeja, Lagos, Nigeria. NPME 2013 is the largest most international complete pharma manufacturing exhibition of the Central & West Africa attracts more than 110 exhibiting companies and nearly 3,500 pharma trade professionals across the region, which includes Ghana, Mali, Chad, Cameroon, EQ Guinea, Central African Republic, Niger, Burkina, Benin, etc.

NPME 2013 is being jointly organized by the Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN) and GPE Expo Pvt. Ltd. and Endorsed by Federal Ministry of Health (Nigeria), National Agency for Food & Drug Administration & Control (NAFDAC - Nigeria), West African Pharmaceutical Manufacturers Association, Economic Community of West African States (ECOWAS), Pharmaceutical Society of Nigeria, and Supported by the Pharmaceutical Export Promotion Council (PHARMEXCIL - India) and Indian Pharma Machinery Manufacturers' Association (IPMMA). An Official Media is PHARMA Pro&Pack magazine and Official Website of NPME 2013 is www.NigeriaPharmaExpo.com.

The NPME 2013 will be held at Blue Roof TV Complex, Ikeja, Lagos, Nigeria – the most suitable venue for such important international business gathering and eventually it is located in the prime industrial corridor of Lagos.

Nigeria is one of the most One of the most promising and rapidly growing pharmaceutical market in West Africa with more than 120 pharma formulation manufacturing facilities. The Nigerian pharma industry is growing at 12 percent annually. The estimated market size would be USD million 717 (2011) (USD 740 million in 2009). 60 percent of drug manufacturing in the ECOWAS (Economic Community of West African States) sub-region takes place in Nigeria, underlining the huge sub regional market.

The three-day long international exhibition, NPME 2013 will be an excellent opportunity to meet one to one ensures focused promotions and meaningful interaction for business. The Show will be catalyst to develop new business opportunities, technology and trade sources, new tie up and technology transfer. Moreover, during this three-day Show, OEM will have great opening to meet the existing Vendors and identify the new one, too.

NPME 2013, an international exhibition will provide an unique platform to showcase Pharma Processing & Packaging Machineries and Materials, API & Bulk Actives, Analytical Lab Instruments & Supplies, Environment Control Systems, Utilities Products & Services, Water Management, Research, Consultants, Turnkey Contractors, Formulations & Contract Manufacturing, Trade Association & Promotion Organizations, Trade Associations, etc.

The leading companies from Nigeria, India, and China will be exhibiting their latest products / services and pharma manufacturing technologies at NPME 2013, Lagos exhibition. Some of the exhibiting companies are; Pradipkumar Pharma Pvt. Ltd., S S Packaging Industries Pvt. Ltd., Airtel Nigeria Ltd., Rapid-Pack Engineering, Skye Bank Nigeria Plc, Worldwide Technologies Ltd., NPM Machinery Pvt. Ltd., PrompTech Pharma Industries, Karnavati Engineering Ltd., Affy Group Of Companies, Contec Airflow (E) Pvt. Ltd., Lovisa Speciality Products Ltd., Sinochem Ningbo Ltd., MD Logistics, Ambica Pharma Machines Pvt. Ltd., GMP Technical Solutions Pvt. Ltd., Anchor Mark Pvt. Ltd., Rotofil Industries, Pacific Tools Pvt. Ltd., CMC Machinery (Cadmach), Bectochem Consultants & Engineers Pvt. Ltd., ACG Worldwide, Adept Engineers, Chinese Chamber, Syncom Formulations (I) Ltd., Jawa International Ltd., Neimeth International Pharma Plc, Sam Pharmaceuticals Ltd., Dana Pharmaceutical Ltd., S K Pharma Machinery Pvt. Ltd., TSA Process Equipments Pvt. Ltd., Pharmalab India Pvt. Ltd., Novo Excipients Pvt. Ltd., Jiangsu Guotai, Shandong Pharma Glass, Austar Ltd., Shree Bhagwati Machtech India Pvt. Ltd., SSPM Systems & Engineers, Parle Elizabeth Tools Pvt. Ltd., Natural Capsules Ltd., Hulian Pharma Machineries, Bentos Pharma Products, Evans Medical Plc, Drugfield Pharma Ltd., SKG-Pharma Ltd., Vitabiotics Nig Ltd., Fabtech Technologies Africa Ltd., Maharshi Udyog, Daily Need Industries Ltd., Fidson Healthcare Plc, N K P Pharma Pvt. Ltd., Fluidpack, Tapasya Engineering Works Pvt. Ltd., Impact Labs Pvt. Ltd., The Bombay Engineering Works, Narendra Packaging Pvt. Ltd., Clean Coats Pvt. Ltd., Emzor Pharma Ind. Ltd., Precikot Pharma Pvt . Ltd., Konark Machine Tools, Anish Pharma Equipments Pvt. Ltd., Bharat Rubber Works Pvt. Ltd., Newtronic Lifecare Equipment Pvt. Ltd., Rahul Ferromet & Engineering Pvt. Ltd., Nomagbo Pharmaceuticals Ltd., Topway Pharmaceutical Ltd., West-Coast Pharmaceutical Works Ltd., Orfema Pharmaceuticals Ind. Ltd., Airtech Systems (India) Pvt. Ltd., Packwel India, Suntec Teknopak Contamination Control Solutions Pvt. Ltd., GMP Machineries & Packaging, etc.

The NPME 2013 will be highly resourceful, informative and meaningful for the entire segment of the pharma trade professionals to acquire vital information required in day to day operations of pharma manufacturing facilities. NPME 2013 will be attended by Biotechnology Specialists, CEO's Engineers, Technocrats and Scientists, Compliance, Corporate Management, Custom Manufacturing / Marketing Services, Equipment Suppliers & Distributors, Maintenance Engineering, Manufacturing / Production Engineering, Operations Management, Packaging Engineering, Pharmacists, Plant Management, Policy Makers, Diplomats and Foreign Commercial Corp., Process Engineering, Procurement Dept.,

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HP 3 Pen


HP 4 Pen

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