NEWS LETTER
APRIL-MAY 2019

BI-MONTHLY NEWS LETTER OF BULK DRUG MANUFACTURERS ASSCIATION INDIA
C-25, Industrial Estate, Sanathnagar, Hyderabad-500018

PRESS RELEASE

Bulk Drug Manufacturers Association (India) and CSIR- Indian Institute of Chemical Technology Collaboration

CSIR-IICT and BDMA entered into a collaboration agreement with an aim to have a constructive relationship between industry and research institute to utilize the expertise and infrastructure of IICT , to provide a focal point for research and development of processes tailored to meet the industrial requirements and also provide specialized services.

CSIR-IICT is a premier R & D Institute, which has been established by Govt. of India to carry out research in chemical sciences for a variety of products necessary for human welfare such as food, health and energy. CSIR-IICT aims to develop state of the art technologies for the chemical, fine chemical and pharmaceutical industries. IICT has state of the art laboratories; pilot plants, analytical facilities supported by highly qualified and experienced technical teams. In addition IICT has one of the best technical library in Hyderabad.

Under the scope of this collaboration BDMA shall identify products of immediate relevance for which commercial scale technologies need to be developed. BDMA shall also identify a list of impurities/ standards / pharmacopeia of critical importance that they routinely procure. CSIR-IICT shall try to synthesize some of these impurity standards / pharmacopeias and stock them for supplying the same to BDMA members on demand.
CSIR-IICT shall extend its analytical equipment and pilot plant facilities to BDMA members and support the members in providing analytical services and pilot scale studies. MSMEs under BDMA will be given special concessions. CSIR-IICT shall offer skill development programs customized to BDMA requirement.

BDMA members will have the benefit of access to research results of ICCT and also have an opportunity to interact with scientists of CSIR-IICT and other thought leaders to fine tune corporate R&D strategies. It is also aimed to provide consultancy services of CSIR-IICT scientists on technical problems, process improvement, etc., on priority on favorable terms and conditions for BDMA members.

In this regard an Interaction meeting between IICT team and BDMA members has been organized on 20th May,2019 at IICT campus to appraise on the Analytical services which can be provided by IICT on regular basis. The response has been over whelming.

IICT did considerable studies on effluents treatment and pollution control technologies. They have already started consultancy work in Gujarat with some established Chemical Industrial estates and getting good response. It is planned to organize a half day program jointly by BDMA and IICT in association with TSPCB to discuss the problems faced by industry, expectations of Statutory authorities and the expertise IICT can provide. We have got in principle acceptance from TSPCB and the program details will be finalized soon. .

IICT is already associated with LSSSDC and providing training relevant to process industries in Hyderabad and Guntur. It is planned to associate IICT with the proposed Technology Centre of BDMA at Jeedimetla to provide training in Life Sciences sector under the National Apprenticeship Promotion Scheme and Pradhan Mantri Kaushal Vikas Yogana. This will definitely address the shortage of skilled manpower in bulk drugs manufacturing sector and also meet the growing demand.

BULK DRUG MANUFACTURERS ASSOCIATION (INDIA) , Hyderabad.

PRESS RELEASE

Bulk Drug Manufacturing Association India in association with Hitech Institute of Advanced Pharmaceutical Sciences will organize short term Pharma Industry Oriented Skill Development Training Programs to Pharmacy graduates and post graduates and Pharmacy students. The training for the first batch students will commence from 6th May 2019 followed by four more batches during May and June 2019. Classes will be conducted at BDMA premises located at Sanatnagar (Near Post office), Hyderabad. The course will be for One Month / Two Months duration, which includes intensive, in depth practical training in Pharma Industry, with an objective of creating professional awareness in pharmacy students to bridge the gap between academic and industrial environments.

Eminent people from Pharma Industry and Drugs Control will deliver lectures on the topics related to Quality control, Quality Assurance, R&D, Regulatory Affairs and manufacture of drugs. This industry oriented training will secure placements successfully to trained students.

Dr. M.Venkata Reddy, Former Director, Drugs Control Administration, Hyderabad is the course Director.

CIRCULAR

Seminar on "Environment Management Technologies for Bulk Drug Industry – A Challenge"

Bulk Drug Manufacturers Association (India) in Association with Telangana State Pollution Control Board and Indian institute of Chemical Technology, Hyderabad is planning to organize a half day seminar on "Environment Management Technologies for Bulk Drug Industry – A Challenge" during the third week of July,2019. Hyderabad.

The main objective of this programme is to sensitize the stake holders on

- Expectations of Pollution Control Board on the performance and compliances of Environmental Treatment and meeting the standards
- Issues being faced by Bulk Drug Industry with respect to sustainable Environmental technologies
- Technologies which IICT can offer for Environmental treatment and compliances with special reference to pollution control in bulk drug industry. .

In this regard we request your inputs with respect to technical difficulties being faced by the industry for environmental compliances so that the same can be compiled and presented in the seminar.

We look forward for your response by 6th of July,2019 by email to : info@bdmai.org

Biopharmaceutical Contract Manufacturing Market Is Anticipated To Expand Robustly During The Forecast Period

Contract manufacturing organizations (CMOs) are companies that offer a broad spectrum of services ranging from drug development to drug manufacturing on contract basis to the pharmaceutical companies. Biopharmaceutical contract manufacturing involves the development and manufacture of biopharmaceutical molecules for biopharmaceutical

companies. Biopharmaceuticals include pharmaceutical products such as proteins, nucleic acids, blood components, and vaccines developed from biological sources.

The biopharmaceutical contract manufacturing market is anticipated to expand robustly during the forecast period. Strong growth of the market can be attributed to the risk hedging nature of biopharmaceutical companies by outsourcing manufacturing to CMOs. This enables biopharmaceutical companies to balance their risk and buy time until key clinical trial milestones are met. Additionally, lack of manufacturing capabilities and high investments required in R&D of biopharmaceuticals induce new market entrants to outsource manufacturing activities. Moreover, strong technical capabilities of the CMOs in cell-line development, scale-up, and process development, and rich pipeline of biologics such as viral vectors, multispecific monoclonal antibodies, peptides, and other oligonucleotides drive the biopharmaceutical contract manufacturing market. However, lack of capacity of CMOs to manufacture large-volume biopharmaceutical drug substances, complexity in transferring biological components, and limited options available for biopharmaceutical companies for large-volume production are projected to hamper the growth of the market.

The global biopharmaceutical contract manufacturing market can be segmented based on product type, platform, application, therapeutic area, services, and region. In terms of product type, the market can be classified into interferons, monoclonal antibodies, vaccines, recombinant hormones, growth factors, and others. Based on platform, the global biopharmaceutical contract manufacturing market can be categorized into mammalian and microbial. In terms of application, the market can be bifurcated into commercial and clinical. Based on therapeutic area, the global biopharmaceutical contract manufacturing market can be segmented into oncology, cardiovascular diseases, metabolic disorders, neurology, respiratory diseases, hematology, autoimmune diseases, and others. In terms of services, the market can be bifurcated into manufacturing and research. The manufacturing services segment can be further divided into bulk drugs and active pharmaceutical ingredient (API) manufacturing, packaging, advanced drug delivery formulations, and finished dose formulations.

Scheme for Development of Pharmaceutical Industry
Dept. of Pharmaceuticals, Govt. of India

Scheme for Development of Pharmaceuticals Industry

The Department of Pharmaceuticals has prepared a Scheme for Development of Pharmaceuticals Industry with the objective to ensure drug security in the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry with the following sub-schemes: (a) Assistance to Bulk Drug Industry for Common Facility Centre; (b) Assistance to Medical Device Industry for Common Facility Centre; (c) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS);(d) Assistance

for Cluster Development; and (e) Pharmaceutical Promotion Development Scheme (PPDS). The said scheme is a Central Sector Scheme with a total financial outlay of Rs. 480 Crore. The guidelines for implementation of the sub-schemes are uploaded on the website of the Department.

The details of the sub-schemes are as follows:

i. Assistance to Bulk Drug Industry for Common Facility Centre:

Under the sub-scheme, financial assistance would be provided for creation of common facilities in any upcoming Bulk Drug Park promoted by State Governments/State Corporations. The Scheme would be implemented through a one-time grant-in-aid to be released to a State Implementing Agency (SIA) set up for the purpose. Some of the indicative activities under the Common facilities include Effluent Treatment Plants, Captive Power Plants, Steam and Cooling systems, Incubation facilities, Common logistic facilities, Advance common testing Centre, Regulatory awareness facilitation Centre and Emergency Response Centre. A total of Rs. 200 Crore has been earmarked for the scheme. The maximum limit for the grant in aid under this category would be Rs. 100 Crore per Bulk Drug Park CFC or 70% of the project cost of CFC whichever is less.

ii. Assistance to Medical Device Industry for Common Facility Centre:

Under the sub-scheme, financial assistance would be provided for creation of common facilities in any upcoming Medical Device Park promoted by State Governments/State Corporations. The Scheme would be implemented through a one-time grant-in-aid to be released to a State Implementing Agency (SIA) set up for the purpose.Some of the indicative activities under the Common facilities include Component Testing Centre, Electro-magnetic interference laboratory, Biomaterial / Biocompatibility testing centre, Medical grade low vacuum moulding, Cabinet moulding injection moulding centers, 2D designing and printing for medical grade products, Sterilization and Toxicity testing centre, Radiation testing centre, etc. A total of Rs. 100 Crore has been earmarked for the scheme. The maximum limit for the grant in aid under this category would be Rs. 25 Crore per Medical Device Park CFC or 70% of the project cost of CFC whichever is less.

iii. Pharmaceuticals Technology Upgradation Assistance Scheme

The objective of the sub-scheme is to facilitate Small and Medium Pharma Enterprises (SMEs) to upgrade their plant and machinery to World Health Organization (WHO)/Good Manufacturing Practices (GMP) standards so as to enable them to participate and compete in global markets. Assistance in the

form of interest subvention against sanctioned loan by any scheduled commercial bank/financial institution, both in Public and Private sector will be provided to 250 pharma SMEs of proven track record. The Scheme is implemented through a Public Sector Financial Institution (PSFI) to be identified by the Government. A total of Rs. 144 Crore has been earmarked for the scheme. The upper limit of interest subvention on loans for technology/infrastructure upgradation shall be restricted to 6% per annum for a period of three years on reducing balance basis. The maximum loan eligible for this purpose will be Rs. 4 Crore, availed by the concerned SME.

iv. Assistance for Cluster Development

This is an existing and approved scheme of the Department (Cluster Development Programme for Pharma Sector (CDP-PS)) now being subsumed under the umbrella scheme. Under the Scheme, financial assistance would be provided for creation of common facilities in any pharma clusters including Bulk Drug, Medical Device, Ayurvedic, Unani and Cosmetics Units. Some of the indicative activities under the Common facilities include Common Testing Facilities, Training Centre, R&D Centres, Effluent Treatment Plant and Common Logistics Centre. The Scheme would be implemented on a Public Private Partnership (PPP) format through one time grant-in-aid to be released in various to a Special Purpose Vehicles (SPVs) set up for the purpose. A total of Rs. 30 Crore has been earmarked for the scheme including Rs. 10 Crore which was allocated in 2017-18. Maximum limit for the grant in aid under this category would be Rs 20.00 Crore per cluster or 70% of the cost of project whichever is less.

V. Pharmaceutical Promotion Development Scheme

This is an existing and approved scheme of the Department now being subsumed under the umbrella scheme. The scheme aims at the promotion, development and export promotion in Pharmaceutical sector by extending financial support for conducting seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/ consultancies, for facilitating growth, exports as well as critical issues affecting Pharma sector. A total of Rs. 6 Crore has been earmarked for the scheme.

Implementation of Scheme for Schedule M Compliance for SSI Pharma Units Dept.Of Pharmaceuticals, Govt. of India

INTRODUCTION

i. As per the second supplement of the Revised Guidelines issued by MSME on the Credit Linked Capital Subsidy Scheme (CLCSS) for Technology Up-gradation of Micro, Small and Medium Enterprises by the Ministry of MSME on 13th July, 2009 the pharma SSI units will now be able to avail the benefits of CLCS Scheme for financial assistance for an expanded list of products from 32 to 179.

ii. As per the CLCSS Scheme of the MSME, 15% Capital Subsidy would be provided on capital investment of up to Rs One Crore. The scheme is available for 179 machinery and equipment as per Annex-I. It will be implemented in the same manner as the CLCSS scheme. SIDBI and other nominated banks would be implementing the scheme as in the case of CLCSS. List of banks is at Annex-II.

iii. The scheme will involve collaboration with the following:

I. Development Commissioner, Micro Small, Medium Enterprises, Ministry of Micro Small, Medium Enterprises

II. Certification agencies (CDSCO / SRA)

III. Banks and Financial institutions like SIDBI

IV. State government officials in Departments of Health and Industry

iv. 1.4 Implementation Methodology: The implementation of the Credit Linked Capital Subsidy Scheme (hereinafter referred to as ‘Scheme’) comprises interalia the following stages:

I. Awareness Building

II. Organizational arrangements

III. Implementation processes

IV. Involvement of all stakeholders

V. Periodic Review and Monitoring

2. AWARENESS BUILDING

For this a three fold strategy is proposed to be adopted:

- Awareness Building Workshops
- Dissemination of Scheme brochures and related material
- Media support

2.1 Awareness Building Workshops (ABW):

2.1.1 Workshop Location:
Workshops at 10 SSI Cluster locations

CCMB, CDFD join hands to address India's genetic disease burden

Shahid Akhter | ETHealthWorld

India's two premier national institutes involved in the cutting edge biological research in genetics on Wednesday signed a Memorandum of Understanding (MoU) to address the genetic disease burden of Indian population.

Hyderabad, India's two premier national institutes involved in the cutting edge biological research in genetics on Wednesday signed a Memorandum of Understanding (MoU) to address the genetic disease burden of Indian population.

CSIR-Centre for Cellular and Molecular Biology (CCMB) and Centre for DNAFingerprinting and Diagnostics (CDFD) will work together to maximize the potential of both the institutes in human disease diagnostics.

CCMB director Dr. Rakesh K Mishra and CDFD director Dr Debashis Mitra signed the MoUs, the objectives of which include provision of quality DNA based diagnostic services to the public at lower costs, to develop newer diagnostic methods and to engage in scientific research to improve understanding of human genetic disorders.

The institutes have also mutually agreed to undertake training and educational activities in the field of genetic diagnostics.

According to a joint statement by the two institutes, more than 50 lakh babies are born each year with genetic disease in India.

"The burden of these disorders has its effects on the economic and social structure of the society. Most of these disorders are presently untreatable and for those which can be

treated, the treatment is very expensive.

The only option to address this problem is the preventive approach which requires prenatal diagnosis and genetic counselling.

Genetic disorders form a major group of the non-communicable diseases. Congenital malformations and genetic disorders are the third commonest cause of mortality in neonates in cities.

They noted that the last few years witnessed tremendous changes in the field of genetics with rapid advancements in technology. The advent of efficient and affordable DNA sequencing technology has a direct impact in improving the understanding of human disease, enabling better ways of diagnosis and treatment.

For more than two decades both CCMB and CDFD have been offering genetic diagnostic services as well, which has made a difference, it said.

Leadership Success Mantra - Annaswamy Vaidheesh

Annaswamy Vaidheesh, Vice President, South Asia & Managing Director, GlaxoSmithKline Pharmaceuticals Ltd., decodes his three decades of his successful leadership.

Shahid Akhter, editor ETHealthworld talks to Annaswamy Vaidheesh, to know more about his leadership qualities and the traits that can treat you to success.

Annaswamy Vaidheesh is a successful senior business leader with over 3 decades of diverse experience in healthcare and FMCG domain. Prior to his current role he was Vice President, Corporate Government Affairs, Asia-Pacific for Johnson & Johnson based out of Singapore and a member of Global Leadership team for healthcare advocacy and policy. Before that he was Managing Director of Johnson & Johnson Medical India (JJMI) and Vice president, Asia-Pacific- Diabetes franchise for five years.

Vaidheesh is widely recognised for chairing various initiatives with industry bodies in India and in Asia Pacific Region. Strategic MOU with China Communist Party School, India Health Insurance development and leading Healthcare agenda in APEC summits are noteworthy. He is currently the President of the Organisation of Pharmaceutical Producers

of India (OPPI), the Chairman of Healthcare Committee of Confederation of Indian Industry (CII) and on the Board of UK India Business Council (UKIBC).