JSS Academy of Higher Education & Research

JSS College of Pharmacy

Sri Shivarathreeshwara Nagara, Mysuru- 570015

Date: April 6th 2024

Report on one-day symposium on

"GMP Compliances and Export/Import Opportunities -Regulator's view"

SESSION I: 10.30 AM to 1 PM

"GMP Compliances and Challenges – International Opportunities"
Speaker: Dr D Roy, Ex Deputy Drugs Controller (India), CDSCO.

"Revised Schedule M requirements"
Speaker: Dr Jagashetty, Ex Drugs Controller, Karnataka

Panel discussion on "Issues in compliance with GMP by SME's"
Moderator: Mr. Om Prakash Sadwani, Ex Joint Commissioner, FDA, Maharashtra

Panelists:

- Dr D Roy. Ex Deputy Drugs Controller (India), CDSCO.
- Dr. Amaresh Tumbagi, Ex Additional Drugs Controller, Karnataka
- Dr Jagashetty, Ex Drugs Controller, Karnataka
- Dr G Selvaraj, Ex Director of Drugs Control, Tamil Nadu
- Mr. M.N. Sridhar, Joint Director of Drug Control and Controlling Authority, Tamil Nadu

SESSION II: 2.00 PM to 5 PM

"Export/ Import regulations and bottlenecks"
Speaker: Dr A Ramkishan, Deputy Drugs Controller (India), CDSCO Hyderabad Zone

"Port office requirements for Export/ Import"
Speaker: Mr. Rajshekhar, Deputy Drugs Controller (India), Bengaluru, CDSCO.

Panel Discussion on "Import and Export of Pharmaceutical products- Opportunities and Challenges"
Moderator: Dr K Bangarurajan, Professor, JSS College of Pharmacy, Mysuru and Ex-JDCI, CDSCO, New Delhi

Panelists:

- Mr. Vijay Shah, Ex Joint Commissioner, FDA, Gujarat
- Dr A Ramkishan, Deputy Drugs Controller (India),CDSCO Hyderabad Zone.
- Mr. Rajshekhar, Deputy Drugs Controller (India), Bengaluru, CDSCO.
- Mr. Appaji, Ex DG, Pharmexcil, Hyderabad
- Dr. Jayant Kumar, Deputy Drugs Controller (India),CDSCO, Mumbai Zone
- Mr. J. Jayaseelan, MD – Delwin Pharmaceuticals Pvt Ltd, Chennai

Faculty of Program:

1. Dr. Balamuralidhara V, Associate Professor and HOD, Department of Pharmaceutics, JSS College of Pharmacy, Mysuru.
2. Dr. K Bangarurajan, Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.
3. Dr. M P Venkatesh, Associate Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.
4. Dr. G.S. Meghana, Lecturer, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.

Dr. T.M. Pramod Kumar, Principal, JSS College of Pharmacy, Mysuru and Dean-Faculty of Pharmacy, JSS Academy of Higher Education and Research (JSS AHER), Mysuru welcomed the guests and for the symposium. He also briefed about the objectives of conducting this symposium.

Centre of Excellence in Regulatory Sciences (CEReS), Dept. of Pharmaceutics, JSS College of Pharmacy, Mysuru organized this symposium to provide an unique opportunity for Small and Medium Enterprises (SMEs) to directly engage with regulatory authorities, which can be immensely beneficial for businesses striving to comply with WHO GMP regulations.

Dr. Vishal Kumar Gupta, Dean-Academics, JSS AHER and Dr. B. Manjunatha, Registrar, JSS AHER, Mysuru addressed the gathering about the importance of GMP and requirements in complying with the ever-changing regulatory landscape.

Session I: "GMP Compliances and Challenges – International Opportunities"

Speaker: Dr D Roy, Ex Deputy Drugs Controller (India), CDSCO.

Dr. Balamuralidhara V, HoD, Dept. of Pharmaceutics introduced the speaker to the august gathering.

Dr. D. Roy shared his view on the "Current Indian Pharmaceutical Industry" and has acquired the title of "World of Pharmacy" today because high-quality generic medications are readily available at reasonable costs in over 220 nations, including the United States and the European Union. In the pharmaceutical industry, India is ranked 12th in terms of value and 3rd in terms of volume of production. The country generates approximately US$ 42.34 billion in revenue annually, of which US$ 24.30 billion is exported

He explained about CTD submission and product registration for exporting pharmaceutical products; submission of the registration fees and the documents in CTD format to the importing nation's regulatory authority. Registration under the WHO Certification Scheme or PICs (Pharmaceutical Inspection Co-operation Scheme) based on COPP granted by National Regulatory Authorities (NRA) by the Convention for the MRA (Mutual Recognition Agreement)

GMP norms followed at the international level includes:

- 21 CFR (USFDA)
- WHO Technical report (823, 902, 908, 929, 937, 953, 961, 986 & 1044) series
- PIC / PICS (Pharmaceutical Inspection Convention/ Co-operation Scheme)
- 'Orange Guide' of MHRA (Medicine & Health Care Regulatory Agency)

Common elements of GMP, significance of each element in GMP and its impact on the quality, safety and efficacy of the product were detailed. Dr. Roy discussed about the key elements of PQS and QRM and also about ICH Q9

Other important issues discussed include: the role of QRM in the product life cycle; product quality review which is an essential matter in the pharmaceutical industry; process capability indices Cp and Cpk; how to calculate the process capability indices; PQR ratings; acceptance criteria of certain critical parameters; qualification parameters of an HVAC system; how to export an API ; manufacturing practices to be upgraded to international GMP standards to ensure quality, safety, efficacy of the product.

Session II: "Revised Schedule M requirements"

Speaker: Dr Jagashetty, Ex Drugs Controller, Karnataka

Dr. M.P. Venkatesh, Associate Professor, Dept. of Pharmaceutics introduced the speaker.

The session started with describing the basics of Schedule M and its importance. Dr. Jagashetty discussed the 5P's of GMP. 5P's is an essential factor in schedule M, Roles and responsibility of people involved in manufacturing. Historical aspects of Schedules journey from 1961 was portrayed. The reason for revision of

schedule M and specific reason for revision of schedule M was detailed. Significant aspects about objectives, parts of Schedule M, Changes in the revised schedule M [PQS, QRS, PQR, Qualification and validation of equipment, supplier Audits etc] was part of his expert lecture.

Other notable discussion issues were about pharmaceutical Quality system, key elements, responsibility of senior management, Quality control operations, review process, managerial responsibilities, necessary control on starting materials, self-inspection, audits, quality to be maintained, deviations.

Further, product quality review aspects and importance on CAPAs, Qualification, validation, GMP requirements, production under loan license or contract, sanitation and hygiene, special attention on computerised systems, handling complaints and adverse reactions, product recalls, change control, materials, personnel, timelines and difficulties, role of regulators were delibrated.

Session III: Panel Discussion on "Issues in compliance with GMP by SME's"

Moderator: Mr. Om Prakash Sadwani, Ex Joint Commissioner, FDA, Maharashtra

Panelists:

- Dr D Roy. Ex Deputy Drugs Controller (India), CDSCO.
- Dr. Amaresh Tumbagi, Ex Additional Drugs Controller, Karnataka
- Dr Jagashetty, Ex Drugs Controller, Karnataka
- Dr G Selvaraj, Ex Director of Drugs Control, Tamil Nadu
- Mr. M.N. Sridhar, Joint Director of Drug Control and Controlling Authority, Tamil Nadu

Mr. Om Prakash Sir started the discussion with strategies that small and medium enterprises (SMEs) can implement to improve compliance with GMP regulations. One of the panelist Dr. D..Roy provided roadmap which encompasses making training investments, keeping up with paperwork, putting in place strong quality control procedures, holding frequent internal audits, and encouraging a compliance culture across the board, so SMEs can increase GMP compliance.

Next issue of discussion: How was Schedule M evolved over time to reflect changes in pharmaceutical manufacturing practices? Dr. Amaresh Tumbagi thrown light on Schedule M changes over time to conform to international standards, legal requirements, and improvements in pharmaceutical manufacture. This has helped to ensure that the most recent procedures are followed for enhanced quality and safety.

The necessary of changes to schedule M and Modifications to Schedule M are required to stay up to date with changes in worldwide quality guidelines, regulatory standards, and pharmaceutical manufacturing technologies. By keeping manufacturing procedures current, these modifications contribute to improved product quality, safety, and adherence to industry best practices – stated by Dr. D. Roy in response to the moderator.

One of the audiences questioned on "Unique safety challenges specific to a particular manufacturing site". The panellist provided a response - particular production sites may have particular safety difficulties because of things like layout, how equipment is set up, how materials are handled, or the surrounding environment. It is essential to address these site-specific issues for both regulatory compliance and worker safety.

Session IV: "Export/ Import regulations and bottlenecks"

Speaker: Dr A Ramkishan, Deputy Drugs Controller (India), CDSCO Hyderabad Zone

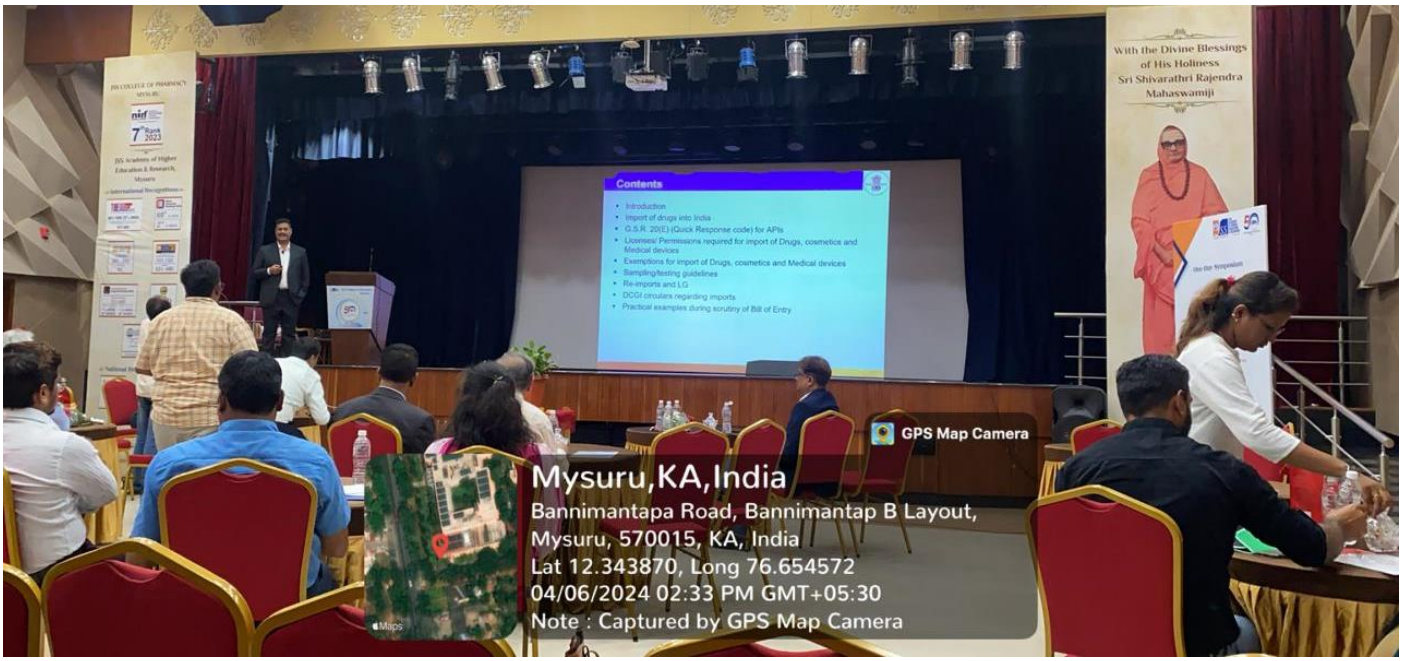
Dr. Meghana G.S, Lecturer, Dept. of Pharmaceutics introduced the speaker.

Dr A Ramkishan provided an overview about the CDSCO port office Hyderabad functions, activities related to scrutiny of Bills, clearance of bills of Entry, and Drawing samples from Import/Export consignments. He explained about the G.S.R 20(E) dated 18th January 2022; about the Export of Drugs and cosmetics, Rules and Regulations, type of Documents will be serutinized for Shipping bills [ex: Form of ADC Export sheet, Compilance to Rule 94 and 147 of Drugs and cosmetic Rules].

Illustrations on notices important for Import and Export like DCG(I) Notice Regarding Export NOC Exemption, DCG(I) office Memorandum Label claim for Export, Notification of MOHFW and the content detailed in these notices are detailed. Important aspects about Biological Samples, chapter 30 of ITC HS Schedule-2 of export policy and recent Notification No.72/2023 Dated 11.03.2024 was also discussed.

Graphical representation of Import and Export of Drugs and dramatic increase in exports was noticed. He explained about the process of import (Rule 43A), port of entries (specific designated places of entry given in official website), sampling, shipment of these samples to testing laboratories and the associated process.

Guidance on forms that are required for permission and license for import of drugs, ND, IND, unapproved drugs, for import of medical devices, general principles for withdrawal of samples for testing, challenges faced in port office are delved into.



Session V: "Port office requirements for Export/ Import"

Speaker: Mr. Rajshekhar, Deputy Drugs Controller (India), Bengaluru, CDSCO.

Dr. Meghana G.S. introduced Mr. Rajashekar to the audience of the program.

Mr. Rajshekhar started the session with Drug regulations in India, he explained the rules and regulations that will apply for the drugs in India citing Drugs and Cosmetics Act 1940 and others. He explained about the drug Regulatory systems in India with their functions and organisation, Geographical location of CDSCO in India.

Then data related to import and export of drugs were presented. Import in the 2019-20 was Rs. 40139 crores and the value of import drugs in 2022 was found to be Rs. 60060 crores for the export value in 2019-20 was found to be Rs. 140537 crores in 2021-22 value increased significantly to Rs. 174955 crores.

Import provisions under the Act for cosmetics sir and mainly the cosmetic rules 2020 and MDR 2017 [mainly MD Rule-19] are discussed. Briefed about Form no.DCGI/MISC/2015(199); as stated, NOC is not required with shipping bills as per new requirements.

Brief discussion on ports of Entry for Import of drugs into India. CDSCO port office functions, work at the port office, Forms that are required for permission/Licenses for Import of ND/IND/unapproved Drugs, Documents that are required for import of Drugs, Cosmetic and Medical Devices, Documents Required for Import under test license, personal use. He mentioned the Exemptions for Import of Drugs, gave summary on Guidance document for port offices, General Criteria for drawing of Samples for testing, Testing Guidance importance, use and how it is applicable.

The samples of EOU certificate, Bill of entry filled under EOU, Bill of Entry for warehouse, screenshot of entry of data into the custom online portal were portrayed. The web portal about the custom online portal was discussed during his presentation.

Session IV: Panel Discussion on "Import and Export of Pharmaceutical products- Opportunities and Challenges"

Moderator: Dr K Bangarurajan, Professor, JSS College of Pharmacy, Mysuru and Ex-JDCI, CDSCO, New Delhi

Panelists:

- Mr. Vijay Shah, Ex Joint Commissioner, FDA, Gujarat
- Dr A Ramkishan, Deputy Drugs Controller (India), CDSCO, Hyderabad Zone.
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- Dr. Jayant Kumar, Deputy Drugs Controller (India), CDSCO, Mumbai Zone
- Mr. J. Jayaseelan, MD – Delwin Pharmaceuticals Pvt Ltd, Chennai

Dr. K Bangarajan, the moderator initiated the discussion by stating the trade barriers affecting the import and export of pharmaceutical products; Quality control and assurance measures in pharmaceutical import-export processes; Market access challenges and opportunities for pharmaceutical products in different regions; Impact of global trends and political factors on pharmaceutical import-export dynamics.

The panelist member, Dr Ramkishan stated that the global pharmaceutical industry is witnessing increased opportunities and challenges in the import and export of pharmaceutical products. The import and export of pharmaceutical products present significant opportunities for companies to expand their market reach and contribute to global healthcare accessibility. Identification of emerging opportunities for market expansion and growth and importance of quality control measures in maintaining product integrity during cross-border trade. Strategies for ensuring compliance with quality standards across different regions were highlighted.

Mr. Rajashekar highlighted the impact of digital transformation on streamlining import and export procedures in the pharmaceutical sector. Utilization of technological advancements to improve efficiency and transparency in trade operations, addressing the significance of effective market access strategies in penetrating new markets and diversifying product portfolios. Examining the role of trade promotion initiatives in enhancing visibility and competitiveness in the global pharmaceutical marketplace were discussed.

Representatives from the industry and SMEs put forward their issues/ bottlenecks in obtaining various permissions and meeting the regulatory requirements. The experts in the panel provided with the requisite details based on the query. One of the important issues came across was process of approval of medical devices where SME was facing issues with their medical device testing and approvals.

The questions raised by the delegates was duly addressed by the experts and the session was concluded.

All the regulatory officers / experts were felicitated during the symposium for their contribution towards the conduct of this symposium and supporting the activities of Centre of Excellence in Regulatory Sciences (CEReS).

The symposium received a good response; a total of 237 delegates participated in the symposium [24 delegates representing SMEs and 213 delegates from various academic institutions].

Dr. M.P. Venkatesh, Associate Professor, Dept of Pharmaceutics and Coordinator – Centre of Excellence in Regulatory Sciences (CEReS) proposed the vote of thanks; extending warm regards to the leadership at JSS AHER, thanking all the Regulatory officers, organizing committee (dept of Pharmaceutics), delegates, volunteers and all who have contributed for the successful organization of the symposium. Special thanks was extended to Dr. K. Bangarurajan for all his efforts in coordinating with the regulatory officers and fruitful conduct of this event.


One-Day Symposium
GPS Map Camera
Mysuru, Karnataka, India
8MV3+HV4, Narashima Raj Mohalla, Bannimantap A Layout, Bannimantap, Mysuru, Karnataka 570015, India
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