

## JSS ACADEMY OF HIGHER EDUCATION & RESEARCH (JSSAHER)

### COLLABORATIONS SUPPORT GROWTH IN CHALLENGING TIMES : LEADERSHIP DEALINGS WITH EXTERNAL STAKEHOLDERS

The WHO-JSSAHER collaborative support growth in challenging times demonstrates the greatest breadth and depth of leadership and management skills. The leadership of JSSAHER strongly believes in supporting the global cause in Health Sciences Education, Research and training that will build resilience in these challenging times that makes the senior team special leading JSSAHER

- **Collaboration supporting the global cause** : Though India is known as the ‘Pharmacy of the World’ for its capabilities in producing quality medicines at affordable prices, the capacity to meet the global requirements during the pandemic rested only with few major Pharma companies. One of the major challenges was the prequalification by WHO of the Pharma Companies of the standards required to export drugs to other countries. In an endeavor to strengthen the Indian Pharma Sector, WHO joined hands with JSSAHER in training the Middle and Small-scale Pharma companies to understand the requirements of WHO prequalification and mentor them to achieve such standards with experts drawn from all over the world.
- **Anticipated change in the higher education system and environment in health sciences & health care**: In an endeavor to strengthen the Indian Pharma Sector, WHO joined hands with JSSAHER in training the Middle and Small-scale Pharma companies to understand the requirements of WHO prequalification and mentor them to achieve such standards with experts drawn from all over the world. Each training program had representation from 30 pharmaceutical units. The participants of the training program: 3 representatives from each pharmaceutical unit and including a person each from Production, Quality and Management domain The total Number of pharmaceutical units engaged is 180 for the entire 6 training programs with 540 participants in 165 training sessions. For the international training program, the pharmaceutical unit represented from Nepal, Bangladesh, Indonesia, Maldives, and Timor Leste. 35 experts around the globe involved as resource persons and provided training and mentorship.
- **Examples of creative management across the institution**: JSS AHER, was invited by WHO to nominate two individuals from JSS AHER to attend the “Virtual cGMP Training Marathon” Webinar organized by the World Health Organization (WHO), HQ, Geneva - Local Production & Assistance Unit (LPA), Regulation and Prequalification Department (RPQ), Access to Medicines and Health Products Division (MHP), starting from 07 September ending on 30 November 2020. Members from JSS AHER are: Dr Vishal Kumar Gupta, Deputy Director (academics), JSS AHER, Mysuru, India and Dr Vikas Jain, Assistant Professor, JSS College of Pharmacy, JSS AHER, Mysuru, India.
- **Greatest breadth and depth of leadership and management skills with relevant leadership dealings with external stakeholders**: WHO has constituted a “Working group on Haemovigilance Tools” for developing standardized haemovigilance tools for safe blood transfusion practices. Dr Surinder Singh, Vice Chancellor, JSS AHER, Mysuru is a nominated member of the working group and participating in the deliberations from 8<sup>th</sup> December 2020 onwards.
- **Improving on standard practice in the health care sector** : JSSAHER has excelled in health care education and training with national and international collaboration ,which is reflected through its vaccine clinical trials, effective, low cost medical devices, outreach activities during the COVID 19 Pandemic.

As the world came to a standstill with COVID 19 lockdown, technology and human resiliency rose to the occasion and connected people beyond boundaries. One such endeavor of an international specialized agency of the United Nations responsible for international public health, the World Health Organization (WHO) in association with the health and life science focused Deemed University, JSS Academy of Higher Education & Research, Mysuru, Karnataka, India (JSSAHER) joined hands to strengthen capacity building in the Pharma Sector. Though India is known as the 'Pharmacy of the World' for its capabilities in producing quality medicines at affordable prices, the capacity to meet the global requirements during the pandemic rested only with few major Pharma companies. One of the major challenges was the prequalification by WHO of the Pharma Companies of the standards required to export drugs to other countries. In an endeavor to strengthen the Indian Pharma Sector, WHO joined hands with JSSAHER in training the Middle and Small-scale Pharma companies to understand the requirements of WHO prequalification and mentor them to achieve such standards with experts drawn from all over the world. This collaboration extended further in conducting training programs in Hemovigilance to the South East Asian region countries and supporting the development of blood safety standards and hemovigilance tools. The key for the success of the collaboration was the technologies and expertise that JSSAHER had and shared with WHO for a global cause.

**WHO – JSSAHER Capacity building program on Current Good Manufacturing Practices (cGMP) Online for Pharmaceutical Units in active pharmaceutical ingredients (API) and formulations for access to quality-assured medical products**

WHO had undertaken a joint SEARO-WHO India Survey on Pharmaceutical Units in India, with an inter-ministerial effort of Govt of India. It led to several key recommendations for several ministries in India for to promote access to medical products for meeting national and global health needs. Strengthening current GMP with the support of WHO among pharmaceutical units engaged in manufacturing APIs, formulations, and medical devices was one major recommendations of the Survey. The Good Manufacturing Practices (cGMP) Online Training was conceptualized, to take the recommendations forward and to particularly address the COVID-19 challenges. A series of 6 workshops is being organized and implemented by all three levels of WHO (Country Office, Regional Office, HQ) in collaboration with JSS Academy of Higher Education & Research (JSS AHER), Mysuru and Indian Pharmaceutical Alliance (IPA).

The pilot cGMP workshop for Pharmaceutical Units was organized from 1<sup>st</sup> – 14<sup>th</sup> December 2020 for a period of 12 days on a unique and dedicated JSS AHER web portal specifically designed for the workshop. 41 Experts including 11 international Speakers shared their knowledge and expertise on the various topics. External partners, US Agency for International Development (USAID), Medicines, Technologies, and Pharmaceutical

Services Program (MTaPS), and Promoting the Quality of Medicines Program (PQM+) of United States Pharmacopoeia (USP) contributed towards developing course content.

The workshop provided an opportunity for them to familiarize with the requirement of strengthening and capacity building of their facilities and systems to meet the WHO Pre-Qualification (PQ) standards.

The WHO in its feedback had mentioned, “It’s the first time anywhere in the world such a Workshop has been attempted by WHO - in person or digital format that we have accomplished. The challenge of COVID19 was channeled into an opportunity for wider access to industry and all stakeholders came together (industry, academia, government, international organizations including WHO) through a web platform, for which JSSAHER performed a critical role”.

### **World Health Organization (WHO) Pilot online Training Program for establishment of National Haemovigilance Systems in South East Asian Region (SEAR) Countries**

World Health Organization Blood Transfusion Safety program has been established to develop strategies for blood safety and promote them on a global, regional and national basis through advocacy and the provision of technical support to WHO Member States.

Whilst the National Haemovigilance systems are well established in many countries, there is a lack of effective Haemovigilance in many resource-limited settings, and implementation in such settings remains an important and challenging problem. In the COVID 19 scenario, it was not possible for the experts to travel to countries and evaluate and train staff in Haemovigilance. Mindful of this situation, the WHO and JSS AHER conceptualized a pilot virtual training program that would include prerecorded Audio-Visual educational modules which was developed by 26 domain experts from 8 different countries. 26 pre-recorded audio-visual modules were relayed during the program, with 8 panel discussions for live interactions between the participants and the experts. 240 participants registered and participated from 5 SEAR countries namely, Nepal, Bangladesh, Indonesia, Maldives, and Timor Leste.



The graphic on the left features a red circular background with the WHO logo at the bottom. It lists the countries: Nepal, Bangladesh, Indonesia, Maldives, and Timor Leste. The background also includes images of red blood cells and a person in a white coat handling a blood sample.

Country	Number of Registrations
INDONESIA	99
BANGLADESH	42
NEPAL	71
TIMOR	2
MALDIVES	26
TOTAL	240

The participants from the 5 SEAR countries understood the need of Haemovigilance in blood safety and showed their interest in development and implementation of

Haemovigilance systems in their respective countries. The feedback collected from the participants on each day of the 5-day program showed that 100% of the participants were interested to attend such programs in the future. 92% of the participants opined that the learning experience of the program was excellent and 8% of them felt it was good. 90% of the participants were satisfied with the duration of the program. 82% of the participants had good internet connectivity throughout the program. The representatives from countries where the hemovigilance system is yet to be developed were motivated to initiate and implement concepts learnt during the program for enhancing the safe transfusion practices. The participating countries felt that conduct of such online programs in future should be continued.

### **Ongoing Collaborations**

JSSAHER further collaborating with WHO in conducting a “ Regional Desk Review (situational analysis) of regulations overseeing quality and safety of Blood and Blood Products in member states of South East Asia region” and Contributing to the “ WHO-Working group on Haemovigilance Tools”. As there are different mechanisms of regulation of blood and blood products in various South East Asian Region (SEAR) countries, harmonization/ standardization of such mechanisms would be the primary approach to bring down such regulatory differences and thus quality of blood and blood products. With an aim to conduct situational analysis of the existing legislations and regulations overseeing blood transfusion systems in member states of South East Asia region and form a regional consortium of regulatory experts of blood and blood products, WHO and JSS AHER has undertaken a Desk review and that can help in the necessary standardization of the systems through effective haemovigilance network.

Further with a strong need to standardize the global haemovigilance systems, the experts from International Society for Blood transfusion (ISBT), International Haemovigilance Network (IHN) and WHO experts including Dr. Surinder Singh, the Vice Chancellor of JSS AHER are actively involved in a global working group. The group aims to establish guidelines and tools for haemovigilance that will bring forward a comprehensive and safe blood transfusion services.

JSSAHER strongly believes in supporting the global cause in Health Sciences Education, Research and training that will build resilience in these challenging times.

**PA** INNOVATION. QUALITY. GLOBAL REACH.

**World Health Organization**

**JSS** ACADEMY OF HIGHER EDUCATION & RESEARCH (DEEMED TO BE UNIVERSITY) MYSURU

### cGMP Online Workshop for Pharmaceutical Units - 1<sup>st</sup> Dec to 14<sup>th</sup> Dec 2020

#### The Team



#### Experts



#### Participants



### WHO-SEAR Countries: Pilot Online Training Program for Haemovigilance – The Team

World Health Organization REGIONAL OFFICE FOR South-East Asia

JSS ACADEMY OF HIGHER EDUCATION & RESEARCH (DEEMED TO BE UNIVERSITY) MYSURU

23<sup>rd</sup> Nov to 27<sup>th</sup> Nov 2020

