



राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान

**NATIONAL INSTITUTE OF PHARMACEUTICAL  
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## Press Release

### A Two Week Intensive Training Program on Pharmaceutical Quality by Design: A Risk Based Approach at National Institute of Pharmaceutical Education and Research (NIPER)-SAS

#### Nagar

Under India's Foreign Policy of Ministry of External Affairs, GOI, National Institute of Pharmaceutical Education and Research, S.A.S. Nagar (NIPER, SAS Nagar, *the institute of National Importance & NIRF Rank 1 institute under Pharmacy Category*) has been chosen by Ministry of External Affairs, GOI, to conduct ITEC programmes in the field of Pharmaceuticals. The Indian Technical and Economic Cooperation (ITEC) Programme was instituted by a decision of the Indian Cabinet on 15 September 1964 as a bilateral programme of assistance of the Government of India. The Development Partnership Administration (DPA)-III was set up in the Ministry of External Affairs in January 2012. The ITEC Programme is fully funded by the Government of India, has evolved and grown over the years. Under ITEC India has economic cooperation with 161 countries in Asia, Africa, East Europe, Latin America, the Caribbean as well as Pacific and Small Island countries are invited to share in the Indian developmental experience.

NIPER-SAS Nagar is conducting such training since last 20 years. Now in September 2018 NIPER SAS Nagar is organizing a two-week Intensive Training Program on Pharmaceutical Quality by Design: A Risk Based Approach from 04<sup>th</sup> September to 14<sup>th</sup> September, 2018. Total 20 participants from 10 countries (Algeria, Bangladesh, Cuba, Egypt, Ethiopia, Kenya, Mauritius, Malawi, Sri Lanka and Sudan) with background of Drug Regulatory, Pharmacist and Quality Control, are attending this course. Resource persons from the pharmaceutical industry, academia and regulatory agencies will deliver lectures and participate in the deliberations. About 8 sessions will be held on hands on experience training on different analytical instruments. Visit to Regional Drug Testing laboratory and 02 Industry visits are also a part of this ITEC program.

The inaugural session was held with lamp lighting and Sarswati Vandna. Prof P V Bharatam, Dean NIPER, welcomed the participants and encouraged them to take maximum benefit of the course. He also thanked ITEC division of Ministry of External Affairs for entrusting upon NIPER the responsibility of conducting ITEC programs.

Prof. Sanjay Jachak, course coordinator, gave an introduction of the course to the guests and the participants. He informed that by employing QbD manufacturers can significantly reduce the losses and stock-outs etc. Regulators will have greater confidence in robust quality of products they are being asked to approve and will be able to reduce the intensity of their regulatory oversight. He also mentioned about the various guidelines of QbD like Good Scientific development (Q8) in combination with quality risk management (QRM) (Q9) and Product Quality Systems (Q10) and Development and manufacture of drug substances (Q11). He introduced about the topics which will be covered during the course.

Prof Raghuram Rao Akkinapally, while welcoming the participants expressed that QbD is becoming an important and widely used term in Pharmaceutical Development. The market and outreach of the medicine has become easier by the quality as the world markets are accepting the Indian products without any hesitation. After ICH guidelines, the pharmaceutical market has shrunk and one can easily supply their product to any country provided the company complies to certain standards which are globally acceptable. He said that India is the pharmacy of the world because India is the third largest manufacturer of the generics. In addition to producing the quality medicine, India is also participating in capacity building through the training course like ITEC.

Mr N R Munjal, MD, IndSwift Ltd, the Chief Guest of the function praised NIPER for its capability in producing skilled man power which is acceptable in every pharmaceutical industry. He further said that Indian Pharmacopoeia are maintaining the standard of publishing monographs of new drugs. He appealed to ITEC participants to promote the Indian monographs in their countries also. Indian monographs are at par with United States Pharmacopoeia and British Pharmacopoeia. In that case they should be accepted the worldwide.

In the end Prof Sanjay Jachak proposed a vote of thanks. The inaugural session ended with a group photo of all the participants with the Chief Guest.

#### **About Photographs :**

1. Chief Guest MD, Indswift Ltd.,( Mr. N.R. Maunjal)
2. Chief Guest Mr. N.R. Munjal inaugurating the ITEC
3. Director NIPER during the welcome address
4. Foreign delegates during the inaugural function
5. Foreign participants of ITEC
6. From L to R Director NIPER, Chief Guest MD IndSwift Mr. Munjal, Course Coordinator Dr. Sanjay Jachak and Dean NIPER Dr. P.V. Bhartam
7. ITEC participant during intro session

8. NIPER Director , Dr. Raghuram Rao Akkinapally addressing the gathering

9. Participants introduction





Two Weeks Intensive  
Training Programme on  
Pharmaceutical Quality  
by Design :  
A Risk Based Approach  
04 to 14 September, 2018  
Sponsored by  
Indian Technical & Economic  
Cooperation Programme (ITEC),  
Ministry of External Affairs,  
Government of India  
Organized by  
National Institute of Pharmaceutical  
Education and Research (NIPER),  
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