## No. DCGI/MISC/2016 (97) Central Drugs Standards Control Organization Directorate General of Health Services Ministry of Health and Family Welfare

FDA Bhavan, Kotla Road, New Delhi-110002.

Dated: 18th August, 2016

## **NOTICE**

The Central Drugs Standard Control organization (CDSCO) in pursuance of implementation of e-governance has launched various services for Import of Drugs, Medical Devices, Drugs for Personal use, Drugs for Test & Analysis and Import of Cosmetics in first and second phase.

Now in third phase, the online service for grant of NOC for conducting Clinical Trials have to be launched. In this regard, a hands-on workshop on "Online Process for Grant of NOC for Clinical Trials" has been organised on 24th August, 2016 between 11 A.M. - 4 P.M. at CDAC NOIDA premises (Centre for Development of Advanced Computing- Academic Block, B 30, Sector-62, Institutional Area, Noida 201307).

The On-Spot registration to the workshop will be done on 24th Aug 2016 itself on first-come first serve basis. Only first 30-participants (one or maximum two person from each Applicant firm/Institution) be accommodated in hands-on training.

Participants need to bring their own laptops compulsorily and bring their data cards optionally. Participants also need to bring soft copy of their documents for a particular application of CT that they would be filing online during the workshop. Those without these prerequisites may not be useful in the training and may be denied access

The link for test application seen is as following:

online portal **220.156.189.68/CDSCO\_FORM44/homepage** for which **User ID** is **testuser@gmail.com** and **Password** is **Test@123.** 

With this notice a copy of Form 44, the filed of checklist, Proforma of executive summary, Proforma of Investigational Medicinal Product Dossier and Proforma of general information to be filled are attached, which you will need to fill step wise during hands on training.

It is desired that, the stakeholders may conduct a test run on their own before coming for workshop, which will help (you and us) to understand the process of on-Line application in better manner.

Your active involvement and participation in doing prior exercise and the workshop exercise is highly solicited

Wishing you all the success,

OFFICE OF DRUGS CONTROLLER GENERAL (INDIA)

- 1. Executive Summary
- 2. Checklist for Form 44
- 3. Guidance
- 4. IMPD Format
- 5. GCT Online Steps