

**File no. QA/NRA assessment/2016/03
Director General of Health Services
Central Drugs standard Control Organisation
Office of Drugs Controller General (India)
(QA Division)**

**FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 21-09-2016**

Meeting Notice


Subject: - Meeting of vaccine manufacturers to discuss upon forthcoming NRA assessment and its tools - regarding

This is to bring to your kind notice that WHO is planning to conduct NRA Assessment of vaccines to be held in the month of February, 2017 which will involve the assessment of National Regulatory Authority for vaccine i.e. CDSCO for various regulatory functions. As a part of NRA assessment, observed audit shall be conducted in selected vaccine manufacturing facilities to be held from 17th-21st October 2016 where Observers from WHO shall assess the performance of the GMP Inspectors of CDSCO and SLA during the entire inspection process.

In this regard it has been decided to convene a meeting of all vaccine manufacturers to discuss the matter related to **NRA assessment and its expectations** to be held on 26/09/2016 from 12:30 PM to 17:00 PM at CDSCO (HQ), FDA Bhawan New Delhi.

It would be appreciated if the undersigned could be informed of the names of two representatives (one person from senior management level who is well versed with technical issues and other one preferably Head QA) before 23rd September 2016, through return e-mail on dcg@nic.in with a copy to qa@cdsco.nic.in or Fax on 011-23236973.

This is for your kind information and mandatory action.


(Dr. G. N. Singh)
Drugs Controller General (India)

To:

1. All vaccine manufacturers (India).

Copy to

1. Officers and staff of vaccine/ QA division, CDSCO (HQ)
2. PS to DCGI
3. CDSCO website
4. DDA(D)