

Meeting Agenda
**Workshop on "Regulatory practices in China &
 Dossier filing with NMPA**

Date: 17th Dec, 2018

Venue: Park Hyatt Hyderabad

Address: Road No. 2 Banjara Hills, Hyderabad

Timing		Programs
08:30-09:00 AM	:	Visitors check-in. Registration for visitors and ID card distribution.
09:00-09:20 AM	:	Introductory speech by Mr.Uday Bhaskar, DG, Pharmexcil.
09:30-10:15 AM	:	Indian pharma product opportunities & challenges faced for China market
10:15-10:30 AM	:	Quick Q & A session
10:30-11:00 AM	:	Tea break
11:00-12:30 PM	:	Regulatory overview (including follows) by Ms.Vicky. - Registration Guidelines - CTD modules - Dossier assessment criteria - All DMF sections. - Critical requirement from CFDA. Change Management system new joint application policy
12:30-12:45 PM	:	Quick Q & A session
12:45-13:45 PM	:	Lunch session
13:45-15:00 PM	:	Speech for CFDA audits by Ms.Pei.
15:00-15:30 PM	:	Tea break
15:30-17:00 PM	:	Face to face discussion between audience and the CSC team. After introduce all members from CSC.
17:00-17:30 PM	:	Closing session followed by vote of thanks by CSC and Pharmexcil