



8th GHTF CONFERENCE INFORMATION SESSION BRIEF

Title: Overview of SG 2

Date/ Time: 9:00 AM – 9:45 AM
Friday, September 22nd

Convenor: Deb Blum
United States Food and Drug Administration
Tel: 301-594-2985
Fax: 301-594-1967
Email: dyb@cdRH.fda.gov

Topic: **Overview of SG2-** Deb Blum
Who we are: countries and organizations represented on SG2
What we are about: brief review of SG2 charge and mission statement
Where we are going: what SG2 will present today, and some new projects we are developing

The NCAR/Vigilance Report Exchange Program- Kim Dix
Overview of the Program
Training considerations
Confidentiality issues

SG2 N21 Manufacturer Reporting Guidance- Ben Khosravi
What constitutes a reporting event, with examples
The exemptions to the reporting rules, with examples

Key Projects- Carl Wallroth
Introduction to N32:Mfr. Universal Dataset; N 33:Mfr. Report Timeframes;
N 36:Mfr. Trending of AEs; Use Error Reporting

Goals for this presentation: Attendees will have increased knowledge and appreciation for the mission of SG2, key SG2 guidances and programs currently available, as well as ongoing SG2 projects.