



U. S. Department of
Health and Human Services



Center for Devices and
Radiological Health

GHTF Software Ad Hoc

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Goals



- ◆ To liaise with existing Study Groups on aspects of regulated medical device software and software used in the manufacture of medical devices.
 - ◆ Technical advice as needed
 - ◆ Resource as needed
 - ◆ Coordinate between Study Groups
 - ◆ Temporary

Work plan



- ◆ We received our mandate at the Irvine Meeting of the Steering Committee in May
- ◆ We have just developed our work plan to fulfill our mandate

Membership

- ◆ Steering committee members -3
- ◆ Existing Study Group members -4
- ◆ New membership -7
 - ◆ experts
- ◆ Representation in our group from;
 - ◆ Regulators: USA, Japan, EU.
 - ◆ Industry: Australia, US, EU, Japan
 - ◆ Vendors: International Tradegroups
 - ◆ Professional societies: US

Membership



- ◆ Non-Regulator Representation from;
 - ◆ IEC TC62a,
 - ◆ ISO TC215
 - ◆ ISO TC210
 - ◆ ISO TC212
 - ◆ HIMSS
 - ◆ ACCE
 - ◆ HL7
 - ◆ Advamed
 - ◆ Nema
 - ◆ And more.....

Broad goals

- ◆ Provide a context for Software in GHTF output, but only where necessary!...
- ◆ Direct this context
 1. Toward standards, or if not possible
 2. Toward existing GHTF documents
 3. Away from complexity and duplication
 4. In a regulatory direction
 5. Then dissolve!

Meeting strategy

- ◆ Send observers to SG meetings if needed
- ◆ Meet shortly after the SG meetings
- ◆ Better information!
- ◆ Better attendance!
- ◆ Utilize on-line meetings, wiki