

## HBD WG4 Meeting Minutes (For all Websites)

Date	Time	Location	Participated Sectors
April 20, 2010 (EST)/ April 21, 2010 (JST)	8:00 – 9:15 PM (EST)/ 9:00 –10:15 AM (JST)	Teleconference	MHLW, PMDA, FDA, JFDA, AdvaMed
Agenda	<ol style="list-style-type: none"> <li>1. STED POC</li> <li>2. GCP Paper Publication</li> <li>3. HBD Concept Paper</li> <li>4. Meeting and HBD presentation planning</li> </ol>		
Discussion Summary	<p>The WG reviewed draft STED POC Guidelines and agreed to make additional modifications. The announcement on the STED POC is to be posted on the FDA's Website. The GCP Paper has been published in the April issue of <i>Regulatory Focus</i> (RAPS.org). The HBD WG4 Concept paper translation into Japanese has been completed. The WG discussed presentation opportunities on HBD updates.</p>		
Next Meeting	May 25, 2010 (EST)/May 26, 2010 (JST)		