

**Pan-American Network on Drug Regulatory Harmonization (PANDRH) - WG of  
Medicines Registration**

**Workplan November 2010-July 2011**

#	Activity/Task	Responsible	Date
1.	Monthly Elluminate meeting	Secretariat	First Friday of each Month (TBC)
2.	Review and update the document on Requirements for Medicines Registration 2.1. Request comments from Members of PANDRH 2.2. To consolidate comments and to circulate a new version	Secretariat	2.1. Dicember/2010 2.2. January/2011
3.	Develop the Guidelines for implementation of the requirements (including the glossary) 3.1. Circulate the draft to the WG 3.2. Deadline for receiving remarks and comments 3.3. Consolidate comments and circulate the new version	Silvia Boni Secretariat	3.1. Nov/2010 3.2. Jan/2011 3.3. Feb/2011
4.	Round of presentations of the state of the art in different Regional integration/economic Blocks <ul style="list-style-type: none"> <li>• ASEAN</li> <li>• EMA</li> <li>• TBD</li> </ul>	Secretariat	TBD (according availability of presenters)
5.	Preparation for the VI PANDRH Conference 5.1. To submit a new version of the Document of harmonized requirements and Guidelines to the Steering Committee (SC) for approval of the Conference 5.2. Appreciation by the SC 5.3. to circulate the document to the PANDRH members 5.4. Presentation of the document during the conference	Silvia Boni Secretariat	5.1. Mar/2011 5.2. Mar/2011 5.3. Jun/2011 5.4. Jul/2011
6.	To prepare a workplan, including tools for implementing the proposal	Silvia Boni Secretariat	Mar to May/2011
7.	WG face to face meeting during the VI Conference	Silvia Boni Secretariat	Jul/2011

**Proposals to be considered for the development of the Workplan August 2011-July 2012**

#	<i>Activity/Task</i>	<i>Responsible</i>	<i>Date</i>
	To review the monitoring and assessment indicators for Medicines Registration To prepare communication / information material		
	Training based on the Guidelines on the Harmonized Requirements for Medicines Registration - Planning of the Training - Development of the training - Assessment of the training		