Summary of Comments on 2011-09_conceptpaper_BPL.pdf

Page: 5, A.2

Author: Bert van Leeuwen Date: 2-10-2011 21:50:45 +02'00'
"..where the QPPV operates" not clear;
Sugg: where the QPPV holds office

Page: 6, A.3.(3)

Author: Bert van Leeuwen Date: 2-10-2011 22:16:12 +02'00'
Reference does not appear to be correct.

Page: 6, Consultation Item no.1

Bert van Leeuwen 2 oktober 2011 22:27
Yes. Details on use of other organisations (e.g. CROs) to perform these tasks.

Page: 7, A.3(7).e

Author: Bert van Leeuwen Date: 2-10-2011 22:32:14 +02'00'
"audit trails conc. the monitoring..." needs a clearer description of the required data.

Page: 7, Consultation Item no.2

Author: Bert van Leeuwen Date: 2-10-2011 23:00:18 +02'00'
Changes to the location of PhVMF and the QPPV should be notified by letter; other changes should not be notifiable; a 'last review date' and a 'last notified date' would be useful

Page: 7, A.5

Author: Bert van Leeuwen Date: 9-10-2011 12:51:41 +02'00'
Version control, incl. the date, should be included in the title page.

Page: 8, A.7

Author: Bert van Leeuwen Date: 2-10-2011 23:10:04 +02'00'
"All completed audits...shall be recorded". Does this mean audit reports or records of the audit having been performed?

Page: 8, Consultation item no.4

Author: Bert van Leeuwen Date: 2-10-2011 23:12:12 +02'00'
Audit reports are internal Quality Managment data; corrective and preventive actions are more relevant to be included.
The (planned) annual audt schedule is appropriate to be included.

Page: 8, A.8

Author: Bert van Leeuwen Date: 9-10-2011 12:56:33 +02'00'
Submission in electronic format should be accepted; printed version to be handed to inspector when at the site.

Page: 10, C.14.(d)
Author: Bert van Leeuwen Date: 9-10-2011 15:03:51 +02'00'
appropriate RSS feeds to be supplied by EMA and read by MAH (proof of reading is documneted response, if required, within another 24 hours)

Page: 11, Consultation item no.7
Author: Bert van Leeuwen Date: 9-10-2011 15:28:52 +02'00'
On the whole yes.

Page: 13, Consultation item no.8
Author: Bert van Leeuwen Date: 9-10-2011 15:30:19 +02'00'
This will need some more detail on coordination between NCAs and EMA

Page: 13, E.20
Author: Bert van Leeuwen Date: 9-10-2011 15:30:19 +02'00'
This general chapter requires more specification: methods used (MAH may use diffeent methods from EMA, MAH may use global daata). Specification how a signal is evaluated (resulting in a (non) changed risk-benefit balance) would be required.

Page: 15, Consultation item no.9
Author: Bert van Leeuwen Date: 9-10-2011 15:39:02 +02'00'
The 'work sharing' and thereby cumulating all tasks on one in one Member State carries the risk of bias; peer review (e.g. EMA and one MS) may be required for balance

Page: 15, Consultation item no.10
Author: Bert van Leeuwen Date: 9-10-2011 15:52:04 +02'00'
The different roles are insufficiently specified. Furthermore, the process of establishing is signal needs more clarification because a) methods may differ and b) MAH may have global data

Page: 30, Annex lV.2.10
Author: Bert van Leeuwen Date: 4-11-2011 1:01:19
Additional explanation/elaboration on the need for informed consent vs. the non-interventional nature of a trial would be appreciated; informed consent may lead to inclusion bias

Page: 30, Annex lV.2.10
Author: Bert van Leeuwen Date: 7-11-2011 0:46:08
The requirement of PRAC/CHMP to conduct a trial should be aligned with the national Ethical Committees in case of interventional trials