Subject:Meeting with Advamed and Siemens - regulated product submissions November 25, 2014

Dear [article 4.1 b]:

Last week, [article 4.1 b] and I met Advamed and Siemens. They wanted to update us on the outcome of the meetings of the IMDRF in Ottawa, in particular on Regulated Product Submissions.

Main messages were:

- It is not clear what the business case (or business gains) of cooperation on RPS are. There will be further work in IMDRF to complete analysis of the business case, which will be done by January -industry will contribute to this exercise.
- There are two areas of cooperation: (1) the table of contents (the index of the information that needs to be submitted) and (2) the electronic template. The priority for them is the table of content
- The point is that even if there is harmonisation of the table of contents, that does not mean a company can just submit the same information to both jurisdictions because under the same folder, there can be different elements. However, harmonisation of the table of contents can lead to convergence of the contents.

On a separate note, they expressed interest in the medical devices single audit pilot program.

Best regards,

[article 4.1 b]