SERVING TWO MASTERS:
COMPARING/CONTRASTING US AND EU REGULATORY SUBMISSIONS AND PROCESSES

Workshop status: Advanced

Art Gertel and Susan Bhatti

Pre-workshop assignment

Objectives

We expect that many of you will be able to draw upon personal experiences with regard to document preparation and, perhaps, filing. If this is the case, please come prepared to share these encounters with aspects of document "user-friendliness" as well as steps you or your company may have taken to address issues of document quality and reviewability as well as the process of preparing regulatory submissions.

Content and Instructions

In particular we will welcome your thoughts and recollections on the issues below. The questions are intended to stimulate your thinking about some aspects of regulatory filings that are important to facilitation of review. In addition, there are several questions pertaining to interactions with Regulatory Authorities. Don't worry if clear-cut answers are not obvious or if you have only had limited interactions with Regulatory Authorities. There is considerable latitude in what might be considered to be the "correct" answer to these questions.

1. What in your view are the critical elements that determine document and dossier quality and readability from the reviewer's perspective?

2. How has the reviewer communicated these to you/your company?

3. If you have had experience with US as well as EU submissions, have the standards and content of any of the documents differed and have you noticed any changes in the focus during recent years?

4. Have you ever sought/received Regulatory Authority guidance re: document format/content prior to initiating preparation of the document?

5. Do you have experience with US accelerated (expedited) or EU conditional marketing authorization submissions? If you have, were the document requirements for these submissions different from a standard submission?

6. What has been your biggest challenge in preparing documents for regulatory authorities?

Assessment criteria

Responses provided to all 6 questions

Time required

Not more than one hour. The assignments should be sent to Susan Bhatti (susan.bhatti@merckgroup.com) and Art Gertel (medscicom@rcn.com)

Deadline for return: Friday 12th April 2019