**Abstract submission ASA BIOP Session**

**Session ID: 200833** *(Title: Tools to enable the use of R by the bio-pharmaceutical industry in a regulatory setting)*

**Title:** Panel Discussion

**Affiliation and email address for each participant**

Juliane Manitz, EMD Serono, [juliane.manitz@emdserono.com](mailto:juliane.manitz@emdserono.com)

Marly Gotti, Biogen, [marly.cormar@biogen.com](mailto:marly.cormar@biogen.com)

Andy Nicholls, GSK, [andy.p.nicholls@gsk.com](mailto:andy.p.nicholls@gsk.com)

Paulo Bargo, Janssen R&D, [pbargo@its.jnj.com](mailto:pbargo@its.jnj.com)

Douglas Kelkhoff, Roche/Genentech, [kelkhoff.douglas@gene.com](mailto:kelkhoff.douglas@gene.com)

Keaven Anderson, Merck & Co, [keaven\_anderson@merck.com](mailto:keaven_anderson@merck.com)

Yilong Zhang, Merck & Co, [yilong.zhang@merck.com](mailto:yilong.zhang@merck.com)

Joseph Rickert, RStudio, [joseph.rickert@rstudio.com](mailto:joseph.rickert@rstudio.com)

Following the presentations by Paul Schuette and Mark Padgham, we would like to engage in an interactive discussion with the audience. Representatives from the R validation hub executive committee are joining the conversation. We hope to discuss different tools to support R-based submissions in a biopharmaceutical regulatory setting with special attention to the risk-based approach for assessing R package accuracy. We also would like to hear back from the audience about their experiences and questions.

Generally, we differentiate two types of R packages: 1) Core and recommended packages that are shipped with the basic installation and a rigorous software development lifecycle assures minimal risk, and 2) Contributed packages that may vary in their accuracy and development rigor, which could be assessed by various metrics. The R validation hub focuses their attention on validating contributed packages. They have developed some of the tools that provide workflow to evaluate the quality of a set of R packages: The R package riskmetric, an associated shiny application to perform risk assessments, and discuss things to consider when testing R packages.