1. **Is there a PDA working group that is evaluating/studying PR for aseptic process?**

2. **What would be your primary criteria for the approval of PR if you were a Regulator?**
   A company should start by reviewing the *FDA Guidance for Industry; Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes* and *PDA Technical Report 30; Parametric Release of Pharmaceutical and Medical Device Products Terminally Sterilized by Moist Heat* to ensure

   I think a company needs to demonstrate that a mature Quality System is in place; the manufacturing process is in control; risks associated with the potential to release a non-sterile product have been identified and mitigated; robust procedures, process controls, and ongoing monitoring are in place to ensure the process remains in a state of control; and they have properly validated the critical parameters and design space of the product/process.

3. **Can you use sterility test to release product if something happens with the PR release criteria?**
   No, the *FDA Guidance for Industry; Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes* states that the submission for parametric release should include "Acknowledgement that adherence to the critical parameters of the parametric release program will substitute for the performance of a sterility test as the primary release criterion for the product and that sterility test results from the finished product will not be used to overrule any failure to meet the acceptance criteria of the parametric release program. In the event of failure, the specific sterilizer load will be rejected by the quality control unit and will not be released unless there is a provision for reprocessing."

4. **Instead of sterility testing; how about using BIs on loads in conjunction with parameter review?**
   Yes, a biological indicator can be used as a load monitor to meet the CFR sterile product release requirements for a laboratory test in a parametric release program.

5. **Do you need to use a specific biological indicator to get Parametric Release?**
   The choice of biological indicator is based upon regional requirements and the sterilization cycle design approach, there is not a specific BI required for Parametric Release.

6. **What grade water is typically used as cooling water for TS cycles?**
   The grade of water used as cooling water can vary based upon the sterilization process. For a superheated water process the primary quality attribute of the water should be microbiologically controlled to prevent the risk of recontamination sterilized product. The water may be sterilized in the chamber with the load, sterilized in a separate vessel, maintained at elevated temperatures, or chemically treated to maintain the desired low microbial content.

7. **What's the typical amount (or is there a typical amount) of 'historical data' required for a submission to use Parametric Release?**
   Typically the FDA asks for conforming release data for a minimum of 10 batches of each configuration manufactured over a period of approximately 1 or more years (to account for seasonal variation in facility bioburden).