1. Technical data package from sending site.
2. Chemistry and manufacturing control (CMC) sections.
3. List of monographs for raw materials, active product ingredients, and finish product.
4. Drug substance/API and excipient physical characterizations (solubility, morphology), specifications, and manufacturers.
5. Drug substance/API and finish product stability data, special requirements (sensitivity to light, relative humidity), compatibility studies, storage shipping conditions.
6. Equipment list (model, size, special features or accessories) for the sending site.
7. Process description and flow chart including operating parameters (critical).
8. Formula manufacturing documents (FMD) or master batch records (MBR).
9. List of in-process test procedures.
10. List of validated test methods, analytical cleaning methods (including recovery on different surfaces), and cleaning procedures.
11. Development reports including critical processing parameters, batch size, results, process robustness study results, if available.
12. Regulatory commitments before and after approval, if appropriate.
13. Process justification and validation reports.
14. Quality (deviations, incidents, investigations, out of specification results, rejections) history of the product.
15. Process capability, trends, and actual yield results.
16. Process optimization/productivity changes.
17. Environmental health and safety (EHS) review: waste disposal, toxicity, fire/explosives, industrial hygiene and safety protection assessments, material safety data sheets (MSDS), subject exposure limit (minimum daily dose).

Lyophilization Cycle Transfer: Case Study-Evaluation of Functional Equivalency Among Lyophilizers

Currently, there is no common industry practice or regulatory guidance available that can be used to technically evaluate suitability of different lyophilizer units for successful transfer of lyophilization cycles. Recently, a report was published that explored development of comprehensive methodology for establishing functional equivalence between (different) lyophilizers, which can then be used to predict suitability of cycle transfers [17]. This report described the comparative and operational qualification methods that were used, which included: (a) evaluation of comparability of relevant technical characteristics of the lyophilizer units, (b) comparison of sublimation rates using a model compound, and (c) evaluation of parametric equivalence during the cycles.

Three large-scale production lyophilizer units (one 220 sq. ft. and two 420 sq. ft.) were evaluated by this procedure. The results showed that the proposed meth-