Process Parameters and Range Settings for Medical Device Process Validation

By **Yeong-Lin Chen**

Jun 27, 2019 7:00 am EDT

INTRODUCTION For process validation practitioners in medical device industry, one of the most difficult validation activities is equipment/process Operational Qualification (OQ), which needs to identify key operating process parameters and set their ranges (or upper and lower limits) for OQ worst case (or OQ window) testing according to GHTF process validation guidance (1) developed for medical device industry. As the GHTF suggestions, Screening Experiment of Design of Experiment (DOE) should be adopted to identify the key input variables (or key process parameters), and then Response Surface...