A Data-Driven Assessment of Single-Use System Reliability: 2016-2019

A BPSA Benchmarking Report, 2020 Update

Please note this report is available to BPSA Members only. To access a copy, you must complete a non-disclosure agreement. For further information, please contact bpsa@socma.org.

BPSA is pleased to release "A Data Driven-Driven Assessment of Single-Use System Reliability 2016-2019." This is referred to as the "2020 Report" reflecting enhanced (pre-Covid) data, built on the structure and elements of an earlier version.

As background, dating back to 2017, BPSA-leadership envisioned a "pilot program" to demonstrate the joint feasibility of collecting and sharing pertinent industry business data. These initial efforts culminated in the November 2019 release of a pilot "system reliability report." The 2019 Report has been widely used by dozens of BPSA Members to enhance risk-assessment evaluations.

The BPSA Report(s) utilize **actual data** assembled from systems integrators around the "business of single-use" allowing for the compilation of complaint data around five SUS (Single-Use Systems) product categories. By request, the data published in 2019 has been shared (requiring a binding non-disclosure agreement) with BPSA-Member organizations in order to assess product quality defects, and evaluate, in real terms, risks associated with the employment of polymer-based bio-process systems for drug and vaccine manufacture.

For further information on how to access this report and other upcoming technical and data initiatives within BPSA, please e-mail bpsa@socma.org.