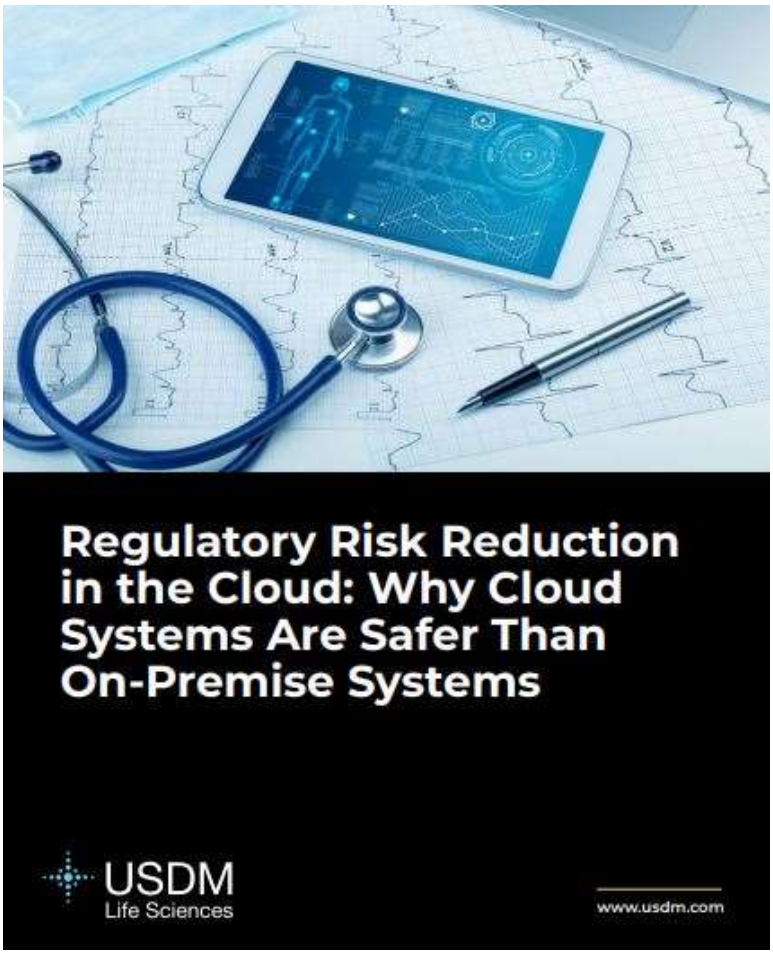
Regulatory Risk Reduction in the Cloud



2020 will be a big year for the cloud in the life sciences industry. With the large number of companies across all areas — including medical device, pharmaceutical, and biotech — beginning to leverage the power of the cloud, coupled with the upcoming release of the FDA's Computer Software Assurance (CSA) guidance, there has never been a better time to dive into the rapidly calming waters the cloud offers.

The current Part 11 guidance and medical device cGMP quality system regulations were derived before the inception of the cloud and lacked clear direction on computer system validation (CSV) and its necessary documentation. Further, these now dated regulations had many unintended consequences due to manufacturers misinterpreting the regulations that led to the over-validatation of computer systems and testing every aspect of their software, deeming it a necessary checkbox in their CSV and manufacturing processes.

This belief created a heavy documentation burden in the CSV process, which resulted in manufacturers rejecting the use of automated systems and new technologies, assuming it would further increase their validation burden and cost