USE OF SUS FOR NON-CONVENTIONAL SYNTHETIC MANUFACTURING PLATFORMS

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The proliferation of SUS has been due to a combination of factors including increased demands on throughput efficiencies as well a growing number of product modalities manufactured at pharmaceutical facilities. Some new modalities (e.g. Anti-Sense Oligonucleotides, Gene Therapy) use predominantly solvent based chemical synthesis processes for upstream manufacturing. As a result, these new modalities present a whole new set of challenges with respect to use of SUS. In these cases, historical challenge agents used to assess the chemical compatibility and performance of SUS may not be representative of the actual manufacturing conditions. Furthermore, as most of the solvents exhibit strong extraction properties, worst-case testing conditions for extractable studies need to be redefined. In this presentation, we will present data on the specific challenges with the application of SUS in Anti-Sense Oligonucleotide manufacturing and propose other material testing and regulatory aspects that may need to be considered when assessing the suitability of SUS systems for these applications.