RECOMMENDATIONS FOR THE ENGINEERING CHARACTERIZATION OF SINGLE-USE BIOREACTORS

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Single-use bioreactors have been available for more than 15 years and are nowadays widely accepted for a broad range of applications. However, process engineering data for these bioreactors, including volumetric mass transfer coefficients, mixing times and power inputs, are still limited. Furthermore, these data are often generated using a number of different methods, making comparisons difficult. In addition, the large variety of bioreactor types and their mixing principles (stirred, wave-mixed, orbitally-shaken, etc.) increases the difficulty in comparing the engineering data.

In order to facilitate the usage of single-use bioreactors, the DECHEMA Upstream Processing (USP) expert group on ‘Single-use technology in biopharmaceutical manufacturing’ has developed recommendations for the process engineering characterization of single-use bioreactors. The methods are based on procedures that were previously developed for multi-use bioreactors and were tested in universities as well as companies (both from the supplier and user sides) for their robustness. The validated recommendations now include measurements of volumetric mass transfer coefficient, mixing time and power input. These parameters are experimentally determined using the dynamic gassing-out method, the decolorization method or sensor method, and the torque method respectively.

The poster gives an overview of the fundamentals and procedures of the methods applied, and current results from the interlaboratory tests. Recent foci include the measurement of carbon dioxide gas-liquid mass transfer and the determination of mechanical stress due to hydrodynamics.