POSSIBLE OBSTACLES AND PITFALLS DURING BIOPHARMACEUTICAL PROCESSING OF HIGH
CONCENTRATION LIQUID FORMULATIONS (HCLF)

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Key Words: high concentration liquid formulation, biopharmaceutical processing, fill and finish

There is an evolving need of high concentration liquid formulations in the field of biologicals over the last years. An increase in protein concentration allows administering the desired therapeutic dose preferably within a single injection due to a considerably reduced drug product volume. Thus, the usage of high concentrated liquid formulations is associated with a higher degree of freedom with regard to e.g. primary packaging material such as syringes, small volume applicators as well as route of administration. Both are leading to a higher patient convenience, ideally to self-administration and thus hospital or medical personnel independency. However, a higher protein concentration can result in increasing viscosities, which entails challenges regarding administration to the patient or biopharmaceutical processing steps (e.g. purification, fill and finish). In literature, key interactions of high concentration liquid formulations are described, which are of importance for the purification (e.g. Donnan effect for diafiltration) or the fill and finish step (e.g. differences in densities). This oral presentation will give an overview of obstacles and pitfalls within certain biopharmaceutical processing steps of HCLFs as well as approaches to tackle them.