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Centrifugal Separation of Monoclonal Antibody for Cancer and Viral Drugs

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Monoclonal antibodies (mAb) are man-made proteins that act like human antibodies in the immune system. mAb has been used for cancer therapeutics (e.g., prembrolizu-mab). Recently, it has also been considered for use in viral drugs for COVID-19 disease (e.g., FDA approved sotrovi-mab). mAb can be conveniently produced from the recombinant protein process for which a gene of a certain type of protein is inserted into a host cell - mammalian cell, a bacteria cell, or a yeast cell. These host cells are cultivated in a fermenter or a bioreactor under proper pH, buffer solution, and elevated temperature. The cells express large quantities of protein out in form of extracellular or intracellular protein. For the latter case, the protein can be in a dense form known as inclusion body. During harvest, the protein is separated from the cell. This may require cell lysing in case of intracellular protein. There are many interesting challenges that face separation using centrifugation using a disk stack or a tubular centrifuge. The protein liquid/solid needs to be separated from impurities to reduce downstream processes (membrane followed by chromatography) problems. One challenge is that the protein liquid needs to be separated from the mammalian cells which does not have a cell wall and the separation needs to be carried out under gentle shear condition so that the cells would not be disrupted. Another challenge is that the inclusion bodies have sizes not too far off from the cell debris which poses a difficult separation by classification [1]. This keynote discusses how these various challenges are being overcome with innovations. Interestingly, the same platform of mAb production has also been used for producing man-made protein from soy plant for use as a substitute for food (beef, chicken, and fish) other than for drugs.