A METHOD FOR ESTIMATING CAPITAL INVESTMENT AND FACILITY FOOTPRINT OF CELL THERAPY FACILITIES

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Capital investment is an important factor to be considered when selecting a manufacturing strategy. For stainless steel facilities (chemical and biopharmaceutical), this is estimated often through the use of the "Lang" factor method. Cell therapy facilities present significantly distinct characteristics to traditional biopharma and chemical engineering facilities, including the use of expensive cleanrooms for open processing, the requirement for additional material storage space, and the reduced utility space and piping requirement. These factors call for the need of a dedicated method for estimating the capital investment and facility footprint of cell therapy facilities. This presentation proposes a method for the estimation of both these parameters. The method described here was developed at University College London, and recognizes that different technologies require different cleanroom classifications and have different equipment footprints. The footprint and area classification of each technology were used to estimate the facility building costs. Additional cost parameters considered in the capital investment calculation include: equipment, validation, commissioning and engineering costs. This method was used to calculate the facility costs and footprint in autologous and allogeneic scenarios, which were compared with the costs of existing cell therapy facilities.