Upstream process development for production of therapeutic proteins using mammalian expression system

Prof. Anurag S. Rathore
Department of Chemical Engineering

Prof. James Gomes
School of Biological Sciences

QbD Step:

Design the space for media component and CPPs to determine the quality of product.

Control Step:

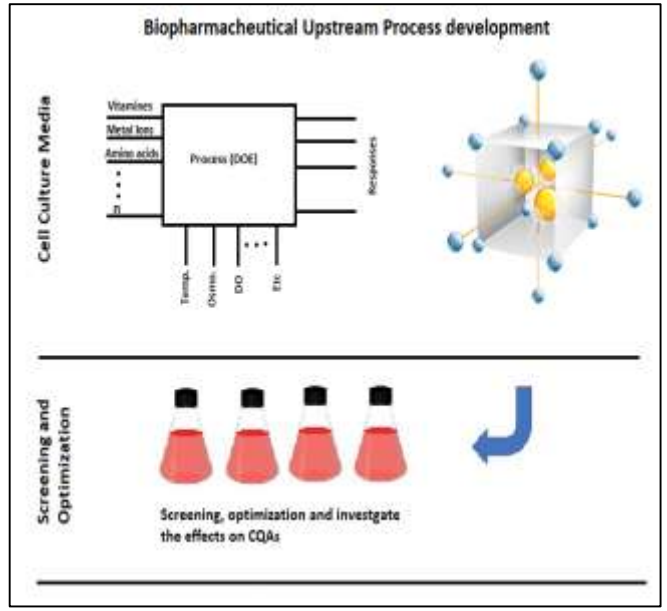
Using the media components and process understanding to control the CPPs nad CQAs

Analyze Step:

Analyze the pertinent CQA as well as monitor the CPPs

DOE Step:

Design of Experiment using potent media components and process parameters.
Include various screening and optimization designs.



Neelesh Gangwar
Chemical Engineering

The Mammalian cell technology which include critical media components, process parameters, have a significant impact on the expression of therapeutic products as well as their critical quality attributes (CQAs) i.e. glycosylation, sialyation, charge variants and aggregation etc(5). Cell culture media components and scale up process parameters play significant role in determining the quality and quantity of final product, which in turn also determine the cost of product(6). Present research aims to implement the approaches, namely Quality by Design (QbD) and Process Analytical Technology (PAT) to obtain high quality product in minimum time. identifying major critical quality attributes (CQAs) which affects the final quality of the product, identification of critical product parameters (CPPs) which affect CQAs, determining the design space to operate the process in a controlled manner. Which will be helpful for continuous integration of process and making it more robust to reduce the batch to batch variability.