BIOT ESBES Graduate Student Design Challenge

2019-20

Challenge Overview and Rules

BACKGROUND:

ACS-BIOT (the Division of Biochemical Technology of the American Chemical Society) and ESBES (European Society for Biochemical Engineering Sciences) are for the third time (since this began in 2017) sponsoring an international design competition. The first competition finals event was held at the ESBES annual meeting in Barcelona, Spain in 2017 and the second finals event was held in Orlando, Florida, USA at the ACS annual Meeting in 2019. The finals event for this third competition will be at the ESBES annual meeting in Portoroz, Slovenia in September of 2020.

What is New about this (Third) Competition:

- The problem statement is being made available to instructors of design courses (in the EU and US). Student teams in these courses can use their coursework to comprise the report they submit for this competition.
- Assistance from experts (such as design course instructors) is allowed, and the competition organizing committee will find (within a few weeks period) a team "advisor/mentor" if one is requested by a team.
- No more than two teams from a given course at a given school (as decided by the course instructor and indicated by a brief letter of endorsement) can submit reports to the competition. All students are welcome to work the problem though.
- Teams (maximum of 5 students) can include some or final inal year undergraduate students, including undergraduate students in final year undergraduate engineering courses that are using the problem statement for this competition. Note: If a team is selected to participate in the FINALS event, the competition will provide funds for only 3 students on the team.
- ESBES and BIOT are organizations with expertise in Biotechnology and Bioprocess Engineering. We understand that instructors, especially of Chemical Engineering Design courses, may have questions before or during their course about this Bioprocess design and

Lentivirus production. We will not be providing a solution, **but we will gladly take questions by email (William.j.kelly@villanova.edu) and then respond with timely feedback and guidance. We will make our replies available to all course instructors.**

- Diversity in team composition (i.e. schools, countries and continents) will still be rewarded by project reviewers/judges giving additional "points", but less points than in the past two contests will be awarded for this diversity.
- Updates on the competition will be provided on a website (not via Facebook)- (http://acsbiot.org.s209162.gridserver.com/index.php/mid-atlantic-local/3rd-annual-esbes-biot-design-competition/3rd-esbes-biot-biotechnical-design-competition/)
- The organizing committee will help individuals from different schools find teammates if requested (email to William.J.Kelly@villanova.edu)
- The organizing committee will help teams obtain use of appropriate design software if requested (email to **Guilherme.ferreira@dsm.com**)
- Teams must REGISTER (email to William.J.Kelly@villanova.edu) for the competition when they receive the problem statement, about 3-4 months before they submit their report. Teams from design courses must register at the beginning of their semester. Teams composed of individuals from different schools will receive the project description when they REGISTER. The latest date to submit reports is July 1, 2020.
- Every Competition has a different technical theme/objective. For this third competition, the topic is "Optimal Manufacturing of Lentivirus for Gene and Cell Therapy Applications

The design Challenge for this Third Competition

This design challenge involves the design of a commercial manufacturing facility for the continuous production of lentivirus for use in gene and/or cell therapy products, including; upstream, downstream and formulation and fill processing.

CHALLENGE EVALUATION CRITERIA

Solutions will be scored on:

(a) grasp and incorporation of the science underpinning the concept and demonstration of product stability, efficacy and associated analytical assessments;

(b) grasp and incorporation of engineering including process design, including material and energy balances, process flow diagram(s), stream and utility tables and (potentially on-line) analytics;

(c) grasp and incorporation of the applicable regulatory science including compliance with FDA and EMA cGMP guidelines, consideration of product safety and of manufacturing safety (including choice of cell lines and attention to removal of problematic impurities such as variant virus particles);

(d) creativity, ingenuity and logic employed, especially with regards to making all or most of the process continuous and specifying appropriate state-of-the-art materials (i.e. chromatography resins) and technology/equipment;

(e) credibility and justification of working assumptions including use of the literature and

reference material;

(f) substantial correctness of computations;

(g) economic and environmental sustainability metrics achieved in your design, including cost of goods manufactured and net present value with due regard for capital and operating expenses, mass indexes in terms of raw material mass usage per mass product produced, waste mass generated per mass product produced, treatment of biological waste for each of these metrics; and

(h) form, clarity and conciseness of presentation of results in written and oral form.

Responses to this competition will be in the form of a written report and a short video presentation summarizing the report. The most competitive responses will be those which make a well-supported case for maximal likelihood of speedy regulatory approval, maximal product stability and efficacy, maximal economic impact (in part due to employment of continuous processing) minimal environmental impact and extent to which innovative scientific and technological innovations are incorporated.

The score will be based on a 100 point scale. The scoring rubric is shown on the last page of this document. There will be bonus points awarded based on the schools in which each team member for a given team is currently enrolled , to encourage and recognize diversity in the submitting teams. One point will be awarded for each unique school represented by the team members, one additional point will be awarded for each unique country represented amongst the schools of the team members, and one additional points will be awarded for each unique continent represented amongst the schools of the team members. Thus, each team will receive between one and nine bonus points based on their composition.

The statement of the challenge problem contains an introduction to the pertinent technical literature. The use of additional textbooks, handbooks, journal articles, regulatory material and lecture notes is permitted and, indeed, encouraged. Be sure to fully cite all sources of information used in the construction of your solution.

CHALLENGE RULES

Students may use any available commercial or open source flowsheet design programs to assist in their preparation of solutions. Students are warned, however, to assess any built-in component physical property data carefully. Students using commercial or library computer programs or other solution aids should so state in their reports and include proper references and documentation. Judging, however, will be based on the overall suitability of the solutions, not on skills in manipulating computer programs.

Submission of a solution for the competition implies strict adherence to the following conditions: **(Failure to comply will result in solutions being returned to the submitters for revision. Revised submissions must meet the original deadline.)**

CHALLENGE ELIGIBILITY

- Teams must be registered 3-4 month before submitting their report
- Entries must be submitted by teams of no more than five students. Note: If a team is selected to participate in the FINALS event, the competition will provide funds for only 3 students on the team.
- Each student participating in the competition MUST BE A MEMBER OF ACS-BIOT OR member organization of ESBES BY THE TIME THAT THE FINAL REPORT IS SUBMITTED (i.e. July 1, 2020).
- Each team member must be in their final year as an undergraduate student or be enrolled in a graduate program of study either full-time or part-time until at least until July 1, 2020. Each team member will include with the submission of the team solution a letter from their advisor, program head or department head confirming their student status.
- At least one team member must be able to travel to the 2020 ESBES meeting in Portoroz, Slovenia Conference in the event that the team is selected as one of the top teams.

CHALLENGE SOLUTION COMPLETION TIMELINE

- The challenge problem will be available to registered teams and design course instructors by July 15, 2019. Submitted solutions are due no later than 4 months after the team had registered and at the latest by July 1, 2020 and must be time stamped no later than 11:59 pm/23:59 h local time.

CHALLENGE RESPONSE FORMAT – WRITTEN REPORT

- The solution itself must contain no reference to the students' names or to the institutions at which they have conducted their graduate studies.
- Final submission of solutions must be in electronic format (PDF or MS Word).
- Final submissions of reports will be via upload to a secure Google Drive site; instructions for uploading to this will be forthcoming to the individual teams via email.
- The main text of the solution must be 60 pages or less; an additional 40 page or less is allowable for supplementary material such as example calculations, supporting figures, etc. The final submission may consist of one or two electronic files. Note that these page limits are upper bounds only, not expected lengths. Conciseness is strongly encouraged. Format requirements: for 8.5x11 inch submissions, 1 inch for all margins/for A4 submissions, 25 mm for all margins; Times New Roman or Arial fonts no smaller than 11 pt with the exception of figures and tables; text in all figures and tables must be clearly legible.

The report should follow the outline suggested in Seider Seader and Lewin.

1. Cover Page
2. Table of Contents
3. Abstract

4. Introduction
5. Process Flow Diagram and Material Balances
6. Process Description and Innovations Relative to “Platform” mAb Process
7. Energy Balance and Utility Requirements
8. Equipment List and Unit Descriptions
9. Equipment Specification Sheets
10. Equipment Cost Summary
11. Fixed Capital Investment Summary
12. Analytical Approach, Product Safety, Efficacy and Biosimilarity
13. Manufacturing Safety
14. Manufacturing Site Selection
15. Economic and Environmental Sustainability Analysis
16. Conclusions and Recommendations
17. Acknowledgements
18. Bibliography
19. Appendix/Supplemental Materials

CHALLENGE RESPONSE FORMAT – VIDEO SUMMARY

Teams will also submit a short video which provides an oral summary of their solution to the Design Challenge. The focus of the video should be to convey the salient points of the challenge response.

- **The video itself must contain no reference to the students’ names or to the institutions at which they have conducted their graduate studies.**
- Final submissions of videos will be via upload to a secure Google Drive site; instructions for uploading to this will be forthcoming to the individual teams via email.
- Videos should be no more than 15 minutes in length. **Please use the first 30 -60 seconds to quickly describe something that the team members found that they all have in common.**

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Challenge Statement

Continuous Production of Lentivirus: