BIOT ESBES Graduate Student Design Challenge

2018

Challenge Overview and Rules

THE CHALLENGE

This design challenge involves the design of a commercial manufacturing facility for the production of cell therapy product containing human mesenchymal stem cells (MSCs) for the treatment of joint cartilage defects; including upstream, downstream and formulation and fill processing.

CHALLENGE RESPONSES

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 analytics;

(c) grasp and incorporation of the applicable regulatory science including compliance with FDA and EMA cGMP guideline, consideration of product safety and of manufacturing safety;

(d) creativity, ingenuity and logic employed, especially thinking outside manufacturing practice – a well-designed "platform" process will be considered a baseline response – we encourage innovation in selection of unit operations, processing mode, plant flexibility and incorporation of analytics

(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, minimal environmental impact and extent to which innovative scientific and technological innovations are incorporated.

The score will be based on a 100 point scale. A scoring rubric will be made available on April 2, 2018. There will be bonus points awarded, based on the schools in which each team member for a given team is currently enrolled for their graduate studies, to encourage and recognize diversity in the submitting teams. Two points will be awarded for each unique school represented by the team members, two additional points will be awarded for each unique country represented amongst the schools of the team members, and two additional points will be awarded for each unique continent represented amongst the schools of the team members. Thus, each team will receive between six and eighteen 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.

Practicing professionals, be they faculty, instructors, members of industry or governmental employees, cannot provide technical aid specifically directed at the solution of the graduate student design challenge.

The 2018 Graduate Student Design Challenge is designed to be solved by a group of three students working together. There are, however, other academically sound approaches to using the problem, and it is expected that some academics may use the problem as classroom material. The following confidentiality rules therefore apply:

1. ***For teams whose solutions may be considered for the contest:*** The challenge problem may not be discussed with anyone (students, faculty, or others, in or out of class) before or during the period allowed for solutions.

2. ***For students whose solutions are not intended for the contest:*** Discussion with faculty and with other students at that college or university who are not participating in the contest is of course permitted.

3. ***For all students:*** The problem may not be discussed with students or faculty from other colleges and universities, or with individuals in the same institution who are still working on the problem for the contest, until after September 15, 2018.

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 by April 1, 2018.
- Entries must be submitted by teams of no more than three students.
- Each student participating in the competition MUST BE A MEMBER OF BIOT OR ESBES BY THE TIME THHAT THE FINAL REPORT IS SUBMITTED (i.e. September 1, 2018).
- Each team member must be enrolled in a graduate program of study either full-time or part-time until at least April 1, 2018. Each team member will include with the submission of the team solution a letter from their graduate advisor, program head or department head confirming their graduate student status.
- At least one team member must be able to travel to the 2019 ACS Orlando, Florida Conference in the event that the team is selected as one of the top three teams.

CHALLENGE SOLUTION COMPLETION TIMELINE

- The challenge problem will be posted on April 2,, 2018. Submitted solutions are due by September 1, 2018 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 60-80 pages In length; an additional 100 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.

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.**