Dear Friends,

**Course Name**: Quality by Design (QbD) and Process Analytical Technology (PAT) for Biopharmaceuticals: Concepts and Applications in Development and Commercialization

We invite you to the special Professional Training on QbD. This **one-day training** course will be provided on October 24, 2018 at the UMass Lowell. Please mark your calendar and register. This course aims to clarify the key concepts that interplay in defining and implementing QbD and PAT towards development and manufacturing of biotech products. This will be achieved via a sequence of lectures and group work.

**Concepts discussed** include Critical Quality Attributes (CQA), Design Space, Risk Assessment, Process Characterization, Process Analytical Technology, Scale-Up and Technology Transfer. At the end of the course, the audience will be able to explain what these concepts mean, the role they play in QbD/PAT implementation and the interplay amongst them.

**Instructor** ([Biosketch](#)): Prof. Anurag S. Rathore, Department of Chemical Engineering, IIT

**Latest Publications** ([Link](#))

**Rationale**: Successful implementation of Quality by Design (QbD) and Process Analytical Technology (PAT) concepts requires that the concepts are put in place when the first activities around designing the product are initiated and then continue to be incorporated into the designing of the process that is used to make the product and other activities associated with the lifecycle of a pharmaceutical product. This course will allow the participants to better understand how their job responsibilities will evolve in the QbD/PAT paradigm, what is the big picture and the role they play in ensuring successful implementation of QbD/PAT.

**Target Audience**: Individuals that are involved in product and process development, regulatory, quality assurance and control and manufacturing of biotech therapeutics. Attendees from academia and regulatory agencies may also benefit depending on their areas of interest and level of experience.

**Objectives**: At the completion of this course the participant will be able to:
- Explain what the above mentioned concepts mean
- Define CQAs
- Explain the link between CQAs and Design Space
- Describe what would he/she need to do differently in their present job in the QbD paradigm
- Explain the role of PAT in QbD paradigm
- Discuss the challenges of implementing QbD
• Explain the role of Risk Assessment and where to go to find the appropriate tool
• Describe at a high level how QbD can be implemented for commercialization of biotech products

Course Outline
09.00-10.00: Introduction to QbD, CQA and TPP
10.00-11.00: QbD Case Studies for Upstream and Downstream Process Development
11.00-11.30: Break
11.30- 1.00: Introduction to Process Analytical Technology (PAT) and Case Studies
  1.00- 2.00: Lunch
2.00- 3.00: Introduction to Multivariate Data Analysis (MVDA) and Case Studies
  3.00- 3.30: Break
3.30- 5.00: Quality Risk Management (QRM) and Failure Modes and Effects Analysis (FMEA)
  5.00- 5.30: Discussion and Wrap-up

The registration for this training can be done at BSTC website (Link). For any question about the registration, please contact us at bpqc@uml.edu

With best regards,

Seongkyu Yoon, PhD/MBA
Associate Professor, Department of Chemical Engineering, UMass Lowell