**Introduction to Design of Experiments (DoE) for Bioprocess Analysis and Optimization**

**October 9–11, 2018**

**Course Fee: $1,650**

In this three-day course, you will learn how the fundamental principles of Design of Experiments (DoE) methods are applied to analysis and optimization of bioprocesses. DoE is critical to defining the design space for a process, which is central to the quality-by-design concepts presented in the ICH Guideline for Development and Manufacture of Drug Substances Q11. This course focuses on the application of DoE methods through the use of JMP statistical software, bioprocess case studies, and hands-on laboratory activities. The case studies, which focus on microbial fermentation and provide real data, look at the effects of factors such as medium components, induction temperature, and time on microbial growth and protein (product) production.

For additional information, please contact John Balchunas, BTEC’s Assistant Director of Professional Development Programs, at john_balchunas@ncsu.edu.

**Course schedule**

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<td>Lecture: Fractional factorial designs – Part I</td>
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<td>Lecture: DoE methodology and application to bioprocess characterization and optimization</td>
<td>Activity: A $2^{k-1}$ fractional factorial design</td>
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<td>Activity: Statistical concepts for DoE</td>
<td>Lecture: Fractional factorial designs – Part II</td>
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<td>Lecture: Statistical concepts for DoE</td>
<td>Activity: A $2^{k-1}$ fractional factorial design</td>
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<td>Activity: Introduction to factorial designs</td>
<td>BTEC facility tour</td>
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<td>Activity: A factorial design with JMP</td>
<td>Activity: Quality-by-design case study</td>
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<td>Lecture: Graphical representation of functions</td>
<td>Lecture: Blocking and confounding in factorial designs</td>
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<td>Lecture: Regression approach to factorials</td>
<td>Activity: a $2^k$ design in two blocks</td>
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<td>Lecture: More-than-two-factor factorial designs</td>
<td>Activity: Design and analysis of screening experiments</td>
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<td>Lecture: Response surface method</td>
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<td>Activity: Defining the design space for a bioprocess</td>
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<td>Lecture: Unreplicated factorial designs</td>
<td>Activity: Chromatography optimization</td>
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<td>Activity: Design and analysis of $2^k$ unreplicated factorial designs</td>
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**DELIVERY METHODS**

- **40% Lecture**
- **10% Discussion/group activity**
- **50% Hands-on laboratory experience**

**COURSE CONTENT**

- **80% Fundamentals and concepts**
- **20% Industry applications**
What short course participants say about this course

“I really got a lot out of this course. Marcello was great in that his material was well organized and thoughtful as far as the important topics to be covered in a 3-day course. He is a great teacher and a very likeable personality. He appeared to be genuinely interested in his students and their understanding of the course content. DOE is completely new to me, so I did have a bit of a difficult time keeping up, but with the external resources Marcello provided I know what I need to practice and I don’t feel intimidated anymore by the software and concepts…What a great opportunity!”

“I felt the instructor was very knowledgeable about the course information which was very important to me. He was able to gauge when the class didn’t quite grasp a concept and was able to immediately adjust the material to our needs.”

Important information for short course participants

Location
This course is held on site at BTEC. The Golden LEAF BTEC building is located at 850 Oval Drive on NC State University’s Centennial Campus.

Payment
BTEC accepts payment from all major credit cards including American Express, Visa, and MasterCard. If you wish to pay by company check, please email melody_woodyard@ncsu.edu for additional information immediately after registering.

Discounts available
A 20% discount is available to:
- Employees of NC BMF member companies
- Groups of five or more from one company registering for the same offering of this course
- Individuals registering for more than one course at a time
- Society of Industrial Microbiology and Biotechnology (SIMB) members
A 30% discount is available to faculty/staff working in academic environments.

Pre-course communication
Registered course participants will receive an email two weeks before the scheduled course with detailed information regarding travel to BTEC, parking information, and a short pre-course questionnaire.

About the instructor

Dr. Marcello Fidaleo is an assistant professor in the Department for Innovation in Biological, Agro-Food and Forest Systems at the University of Tuscia, Italy, where he teaches unit operations and design and analysis of experiments for the food industry. His research interests include membrane processes and enzymatic and microbial processes in the area of food biotechnology. He has carried out research as a visiting scholar at the Biotechnology Institute of the University of Minnesota and as a Fulbright scholar at the Department of Chemical and Biomolecular Engineering of North Carolina State University.

Dr. Fidaleo holds a master’s degree in chemical engineering from the Sapienza University of Rome and a doctorate in food biotechnology from the University of Tuscia.

Short course cancellations

CANCELLATION BY REGISTRANT
To cancel a registration and be eligible for a refund of course fees, you must notify BTEC by email. Fees are refunded according to the following schedule:
- 100% refund – If notification is received at least 15 business days in advance of course start date
- 75% refund – If notification is received 10–14 business days in advance of course start date
- 50% refund – If notification is received 6–9 business days in advance of course start date
- No refund will be issued if notice is received 5 or fewer business days in advance of course start date

Substitutions may be made up to 2 business days prior to the course start date.

CANCELLATION BY BTEC
BTEC retains the right to cancel a professional development short course no less than 10 business days in advance of the scheduled course start date. Registrants will be notified by BTEC if a course is cancelled and will receive a full refund of registration fees paid. BTEC is not responsible for airfare penalties or other costs incurred due to cancellation.