Cover Memo: REQUEST TO CHANGE THE REQUIREMENTS FOR BME 3261 Biomechanics and Biomaterials Lab

13th October, 2020

To Whom It May Concern:

The Biomedical Engineering Program of the BCES Department would like to change the requirements for the BME 3261 course.

We request to remove the existing prerequisite PHY 2091 and add a new prerequisite BME 3081. The final prerequisite string will be as follows BME 2081 and 3081 and BME 3260  Corequisite: BME 3081

*reason for change: because the BME 3081 class is currently only listed as a corequisite which makes it difficult for seniors to register for it. Removing PHY 2091 as a prerequisite gives students, especially transfer students, flexibility in their schedules and they will still be prepared for this class.

Thank you for your consideration.

Mehmet Kaya, Ph.D.
Assessment and Undergraduate Curriculum Coordinator
Biomedical Engineering Program
Florida Institute of Technology
Room 305, 150 W. University Blvd.
Melbourne, FL 32901
Phone: (321) 674 7147
email: mkaya@fit.edu
## REQUEST TO CHANGE THE REQUIREMENTS FOR A COURSE

Any change, addition or removal of any restriction, or change in credit hours or availability for a course requires this form, accompanied by any supporting documentation, be completed and approved as indicated below.

**COLLEGE: COES**  
**DEPARTMENT: BCES - Biomedical Engineering**

### REQUEST IS FOR CHANGE IN COURSE

<table>
<thead>
<tr>
<th>B</th>
<th>M</th>
<th>E</th>
<th>3</th>
<th>2</th>
<th>6</th>
<th>1</th>
<th><strong>Course Title</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Biomechanics and Biomaterials Lab</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Prefix**  
**Number**  
**Course Title**

### TO BE INCLUDED IN 20___/20____ CATALOG

Course changes are effective beginning with the fall term in which they appear in the University Catalog.

**IS REQUEST FOR A CHANGE IN THE NAME LISTED ABOVE?**  
☐ Yes  ■ No  
If yes, requested name ____________________________

**IS REQUEST FOR A CHANGE IN CREDITS FOR COURSE LISTED ABOVE?**  
☐ Yes  ■ No  
If yes, current credits ____________ requested credits ____________

**IS REQUEST TO CHANGE RESTRICTIONS FOR COURSE LISTED ABOVE?**  
☐ Yes  ■ No  
If yes, please check all that apply:

- Add  ☐ Remove  ■ Prerequisite  ☐ Corequisite  
  **BME 3081**  
  **Number**  
  **Corequisite**  
  **PHY 2091**  
  **Number**  
  **Other Restrictions**  
  ☐ Yes  ■ No  
  If yes, please use box below:

**Other restrictions may include changing the grade mode (P/F, S/U, A-F, CEU), deactivating a course already in the system, majors or class levels restricted from registration, or other restrictions.**

**Please enter the complete prerequisite/restriction list as it should appear if this change is approved:**

**Prerequisite:** BME 2081 and 3081 and BME 3260  
**Corequisite:** BME 3081

**reason for change:** because the BME 3081 class is currently only listed as a corequisite which makes it difficult for seniors to register for it. Removing PHY 2091 as a prerequisite gives students, especially transfer students, flexibility in their schedules and they will still be prepared for this class.

**☐ Yes  ■ No**  
**Is this request for the course to be used to measure program-level student learning outcomes?** If yes, review and signature is required

**☐ Yes  ■ No**  
**Is this request for the course to satisfy the scholarly inquiry requirement?** If yes, attach “Q” materials for review.

**☐ Yes  ■ No**  
**Will this change impact any existing programs?** If yes, attach “Changing Graduation Requirements” form for each program that is impacted.

### APPOVALS: Once appropriate department approvals are completed, submit to the Office of Graduate Programs, or Undergraduate Curriculum Committee Chair for placement on agenda.

1) **Date**  
**Or**  
**Chair, Graduate Council**  
**Date**

2) **Date**  
**Or**  
**Chair, Undergraduate Curriculum Committee**  
**Date**

3) **Date**  
**Or**  
**Chair, APAC**  
**Date**

### CATALOG & CURRICULUM MANAGER’S USE ONLY

**SCACRE**  
**SCADETL**  
**SCAPREQ**  
**SCABASE**  
**SCARRES**  
**ACATALOG**  
**Operator Initials**  
**Date**

---

**FLORIDA’S STEM UNIVERSITY**

Florida Institute of Technology • Office of the Registrar • 150 West University Boulevard, Melbourne, FL 32901-6975 • 321-674-8114 • Fax 321-674-7827

RGR-453-0220
Cover Memo: REQUEST TO CHANGE THE REQUIREMENTS FOR BME 4410 Introduction to Biomedical Imaging

13th October, 2020

To Whom It May Concern:

The Biomedical Engineering Program of the BCES Department would like to change the requirements for the BME 4410 course.

We request to remove the existing prerequisite MAR 3210 as well as BIO 3210 and add a new prerequisite BIO 3201. The final prerequisite string will be as follows: BIO 3201 and (MTH 2201 or MTH 3200) and PHY 2002.

*reason for change: because the BME curriculum has changed so students no longer take MAR 3210 or BIO 3210 but take BIO 3201 instead. The BIO 3201 has similar content but it is more directly related to the human body. Thank you for your consideration.

Mehmet Kaya, Ph.D.
Assessment and Undergraduate Curriculum Coordinator
Biomedical Engineering Program
Florida Institute of Technology
Room 305, 150 W. University Blvd.
Melbourne, FL 32901
Phone: (321) 674 7147
email: mkaya@fit.edu
REQUEST TO CHANGE THE REQUIREMENTS FOR A COURSE

Any change, addition or removal of any restriction, or change in credit hours or availability for a course requires this form, accompanied by any supporting documentation, be completed and approved as indicated below.

COLLEGE COES
DEPARTMENT BCES - Biomedical Engineering

REQUEST IS FOR CHANGE IN COURSE

Prefix Number Course Title
BME 4110 Tissue Engineering

TO BE INCLUDED IN 2021/2022 CATALOG

Course changes are effective beginning with the fall term in which they appear in the University Catalog.

IS REQUEST FOR A CHANGE IN THE NAME LISTED ABOVE? ☐ Yes ☐ No
If yes, requested name ____________________________

IS REQUEST FOR A CHANGE IN CREDITS FOR COURSE LISTED ABOVE? ☐ Yes ☐ No
If yes, current credits ____________________________ requested credits ____________________________

IS REQUEST TO CHANGE RESTRICTIONS FOR COURSE LISTED ABOVE? ☐ Yes ☐ No
If yes, please check all that apply:
☐ Add ☐ Remove ☐ Prerequisite ☐ Corequisite ☐ and ☐ or
☐ Add ☐ Remove ☐ Prerequisite ☐ Corequisite ☐ and ☐ or
☐ Add ☐ Remove ☐ Other Restrictions* ☐ Yes ☐ No
If yes, please use box below:

*Other restrictions may include changing the grade mode (P/F, S/U, A-F, CEU), deactivating a course already in the system, majors or class levels restricted from registration, or other restrictions.

Please enter the complete prerequisite/restriction list as it should appear if this change is approved:

Reason for change: because the BME curriculum has changed so students no longer take MAR 3210 but take BIO 3201 instead. The BIO 3201 has similar content but it is more directly related to the human body.

☐ Yes ☐ No Is this request for the course to be used to measure program-level student learning outcomes? If yes, review and signature is required*

☐ Yes ☐ No Is this request for the course to satisfy the scholarly inquiry requirement? If yes, attach "Q" materials for review.

☐ Yes ☐ No Will this change impact any existing programs? If yes, attach "Changing Graduation Requirements" form for each program that is impacted.

APPROVALS: Once appropriate department approvals are completed, submit to the Office of Graduate Programs, or Undergraduate Curriculum Committee Chair for placement on agenda.

1) 321-674-8114

2) 321-674-8114

3) 321-674-8114

4) 321-674-8114

5) 321-674-8114

Chair, Graduate Council
Date

OR

Chair, Undergraduate Curriculum Committee
Date

*CAGERT, APAC

Date

CATALOG & CURRICULUM MANAGER'S USE ONLY

SCACRSE_________________ SCADETL_________________ SCAPREQ_________________
SCABASE_________________ SCARRLES_________________ ACALOG_________________
Operator Initials_________________ Date_________________

FLORIDA'S STEM UNIVERSITY
Florida Institute of Technology • Office of the Registrar • 150 West University Boulevard, Melbourne, FL 32901-6975 • 321-674-8114 • Fax 321-674-7827
Cover Memo: REQUEST TO ADD A NEW COURSE: BME 4150 FDA Medical Device Curriculum

13th October, 2020

To Whom It May Concern:

The Biomedical Engineering Program of the BCES Department would like to add a new course: BME 4150 FDA Medical Device Curriculum.

Further, we request to add a prerequisite BME 3260 (Biomaterials). The final prerequisite string will be as follows: BME 3260.

*reason for request: This course has been taught as a Special Topics in BME course: BME 4050: FDA Medical Device Curriculum. This course has been well received and students have shown great interest in it and we would like to change it to a regular BME course.

Further, the course does not have a prescribed textbook, since it deals with the constantly evolving FDA policies and protocols. Thus, we are using material directly from the FDA website as the reference and reading material for this course so as to be up to date with the most current standards.

Venkat Keshav Chivukula, Ph.D.
Undergraduate Curriculum Coordinator
Biomedical Engineering Program
Florida Institute of Technology
Room 356 LINK, 150 W. University Blvd.
Melbourne, FL 32901
Phone: 321-674-7311
email: vchivukula@fit.edu
ADDIMG A NEW COURSE TO THE CURRICULUM

New courses are available beginning with the fall term in which they appear in the University Catalog.

COURSE NO. 4 1 5 0 CREDIT HOURS 3 ACADEMIC YEAR TO BE ADDED TO THE FILE Fall 2021

CLASS HOURS 45/sem LECTURE HOURS 45/sem LAB HOURS 0/sem RESEARCH HOURS 0/sem CONTACT HOURS (CEU) N/A

DEPARTMENT Biomedical & Chemical Engineering and Sciences

SCHEDULE TYPE Lecture (A)

COMPUTER TITLE FDA MED DEVICE CURRICULUM

CATALOG NO. BME 35260

CATALOG DESCRIPTION OF COURSE Restricted to 25 students, including spaces

This course will be entered into the system as: Bi-Level [ ] Cross-Listed [ ] Dual-Numbered [ ] Full-Load [ ] None of these/Standard Listing [ ]

In addition, please attach a course syllabus and/or more detailed description.

RESTRICTIONS [ ] Prerequisite ONLY [ ] Corequisite ONLY [ ] BOTH Prerequisite/Corequisite and [ ] or

GRADES TO BE ISSUED

A, B, C, D, F

A, B, C, D, F, CEU/Audit

CEU

S, U

P, F

Other

Please indicate old course information and the date/term the course may be removed from the system:

[ ] Yes [ ] No Will this course be used to measure program-level student learning outcomes? If yes, review and signature required.**

[ ] Yes [ ] No Will this course be used to satisfy the scholarly inquiry requirement? If yes, attach "Q" materials for review.

[ ] Yes [ ] No Will this course impact any existing programs? If yes, attach "Changing Graduation Requirements" form for each program impacted.

[ ] Yes [ ] No Will this course be used to satisfy the Cross Cultural (CC) requirement? If yes, attach confirmation memo from QEP Committee.

APPROVALS: On completion of description and course number verification, affix appropriate signatures as indicated, and submit to the Office of Graduate Programs, or Undergraduate Curriculum Committee Chair for placement on agenda.

Mehmet Kaya

Christopher Bashur

Director, APAC

FLORIDA'S STEM UNIVERSITY

Florida Institute of Technology • Office of the Registrar • 150 West University Boulevard, Melbourne, FL 32901-6975 • 321-674-8114 • Fax 321-674-7827

RGR-452-0200
BME 4150 FDA MEDICAL DEVICE CURRICULUM
Fall 2021

2021-22 Catalog Data: This course is a survey of regulatory science in medical device industry. It covers regulations covering product development process; marketing approval process; manufacturing controls and post market activities; and regulatory compliance. Commercialization will also be discussed.

Credits & Contact Hours: 3 Credits, 15 Lectures (2 hours 45 minute/lecture)

Required or Elective or Selected Elective: Elective

Prerequisites and Co-requisites courses: BME 3260

Co-requisites by Topic: None

Textbook (T) and References (R) Required: None

Recommended Reading:
Class handouts

Reference materials:

I. FDA Center for Device and Radiological Health
   https://www.fda.gov/training-and-continuing-education/cdrh-learn

II. Reference standards and guidance documents discussed in the case studies in the class.

Instructor:
Alex Chaharom; Office: Link 340; Phone: 617-755-5708, email: echaharom@fit.edu

Course Outcomes: Upon completion of this course the student will be able to:
1. Understand fundamental concepts of medical device law and regulatory process
2. Demonstrate an understanding of regulatory pathways on approving different classes of medical devices
3. Understand application of risk based regulatory approval process to medical devices.
4. Demonstrate regulatory assessment for new technologies and devices through available databases and guidance documents provided by FDA.
5. Understand implementation of phase approach product development and commercialization.

Topics Covered

1. Fundamental concepts of premarket regulatory activities in the United States. (2 lectures)
2. Identification of available regulatory pathways for medical devices. (2 lectures)
3. Identification of fundamental concepts of safety assurance for medical devices. (2 lectures)
4. Introduction to the medical device First in Human (FIH) Investigational Device Exemption (IDE) Application. (1 lectures)
5. Introduction to the medical device Pre-market Approval (PMA) and the steps to obtain a PMA and its data requirement. (2 lectures)
6. Examination of the general principles of nonclinical and clinical investigations. (2 lectures)
7. Understanding of the “substantial equivalence” decision-making process for a 510(k) submission. (1 lectures)
8. Review of the key business and commercialization processes. (1 lectures)

**Grading Policy**
Homework (10%), Midterm x2 (30%), Final Exam (40%), Class Project – (20%)

**Grading System**
A = 90-100   B = 80-89   C = 70-79   D= 60-69   F= 0-59

**Assessment matrix for BME 4150**

<table>
<thead>
<tr>
<th>Course Outcome</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>♦</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>♦</td>
<td></td>
<td>♦</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>♦</td>
<td>♦</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>♦</td>
<td>♦</td>
<td>♦</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>♦</td>
<td>♦</td>
<td>♦</td>
<td>♦</td>
<td>♦</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Key**

- ♦ = The course objective *strongly* addresses the Program Outcome
- ◊ = The course objective *lightly* addresses the Program Outcome

**Student Outcome Descriptions**

1. An ability to identify, formulate, and solve complex engineering problems by applying principles of engineering, science, and mathematics.

2. An ability to apply engineering design to produce solutions that meet specified needs with consideration of public health, safety, and welfare, as well as global, cultural, social, environmental, and economic factors.

3. An ability to communicate effectively with a range of audiences.

4. An ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts.

5. An ability to function effectively on a team whose members together provide leadership, create a collaborative and inclusive environment, establish goals, plan tasks, and meet objectives.

6. An ability to develop and conduct appropriate experimentation, analyze and interpret data, and use engineering judgment to draw conclusions.

7. An ability to acquire and apply new knowledge as needed, using appropriate learning strategies.

---

**Prepared By:** Alex Chaharom, Adjunct Faculty, Biomedical Engineering Department

**Modified by:** Venkat Keshav Chivukula, PhD, Assistant Professor, Biomedical Engineering Department

10/7/2020
**Cover Memo:** REQUEST TO CHANGE THE REQUIREMENTS FOR BME 4410 Introduction to Biomedical Imaging

To Whom It May Concern:

The Biomedical Engineering Program of the BCES Department would like to change the requirements for the BME 4410 course.

We request to remove the existing prerequisite MAR 3210 as well as BIO 3210 and add a new prerequisite BIO 3201. The final prerequisite string will be as follows: BIO 3201 and (MTH 2201 or MTH 3200) and PHY 2002.

*reason for change: because the BME curriculum has changed so students no longer take MAR 3210 or BIO 3210 but take BIO 3201 instead. The BIO 3201 has similar content but it is more directly related to the human body. Thank you for your consideration.*

Mehmet Kaya, Ph.D.

Assessment and Undergraduate Curriculum Coordinator
Biomedical Engineering Program
Florida Institute of Technology
Room 305, 150 W. University Blvd.
Melbourne, FL 32901
Phone: (321) 674 7147
e-mail: mkaya@fit.edu
REQUEST TO CHANGE THE REQUIREMENTS FOR A COURSE

Any change, addition or removal of any restriction, or change in credit hours or availability for a course requires this form, accompanied by any supporting documentation, be completed and approved as indicated below.

COLLEGE: COES
DEPARTMENT: BCES - Biomedical Engineering

REQUEST IS FOR CHANGE IN COURSE: BME 4410
TO BE INCLUDED IN 2021/2022 CATALOG

Course changes are effective beginning with the fall term in which they appear in the University Catalog.

IS REQUEST FOR A CHANGE IN THE NAME LISTED ABOVE?  □ Yes  ■ No  If yes, requested name ________________________

IS REQUEST FOR A CHANGE IN CREDITS FOR COURSE LISTED ABOVE?  □ Yes  ■ No  If yes, current credits __________, requested credits __________

IS REQUEST TO CHANGE RESTRICTIONS FOR COURSE LISTED ABOVE?  □ Yes  ■ No  If yes, please check all that apply:

☐ Add   ☐ Remove   ☐ Prerequisite   ☐ Corequisite   BIO 3201 and or

☐ Add   ☐ Remove   ☐ Prerequisite   ☐ Corequisite   MAR 3210 and or

☐ Add   ☐ Remove   ☐ Other Restrictions*  ■ Yes  ■ No  If yes, please use box below:

*Other restrictions may include changing the grade mode (P/F, S/U, A-F, CEU), deactivating a course already in the system, majors or class levels restricted from registration, or other restrictions.

Please enter the complete prerequisite/restriction list as it should appear if this change is approved:

*Remove BIO 3210
The final prerequisite string:
Prerequisite: (MTH 2201 or MTH 3200) and PHY 2002 and BIO 3210

*Reason for change: because the BME curriculum has changed so students no longer take MAR 3210 or BIO 3210 but take BIO 3201 instead. The BIO 3201 has similar content but it is more directly related to the human body.

☐ Yes  ■ No  Is this request for the course to be used to measure program-level student learning outcomes? If yes, review and signature is required*

☐ Yes  ■ No  Is this request for the course to satisfy the scholarly inquiry requirement? If yes, attach "Q" materials for review.

☐ Yes  ■ No  Will this change impact any existing programs? If yes, attach "Changing Graduation Requirements" form for each program that is impacted.

APPROVALS: Once appropriate department approvals are completed, submit to the Office of Graduate Programs,
or Undergraduate Curriculum Committee Chair for placement on agenda.

1) Mehmet Kayali
   Originator
   11/16/2020

2) Christopher Bashur
   Department Head/Program Chair
   5/8/2020

3) Dean or Associate Dean
   11/16/2020

4) *Director, APAC
   Date

5) Chair, Graduate Council
   Date
   OR

   Chair, Undergraduate Curriculum Committee
   Date

CATALOG & CURRICULUM MANAGER'S USE ONLY

SCOURSE: SCADE11L  SCAPREQ:
SCBASE: SCARRES  ACALOG: Operator Initials: Date

FLORIDA'S STEM UNIVERSITY
Florida Institute of Technology • Office of the Registrar • 150 West University Boulevard, Melbourne, FL 32901-6975 • 321-674-8114 • Fax 321-674-7827

RGR-453-0220