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Chair of the Assembly of the Academic Senate
Faculty Representative to the Regents
University of California
1111 Franklin Street, 12th Floor
Oakland, California 94607-5200

May 28, 2024

**KATHERINE S. NEWMAN
PROVOST AND EXECUTIVE VICE PRESIDENT
UNIVERSITY OF CALIFORNIA**

Re: Approval of Master of Engineering in Medical Device Development at UCD

Dear Katherine:

In accordance with the *Universitywide Review Processes For Academic Programs, Units, and Research Units* (the “Compendium”), and on the recommendation of CCGA, the Academic Council has approved UC Davis’s proposal to establish a Master of Engineering in Medical Device Development self-supporting graduate and professional degree program.

Because this is a new degree title, and the Assembly of the Academic Senate is not meeting within 30 days of CCGA’s approval, Council must approve the program per Senate Bylaw 125.B.7.

I am enclosing CCGA’s report on its review of the new program, and respectfully request that your office complete the process of obtaining the President’s approval.

Sincerely,

James Steintrager, Chair
Academic Council

Cc: Academic Council
Institutional Research and Academic Planning Analyst Procello
UCD Senate Executive Director Arevalo
Executive Director Lin

**COORDINATING COMMITTEE ON GRADUATE AFFAIRS (CCGA)**

Dean J. Tantillo, Chair
deanjtantillo@ucdavis.edu

ACADEMIC SENATE

University of California
1111 Franklin Street, 12th Floor
Oakland, California 94607-5200

April 23, 2024

ACADEMIC SENATE CHAIR JAMES STEINTRAGER

Dear Chair Steintrager,

On April 3, CCGA met and reviewed the proposal from the Davis campus for a self-supporting Master of Engineering in Medical Device Development. Via email vote later that month, the proposal was approved 8-0-1.

This proposal is a resubmission of a proposal originally sent to CCGA in early 2023. At that time, the proposal was returned to the campus for revision. The new proposal was submitted in fall of 2023 after considerable work and consultation. The new proposal, which addressed previous concerns point-by-point, was then reviewed by CCGA and UCPB.

The Master of Engineering Program (M.Eng.) in Medical Device Development is designed to provide rigorous and practical industry-focused training in the development and commercialization of medical devices. This will be accomplished by developing skills in four areas that are essential for the effective translation of concepts to devices in the private sector but are not normally covered in any depth in an undergraduate engineering or physical sciences curriculum. Skills in these areas are normally accrued slowly by an individual while working in the private sector in a relatively inefficient manner that is highly dependent on the position and project. This program seeks to “jumpstart” an individual’s career by providing these skills in a nine-month program.

The key objectives of the program are to:

- 1) Catalyze the translation of research at UC Davis into medical solutions that will impact patient care.
- 2) Provide a rigorous and experiential training program to create a highly skilled and sought-after Master’s level workforce pertinent to the medical device industry.
- 3) Connect the Department of Biomedical Engineering more closely with the School of Medicine, the Graduate School of Management, and the local industry to provide medical industry-related experience.
- 4) Leverage resources to create a mechanism and pipeline for innovation, commercialization, and job creation.
- 5) Establish a local, national, and global reputation of innovation, translation, and excellence.

In addition, the M. Eng. program will develop a well-trained work force in the Sacramento and Bay Area regions and will stimulate the creation of new companies, leading to more high paying jobs in the area.

The initial assessment of the external reviews was a general agreement with the rationale and learning objectives of the program. Reviewers emphasized the thoughtful design, rigor, distinctiveness, and outline potential advantages of the curriculum's 'lockstep' design. Consensus was that there will be a demand for the program and likely career opportunities for its graduates. However, the initial review also noted three concerns and two weaknesses that were addressed thoroughly by the campus. (These are detailed in the Lead Reviewer's report, attached.) The UCPB reviewer report is also attached.

As you know, CCGA's approval is the last stop of the Academic Senate side of the systemwide review and approval process except when the new degree title must be approved by the Academic Council. I submit this for your review; please do not hesitate to contact me if you have questions regarding the proposal.

Sincerely,

A handwritten signature in green ink, appearing to read 'J. Tantillo', with a stylized flourish at the end.

Dean J. Tantillo
Chair, CCGA

c: Steven Cheung, Academic Senate Vice Chair
Monica Lin, Academic Senate Executive Director
Michael LaBriola, Academic Senate Assistant Director
CCGA Members
Chris Procello, Academic Planning and Research Analyst
Jean-Pierre Delplanque, UCD Dean of the Graduate Division
Edwin M. Arevalo, UCD Academic Senate Executive Director
Kelly Adams, UCD Academic Senate Associate Director



April 10, 2024

To: Coordinating Committee on Graduate Affairs
From: Tonya Williams Bradford, Lead Reviewer (UCI GC Chair)
Re: Revised Proposal for New Graduate Program – Master of Engineering (M. Eng.) in Mechanical Device Development

Summary

The Coordinating Committee on Graduate Affairs (CCGA) recommends that UC Davis (UCD) proposers of the new Master of Engineering (M. Eng.) in Mechanical Device Development be approved.

Background

The new degree is a three-quarter SSGPDP Master's program with a capstone project. CCGA received the initial proposal in February 2023. Four (4) reviews were solicited and two were provided. CCGA discussed the initial proposal during the April 5, 2023 and May 3, 2023 meetings. CCGA invited UCD to submit a revised proposal in the May 17, 2023 communication noting that the proposal provided promise even as there were concerns to address.

Materials and Reviews

The initial review by CCGA included the following documents:

1. Proposal, November 24, 2021, with appendices
2. UCD's Graduate Council review and vote
3. Letters from two (2) external reviewers [four reviewers were sought]
 - a. UC San Diego
 - b. Mayo Clinic College
4. Review by Committee on Planning and Budget

For the revision, the following materials were consulted:

1. CCGA transmittal memo and Review of Program Proposal outlining three concerns and two weaknesses dated May 17, 2023
2. Summary response memo from UCD Academic Planning and Development response dated August 15, 2023
3. UCD Revised Proposal for the Master of Engineering in Medical Device Development [redlined] dated August 15, 2023
4. UCD Revised Proposal for the Master of Engineering in Medical Device Development dated November 21, 2023
5. UCPB Memo dated April 9, 2024

From the initial assessment of the external reviews summarized in the initial CCGA review: "All reviewers stated a general agreement with the rationale and learning objectives of the program. Reviewers emphasize the thoughtful design, rigor, distinctiveness, and outline potential advantages of the curriculum's 'lockstep' design. Consensus is that there will be a demand for the program and likely career opportunities for its graduates. Reviewers agree that hiring lecturers to administer the core program is a viable option, besides the size and demonstrated expertise of faculty teaching elective classes. Involving

‘real-world experts’ as ‘qualified adjunct instructors’ and clinical participation are welcomed. Starting a rigorously and clearly evaluated capstone project in the first quarter is considered a distinguishing factor of this program.”

Additional Considerations

The CCGA review noted three concerns and two weaknesses for the program to address in its revision to the proposal. For each query, the program has provided a response—those are summarized in the following table:

<i>CCGA Specified Concern or Weakness</i>	<i>CCGA Request for Response</i>	<i>UCD Response</i>
Financial Aspects (concern)	Additional financial detail for UCPB	Provided an updated budget with a review by Budget and Institutional Analysis which assessed the program as “financially sound and low-risk to the unit and campus.”
Program Distinction (concern)	Distinctiveness relative to other UC programs	Review of 30 programs with a focus on those in California; key point of difference is in required business and management courses which aligns to job advertisements.
Demonstrated Need and Benefit (concern)	Caters to niche market—provide quantitative support for need	Continuing Education completed a market analysis (June 2023) and the College of Engineering conducted a survey of engineering graduating seniors (June 2023). Provide quantitative and qualitative support for program need.
Hiring Lecturers and Administrators (weakness)	Assess impact of this approach on financial viability	The professional nature of the program and intention to not have ladder faculty teaching overload lead to hiring of adjunct faculty. Budget includes funding to support.
Program Flexibility and Length (weakness)	Consider the single elective and its timing	Comparable programs have same length (Berkeley, University of Washington, Northwestern). Elective is not required for capstone and is placed to allow the completion of required sequences of courses.

In summary, the external letters provided significant support for the academic soundness and need for this SSGPDP. The program concerns and weaknesses presented by CCGA reflect a mix of financial and academic requests for clarification and substantiation. Regarding the financial concerns, UCPB recognizes a robust revenue stream though has concerns about return to aid. UCPB unanimously voted to approve the proposal. With respect to the academic aspects of the aforementioned concerns and weaknesses, UCD has provided robust and thoughtful responses.

CCGA Recommendation

The initial request for additional information did not consider the diversity of the proposed program. However, it is important to note that there is mention of monitoring recruitment of diverse cohorts. Beyond monitoring, it is imperative that the Program leadership proactively engage with engineering associations that support underrepresented minorities (e.g., NSBE, SHPE) to introduce, attract, and recruit diverse candidates to this Program.

The UCD responses to the inquiries made in the May 17, 2023 CCGA memo, the 2024 input from UCPB, along with the initial external reviews result in our assessment that this program be approved.



UNIVERSITY COMMITTEE ON PLANNING AND BUDGET (UCPB)
Donald Senear, Chair
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April 9, 2024

**DEAN TANTILLO, CHAIR,
COORDINATING COMMITTEE ON GRADUATE AFFAIRS**

RE: UC DAVIS MASTER OF ENGINEERING IN MEDICAL DEVICE DEVELOPMENT

Dear Dean,

UCPB has reviewed the revised proposal for the UC Davis Master of Engineering in Medical Device Development. In its review of the original proposal last year, the committee noted concerns with the budget provided, possible impact on campus resources, and the presumed value of the program to prospective students.

This one-year program offers thirty-six units of instruction, that combines 11 courses taken in lockstep, with an experiential, clinically directed capstone project, plus a 12th course selected from the department's state-supported electives. The program has now added admissions requirements to ensure that all enrollees have the background to benefit from the program. UCPB questioned a claim in the original that nine months of such instruction substitutes for five to seven years of industry experience. The proposal clarifies that this refers to anticipated potential earnings, rather than to design or development experience.

The budget has been revised to account for increased revenue from higher tuition, and includes more detail on costs, such as adding line items for equipment purchases. The tuition proposed has been raised from \$42,500 to \$49,700 with three percent annual increases, in line with advice offered by several of the reviews. This is comparable to the other UC biomedical engineering master's programs at UCSF/Berkeley, UC Irvine, and UC San Diego. Notably, these other UC programs are at capacity, suggesting a likelihood that this more specialized program will find sufficient demand to meet its projected enrollment. UCPB continues to express some concern that the educational value provided through one year of coursework and a capstone course might be exceeded by the cost of the program. However, it acknowledges an updated market analysis in the revised proposal suggesting that students will be able to earn enough to recover their cost in one and a half years of employment after completing the program, and notes that other reviewers of the proposal were quite enthusiastic.

The hiring plan suggests four teaching assistants and four part-time lecturers, who will be practitioners in the field. The proposal stresses that existing ladder-rank faculty will not serve as

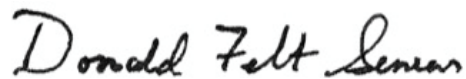
fallback for teaching, although they will provide program oversight and course development. Some staff time is budgeted as well.

One issue UCPB continues to feel strongly about is the minimal commitment to financial aid. The program continues to commit only five percent of program fees to financial aid, beyond which it aspires to private donations to support scholarships and directs students to low-cost government loans. As noted in our previous review, this is a much lower commitment to aid than UCBP finds in other proposals. With the higher tuition and given the projected surplus by year four, the program should be able to provide more generous financial aid to enable it to support a more robust recruitment and retention plan for URM students.

In addition, while the program is projected to return sufficient net revenue to the department to reimburse its startup and course development costs, the budget does not explicitly account for these. It also does not include an assessment for enrollment of program students in the department's state-supported elective courses. Given the revenue projections, these oversights were not considered serious enough to delay a program that UCPB finds interesting and desirable. However, UCPB does recommend that the repayment of startup costs, reimbursement for the cost of state-supported instruction and sufficiency of financial aid be assessed carefully in the three-year program review.

UCPB voted unanimously to approve this program proposal.

Sincerely,

A handwritten signature in cursive script that reads "Donald Felt Senear".

Donald Senear, Chair

cc: UCPB

Master of Engineering (M.Eng) in Medical Device Development program, Department of Biomedical Engineering, UC Davis College of Engineering

Terry Gaasterland, UC San Diego (prior lead reviewer, Jill Hollenback, UCSF)

The program will develop a well-trained workforce for the biomedical device and pharmaceutical industry for the Sacramento and Bay area leading to more jobs in the region, as well as workforce for California and nationally. This capable workforce will benefit startup companies in the medical device arena.

Originally returned by CCGA in May 2023 for revision based on UCBP's determination that the budget provided was not clear.

130 page proposal. Previous version May 2023, revised original 90-page proposal from January 4, 2021.

Composition of the program: 3-quarter (one academic year) Master's II plan with a capstone project.

36 units of instruction with 12 courses and a capstone project. Emphasis is placed on product development, commercialization, financing, and leadership skills.

The capstone project focus will be on product development, clinically directed training in device design, prototype construction, and commercialization in collaboration with clinicians.

The expectation is that the 9-month program will be equal to 5-7 years of industry experience.

Students will start in the Fall, enroll in 4 courses per quarter, with normative time-to-degree of 3 academic quarters with no maximum.

Required Courses:

3 in Product Development and Manufacturing

3 in Business Management and Leadership

2 in Engineering Skills

2 capstone courses

1 introduction to clinical operations

Electives:

Focus on Biostatistics offered in the proposing Department

1 elective required; 15 elective courses available.

Location:

Aggie Square campus in Sacramento

Strengths:

Strong rationale and learning objectives.

The curriculum works in "lockstep" with courses building upon each other.

There is a demand for the capable workforce that the program will produce.

Intention is to hire lecturers to deliver the required courses, with "real world experts" as qualified adjunct instructors and providers of opportunities for clinical participation.

Similar programs at UCSF/UCB, UCI, UCSD (referred to in the proposal) are at capacity.

Weaknesses:

budget?

Niche market - need was not demonstrated?

Although hiring lecturers to teach required courses may be viable, it will need to be financially sustainable.

Tuition:

\$49,700 (\$1380/credit) Lower than tuition at UCB/UCSF and UCI; these other programs are \$54,129 and \$48,050 respectively.

3% increase in year 2 and again in year 3.

Enrollment:

20 students, expected to be self-sustaining.

Investment:

\$200,000 from Dept of Biomedical Engineering

IDC = 16.3% = campus-specific IDC rate for off-campus programs set by UCOP. The on-campus rate is 32.6%.

Budget includes \$50,000 per year to lease space at the Aggie Square facility in Sacramento.

Is equipment budget sufficient? For students to do hands-on engineering work, there will need to be a lab manager, a small machine shop, 3D printing space, access to electronic tools and equipment, and appropriate software with licenses for academic seats.

Strengthened Market Analysis.

survey of current engineering undergrads.

updated market analysis performed by Continuing and Professional Education at UC Davis (Appendix I), including return on investment for students.

BME jobs with M.Eng earn \$100-110K starting salary; compared with \$65-70K for B.Eng.

Increase is \$35K, with recoup of investment after 1.5 years.

Added reviews from College of Engineering and the Graduate School of Management at UC Davis. They endorsed the program.

Revised Budget:

added equipment, increased tuition revenue, new Budget Justification.
Startup is not required to be repaid.

Program Distinction:

lower cost of attendance.
integration of business and management courses in the M.Eng curriculum.
completion in 9 months is possible.

Market Analysis of BME jobs shows \$96,100 average salary for Masters level; Bachelors level jobs reach that level at 5-7 years of experience.

If courses will be taught by ladder rank faculty, the teaching will be considered overload and they would be compensated. They are not a realistic fall-back plan.

Since this is a professional program, the core curriculum is best taught by practitioners and industry experts as instructors.

BUDGET JUSTIFICATION:

STUDENTS

Year 1 15 students

+5 per year after that:

years 2,3,4,5,6 = 20 25 30 35 40

Year 6 = steady state.

FEES

\$49,700 tuition in Fall 2025

REVENUES (without 3% increase)

Year 1 745,500

Year 2 994,000

Year 3 1.25 million

Year 4 1.50 million

Year 5 1.75 million

Year 6 2.00 million

EXPENSES

4x 25% TA per quarter (one per class)

4x part-time lecturer per quarter (each to teach 3 courses, one per quarter, three per year) to meet
12 course teaching load of the program = \$40K each = \$160,000

25% COO of Dept of BME
10% financial analyst
10% admin

\$30,000 equipment for 3 teams of 5 students in Year 1 = \$10,000 per team (not \$13,000 as listed in their BJ).

Equipment will be \$13,000 per year per 5 students. At steady state, 40 students = \$104,000.
TEAM lab will be \$3000 per team of 5 students per year. At steady state, \$24,000

5% reinvested in Financial Aid.

Detailed budget on Page 76 of the PDF. Balances.

Cost per student by year 4 \$32,534

COMMENTS:

Elective course requirement is state-supported. Payment would be required.

5% return to aid is low. We would like to see at least 10%. The net surplus for the program in Year 4 will approach \$500,000, so 10% return to aid by year 4 should be feasible.