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Bridging the Gap between biomedical engineering education and medical device industry practice: A curriculum and skills analysis

Abimbola Ayoola *

Department of Biomedical Engineering, University of Bridgeport, Bridgeport. CT, USA.

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Abstract

The medical device industry operates within a highly regulated, risk-sensitive, and innovation-driven environment. Engineers entering this sector must possess not only technical design skills but also competence in regulatory pathways, quality systems, risk management, clinical evaluation, and cross-functional collaboration. However, biomedical engineering (BME) curricula traditionally prioritize analytical and technical rigor over translational and regulatory preparedness. Bridging this gap requires deliberate curriculum reform and structured academia industry collaboration

Keywords: Biomedical; Engineering; Curriculum; Technical; Medical device; Industry

1. Introduction

Bioengineering and Biomedical engineering programs play a critical role in preparing graduates for careers in the rapidly evolving medical device and healthcare technology sectors [8,9]. Universities aim to equip students with rigorous training in engineering, biological sciences, and medicine, while simultaneously fostering innovation, ethical responsibility, and professional accountability [10]. This multidisciplinary educational approach is designed to develop graduates who can address complex healthcare challenges, contribute to technological advancement, and uphold the moral obligations associated with designing and deploying medical technologies that directly impact patient safety and clinical outcomes[11]. Despite these efforts, a persistent gap remains between academic preparation and the practical requirements of the medical device industry, highlighting the need for curriculum designs that integrate experiential learning and industry exposure.

As demand for biomedical engineers continues to rise, the need for educational frameworks that blend robust theoretical instruction with practical, industry-focused expertise is becoming increasingly important. Although biomedical engineering programs offer comprehensive academic preparation, there remains an ongoing disparity between classroom education and the actual requirements of the healthcare and medical device sectors[9].

This gap may hinder graduates' ability to transition smoothly into the workforce, where practical experience, regulatory knowledge, quality management systems, industry-standard engineering practices, and cross-functional teamwork are essential [10]. Addressing this gap by incorporating industry-informed experiences such as experiential learning, regulatory exposure, and industry partnerships into biomedical engineering education is essential to better prepare students for professional practice and to meet the evolving needs of the healthcare sector [10]. Biomedical engineering graduates are frequently criticized by employers for lacking job-relevant technical skills, regulatory knowledge, and hands-on industry experience necessary to perform effectively upon entry into the workforce[8]. The disparity between academic training and industry requirements may adversely affect innovation timelines, drive up employer expenses for training and onboarding, lead to delays in manufacturing, raise quality-related costs, and, in critical circumstances,

* Corresponding author: Abimbola Ayoola

jeopardize patient safety [9,11]. These challenges highlight a persistent disconnect between university-based biomedical and bioengineering education and the practical realities of the medical device industry. This paper examines the critical gaps that exist between academic training and industry practice, explores the underlying causes of these gaps, and proposes actionable strategies to better align biomedical engineering education with the evolving requirements of the medical device sector.

2. Overview of Biomedical and Bioengineering Engineering

Biomedical Engineering (BME) originated as a training program in the 1950s, making it a relatively recent addition compared to other engineering disciplines.[13] The field developed from foundational departments such as mechanical and electrical engineering, where faculty members expressed interest in addressing biological and medical and engineering challenges[14].

In 1974, the National Academy of Engineering identified a technological gap between the fields of engineering and medicine. The inherently interdisciplinary nature of biomedical engineering presents challenges for students seeking comprehensive knowledge across all pertinent disciplines. This gap may result in insufficient understanding and limited collaboration between healthcare and engineering professionals, which can impede the development and implementation of effective biomedical solutions and restrict the capacity of biomedical engineering to address significant health concerns[15].

According to the Biomedical Engineering Society (BMES), biomedical engineering (BME) is defined as "the bridge between medical and engineering disciplines that facilitates comprehensive improvements in healthcare."[12]

Biomedical engineering fundamentally entails comprehending living systems and applying engineering principles and innovation to improve processes, systems, devices, and research that contribute to the advancement of health systems universally [15].

Biomedical and bioengineering is a multidisciplinary area combining engineering, biology, and medicine to enhance healthcare, boost human health, and expand our understanding of biological systems. It brings together expertise from mechanical, electrical, chemical, and materials engineering along with life sciences and clinical know-how, tackling intricate medical issues by developing new technologies, diagnostics, and treatments[16].

Education and training in biomedical and bioengineering emphasize interdisciplinary problem-solving, ethical responsibility, and translational impact. Academic programs commonly integrate engineering fundamentals with biological sciences preparing graduates to collaborate across disciplines[18].

As global health challenges continue to evolve, biomedical and bioengineering plays a vital role in addressing issues such as aging populations, chronic disease, healthcare accessibility, and technological equity. Through sustained collaboration among engineers, clinicians, researchers, and communities, the field remains central to the development of innovative and sustainable healthcare solutions[17].

3. Overview of the Biomedical and Bioengineering Curriculum

Biomedical engineering curricula are designed to prepare students to apply engineering principles to biological and medical problems through a structured integration of foundational sciences, core engineering competencies, and domain-specific biomedical training. Most programs begin with a strong grounding in mathematics, physics, chemistry, and biology, alongside introductory engineering courses that develop analytical thinking, problem-solving skills, and computational literacy.[19] As students' progress, the curriculum emphasizes core engineering disciplines such as mechanics, electrical circuits, signals and systems, materials science, and thermodynamics, contextualized for biological and physiological applications. Fundamental biomedical engineering courses typically include physiology for engineers, biomechanics, biomaterials, biomedical instrumentation, and biomedical imaging, enabling students to understand interactions between engineering systems and complex biological processes[19].

Advanced coursework and technical electives allow students to specialize in areas such as medical device design, tissue engineering, neural engineering, rehabilitation engineering, or computational biomedical engineering. Laboratory-based learning is a key component of the curriculum, offering hands-on experience in experimental design, data analysis, and regulatory considerations. Some programs also incorporate clinical exposure, industry partnership and internships, or community-engaged learning to enhance real-world relevance and societal impact[20].

Design education forms a central pillar of biomedical engineering curricula. Capstone design projects, often conducted in multidisciplinary teams, require students to identify unmet healthcare needs and develop user-centered engineering solutions while addressing ethical, safety, and regulatory constraints. Increasingly, few curricula also integrate professional skills such as communication, teamwork, entrepreneurship, and ethical responsibility to prepare graduates for careers across academia, industry, healthcare, and policy sectors[19].

3.1. Typical Core Curriculum Components Across Programs

Although exact course lists vary, BME programs at leading schools usually include the following types of coursework [21]:

- Foundational Sciences includes calculus, differential equations, physics, chemistry, biology.
- Engineering Fundamentals includes signals and systems, circuits & electronics, mechanics and materials.
- Biomedical Core includes Physiology for engineers, biomaterials, biomechanics, bioinstrumentation, biomedical imaging, systems biology & modeling.
- Hands-On & Research includes laboratory sequences, design projects and capstone experiences, research practica or industry internship.

3.2. Below Is the Review of Top 5 Biomedical Engineering Curriculum in The USA:

3.2.1 Johns Hopkins University (BME 2.0)[21] offers a curriculum that include;

- Foundational math, physics, chemistry, and biology.
- Core biomedical engineering knowledge (molecular biology, linear systems, modeling & simulation).
- Advanced focus areas such as Biomedical Data Science, Computational Medicine, Imaging & Medical Devices, Neuro engineering.
- Design team and clinical immersion embedded throughout the curriculum.

3.2.2 Cornell University[22] offers a curriculum that includes;

- Strong engineering and quantitative foundations.
- Core biomedical engineering courses including cellular/molecular principles, circuits & systems, biomaterials, and design sequences.
- Concentrations in biomedical imaging, biomaterials and drug delivery, mechanics, and molecular/systems engineering.
- Year-long senior capstone practicum synthesizing knowledge into engineered solutions.

3.2.3 University of Michigan – Ann Arbor [25,26] offers a curriculum that includes;

- Core requirements of math, physics, chemistry, and life sciences.
- Option to pursue tracks such as Biocomputation, Biomedical Imaging & Bioelectrics, Biomechanics, Neural Engineering, Systems Biology, and Tissue Engineering.
- Directed research and design experiences integrated into the curriculum.

3.2.4 Columbia University [27] offers a curriculum that includes;

- First two years focus on physical and chemical sciences alongside engineering fundamentals.
- Upper years cover biomedical engineering core topics like quantitative physiology and experimental measurement of biomedical systems.
- Flexible electives from across engineering and sciences complement the core curriculum.
- Two-semester senior design capstone required.

3.2.5 Cornell University[23,24] offers a curriculum that includes;

- Quantitative approach to biology & engineering
- Math, physics, chemistry, and biology foundations
- Biomedical engineering core (biomaterials, biomechanics)
- Electives and senior design in areas such as medical device development and computational bioengineering.

4. Gaps Between BMEs Curriculum and Regulatory, Industry, and Clinical Research Standards

This analysis points out the gaps between BME curriculums and regulatory, industry and clinical knowledge, using the university curriculums listed above as a reference.

4.1. Insufficient understanding of regulatory approval and submission processes

Leading Biomedical Engineering (BME) programs such as Johns Hopkins University (BME 2.0), Cornell University, University of Michigan – Ann Arbor, and Columbia University provide strong foundations in engineering science, biomedical systems, and research design [21–27]. However, the review of program structures compared with regulatory frameworks and industry standards reveals the following gaps.

The BME programs emphasize molecular biology, systems modeling, Imaging and devices, quantitative physiology, design capstone experiences. Nevertheless, there is a limited amount of targeted coursework specifically devoted to:

- Medical device classification and approval pathways
- Premarket Notification (510(k)) and Premarket Approval (PMA)
- Investigational Device Exemption (IDE)
- Regulatory submission structure

These processes are governed by the U.S. Food and Drug Administration under 21 CFR Parts 807, 812, and 814 [28,29,30]. As a result, graduates may lack understanding of regulatory approval processes and requirements needed to bring medical devices to the market.

4.2. Insufficient Knowledge of Quality Management Systems (QMS)

Medical device manufacturing in industry requires compliance with:

- 21 CFR Part 820 (Quality System Regulation - QSR)
- ISO 13485: Medical devices – Quality management systems
- ISO 14971: Application of risk management to medical devices

Although design projects are required at institutions like Cornell and Columbia, core BME programs usually do not mandate structured training in design control documentation, Corrective Action and Preventive Action (CAPA),manufacturing processes, risk management or internal audit systems. As a result, graduates may lack operational knowledge of compliance-driven product development and requirement in medical device manufacturing environments.

4.3. Gaps in Clinical trial design, clinical execution and Research Knowledge

Although clinical immersion is a key element in programs such as Johns Hopkins BME 2.0, not all programs consistently require structured courses on topics like Institutional Review Board (IRB) procedures, human subjects protection (45 CFR 46), Good Clinical Practice (GCP), or clinical trial design for device approval. Clinical research is an essential step in translating engineering innovation to patient care, but it is still not fully embedded within the core BME curriculum.

BME programs emphasize laboratory research and engineering experimentation but often lack required coursework in:

- Clinical trial phases (feasibility, pivotal trials)
- Study design (randomized controlled trials, cohort studies)
- Biostatistics for clinical data
- Clinical endpoints and outcome measures

Clinical investigations for medical devices are regulated under FDA IDE requirements and human subject protections (45 CFR 46 – Common Rule) and ISO 14155. While graduates possess the skills to design devices, they often have limited understanding of generating the clinical evidence necessary for regulatory approval. Additionally, there is insufficient knowledge and preparation among graduates regarding translational and clinical regulatory processes.

4.4. Insufficient Training in Good Clinical Practice (GCP)

Good Clinical Practice (GCP) standards provide essential guidance on ethical and scientific quality in clinical trials. Nevertheless, GCP certification is generally not included or mandated in the curricula of Biomedical Engineering (BME) programs. Additionally, coursework rarely incorporates simulations of monitoring, adverse event reporting, or trial documentation. Limited Exposure to Institutional Review Board (IRB) Processes. While clinical immersion experiences are available (such as Johns Hopkins BME 2.0), structured training in IRB submission, informed consent, risk-benefit analysis, and protection of vulnerable populations is not always required.

In addition, students demonstrate a limited comprehension of the ethical approval processes required prior to commencing clinical trials. Furthermore, students are inadequately equipped for professional roles in clinical research engineering, clinical affairs, or medical device trial.

4.5. Weak Integration of Post-Market Clinical Surveillance in Curriculums

The medical device industry requires post-market surveillance studies, real-world evidence generation, post-approval studies, adverse event reporting systems. Biomedical engineering curricula or coursework seldom incorporate post-market surveillance. Furthermore, design capstone projects generally omit post-market surveillance studies. As a result, students are not equipped with training or understanding related to the long-term clinical assessment of medical technologies.

4.6. Product Lifecycle and Commercialization Gap

Leading BME programs prioritize innovation and capstone design. However, the industry expects graduates to demonstrate proficiency in product lifecycle management, manufacturing scale-up, supply chain operations, cost analysis, reimbursement strategies, and market access. These areas are often offered as electives rather than as core curriculum requirements. Based on this, the students have limited exposure to commercialization pathways beyond prototype development.

4.7. Limited Knowledge in Manufacturing and Design for Manufacturability (DFM) or Design for Six Sigma (DFSS)

While biomechanics and biomaterials are core topics, fewer programs require structured coursework in process validation, lean manufacturing, statistical process control, design for manufacturability (DFM), design for Six Sigma (DFSS)

Industry medical device environments operate under good manufacturing practices and validated production system. While students possess knowledge in design, biomaterials, and mechanics, they have had minimal experience with large-scale engineering application and constraints encountered during production.

4.8. Insufficient knowledge in medical device Software, AI, and Digital Health Compliance

Programs such as Johns Hopkins BME 2.0 offer tracks in Biomedical Data Science and Computational Medicine, while Cornell University provides concentrations in Medical Device Development and Computational Bioengineering. Nonetheless, topics such as regulatory frameworks for Software as a Medical Device (SaMD), FDA digital health guidance, cybersecurity requirements for networked medical devices, and protocols for AI/ML validation and algorithm change are not uniformly included in the core curriculum. Consequently, the student may not possess adequate training in technical software, digital systems, cybersecurity, or AI/ML applications for medical device instruction, particularly when such training is not accompanied by concurrent regulatory validation and compliance guidance.

4.9. Limited Professional and Cross-Functional Industry Skills

Roles within the medical device industry include:

- Writing for regulatory submissions and the development of standard operating procedures for manufacturing.
- Translating or transcribing regulatory standards and integrating them into organizational processes.
- Collaborating across functions such as R&D, regulatory affairs, quality assurance, manufacturing, clinical operations, supply chain management, sterilization, and marketing.

Industry biomedical engineers often collaborate with Quality assurance, Regulatory affairs, Marketing and reimbursement specialists, Clinical research teams, research and development teams, software teams and they also perform these roles aswell.

While team-based design projects are common at the institutions reviewed, there is a notable shortfall in structured education on regulatory communication and fostering a compliance-oriented culture. Additionally, although collaborative design experiences are broadly implemented, robust interdisciplinary industry simulations are relatively rare. As a result, graduates may be underprepared for roles that require experience in highly regulated, cross-functional environments.

Table 1 Overview of Leading BME Programs and Gaps in the Medical Device Industry Experience

Domain or Functional Areas	**Strength in BME Reviewed Programs**	**Medical Device Industry Gaps**
Foundational Sciences	Strong	None
Engineering Fundamentals	Strong	None
Biomedical Core	Strong	No or limited regulatory integration
Design &Capstone	Very Strong	Weak documentation/compliance simulation
Regulatory Science and regulatory submission	Limited	Major gap
Quality management Systems & Risk management	Limited	Major gap
Product lifecycle and Commercialization	Moderate	Significant gap
Manufacturing	Limited	Significant gap
Digital Health Compliance/Medical device software/AI	Emerging	Gap in medical device industry such software application and its regulatory requirement
Clinical Trial Design and Research	Limited	Significant gap
Good Clinical Practice	Minimal	Significant gap
IRB & Ethics Processes	Limited	Significant gap
Post-Market Clinical Surveillance	Limited	Significant gap
Professional and Cross-Functional Industry Skills	Limited	Significant gap

5. Factors Contributing to Gaps Between the BME Curriculum and Regulatory, Industry, and Clinical Research Standards

5.1. Universities Are Academically Oriented Toward Research Rather Than Regulation

Top BME programs are historically rooted in engineering science and translational research within research-intensive universities. Faculty expertise and program priorities are often aligned with grant-funded laboratory research, publications in biomedical science and engineering, technological innovation and discovery. Regulatory science, quality systems, and compliance processes are typically practice-driven domains rather than traditional academic research areas. Consequently, curriculum emphasis is placed on advanced technical research specialization rather than regulatory compliance frameworks such as 21 CFR Parts 807, 812, 814, and 820 enforced by the U.S. Food and Drug Administration [28 -31]. Regulatory science remains largely practice-driven and industry-based rather than academically institutionalized.

Consequently, regulatory education is seldom regarded as a fundamental engineering discipline. Academic curricula typically allocate space to advanced modeling, biomaterials, imaging, and computational medicine rather than to regulatory frameworks. Although regulatory oversight by the U.S. Food and Drug Administration specifically under 21 CFR Parts 807, 812, 814, and 820 governs the process for translating devices to the market, comprehensive instruction in these regulatory areas is frequently limited or offered as elective coursework.

5.2. Universities Align Curriculum Credits with Accreditation Standards

Undergraduate Biomedical Engineering programs are required to incorporate comprehensive foundational coursework in mathematics, physics, chemistry, biology, and engineering sciences to satisfy accreditation standards established by organizations such as ABET [32]. Accreditation criteria including those set forth by ABET mandate specific credit allocations for fundamental engineering and science courses [32]. Because of constraints in credit hours, subjects such as regulatory science, quality management systems (ISO 13485), clinical trial methodology, health economics, manufacturing systems, processes, and validation are frequently deprioritized or offered as elective courses rather than being included in the core curriculum. Because of this structural limitation, there is limited familiarity with FDA regulations, ISO 13485, ISO 14971, and Good Manufacturing Practices, even though these are fundamental to industry practices.

5.3. Rapid Evolution of Regulatory and Digital Health Landscapes

Regulatory frameworks in digital health, artificial intelligence, and Software as a Medical Device (SaMD) have undergone significant advancement in recent years. The FDA has published several guidance documents focused on digital health topics, including cybersecurity, AI/ML adaptation, and software validation.

Academic curriculum revision cycles generally progress more slowly than regulatory developments, largely due to faculty governance procedures, institutional approval processes, and constraints related to resource awareness and allocation. While some programs such as computational medicine and biomedical data science initiatives exemplified by Johns Hopkins BME 2.0 [21] are included, curricular changes frequently do not simultaneously address the integration of AI validation frameworks, SaMD regulatory pathways, or cybersecurity compliance requirements. This misalignment contributes to an increasing disparity between evolving regulatory standards and academic training.

6. Strategies for Integration and to the Bridge the Gaps

6.1. Integration of Clinical studies, Regulatory requirements, manufacturing process into the coursework.

Integrating formal coursework in clinical studies, regulatory science, submission procedures, manufacturing processes, and industry standards can help students understand medical device classification, regulatory pathways, and quality management systems. This approach supports wider efforts to update education in medical product development[33].

6.2. Design Courses Incorporating Real-World Constraints

Embedding regulatory milestones into capstone design courses will enhance students' preparedness by integrating risk analysis, validation planning, and documentation requirements [34]. Engineering education literature supports project-based learning models that incorporate authentic constraints [34]

6.3. Strengthening Academia–Industry Partnerships

Collaboration between universities and industry professionals will improves curriculum relevance and exposes students to current professional standards [35]. Industry engagement through internships, guest lectures, and co-op programs reinforces regulatory and commercialization competencies. Also, having industry advisors that votes or contributes to building and structuring of the academic curriculum will be beneficial.

6.4. Accreditation Curriculum Reform Aligned with Industry Requirements

Adopting outcomes-based educational frameworks promoted through accreditation reform can facilitate integration of professional competencies including regulatory awareness and ethical responsibility [36]

7. Conclusion

A review of curricula from top institutions [21–27] alongside regulatory standards from the U.S. Food and Drug Administration and international ISO frameworks shows that BME programs provide thorough scientific, research, innovation, and capstone design training. They cover Engineering Fundamentals, Foundational Sciences, Biomedical core subjects, and include hands-on research elements. Nonetheless, notable deficiencies exist in areas such as regulatory systems and approval processes, clinical research design and Good Clinical Practice, IRB and ethical review procedures, post-market clinical monitoring, quality management system and risk assessment, commercialization and product lifecycle management, professional and cross-functional industry skills, digital health regulatory validation, and manufacturing practices.

To align with contemporary practices in industry application of biomedical engineering, the curriculum should systematically encompass instruction on regulatory frameworks, clinical research methodologies, compliance-oriented design documentation, and foster robust collaboration with both industry partners and clinical research environments. Addressing these requirements necessitates dedicated courses on regulations, modules covering quality systems, capstone projects emphasizing compliance, and strengthened partnerships among academic institutions, industry representatives, and regulatory bodies within biomedical engineering education

Bridging the gap between biomedical engineering curricula and regulatory as well as industry knowledge is crucial for equipping graduates to excel in today's biomedical innovation landscape. Integrating industry practices and regulatory requirements into academic programs strengthens collaboration between academia and industry, offering evidence-based approaches to align educational objectives with workforce needs [33,34]. By incorporating these aspects into biomedical engineering education, institutions can improve graduate preparedness, accelerate employment opportunities, advance translational innovation, and uphold patient safety.

Compliance with ethical standards

Disclosure of conflict of interest

There is no conflict of interest in any of the contents used or mentioned in the journal.

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