Review Article

Clinical Laboratory Sciences in Taiwan: Education, Accreditation, and Emerging Competencies

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ABSTRACT

Laboratory sciences play a pivotal role in modern healthcare, serving as the foundation for disease prevention, diagnosis, and monitoring. In Taiwan, formal education in this field began in 1956 with the establishment of the first undergraduate program in Asia, and has since evolved into a comprehensive system encompassing undergraduate, graduate, and continuing professional education. This review outlines the historical evolution and current structure of laboratory medicine education in Taiwan, the accreditation and certification frameworks that govern the profession, the integration of emerging technologies and competencies, workforce development strategies, and future directions for the discipline.

Keywords: Clinical Laboratory Science, History, Education, Accreditation and Certification, Taiwan

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Introduction

Formal education in laboratory sciences in Taiwan commenced in 1956 with the founding of the Department of Medical Technology at National Taiwan University (NTU), now known as the Department of Clinical Laboratory Sciences and Medical Biotechnology (CLSMB). The initiative originated from recommendations by Dr. Wilburt C. Davison, Dean of Duke University School of Medicine, during his advisory visit to NTU in 1954. His vision was to cultivate professional laboratory scientists to improve diagnostic standards and meet the demands of rapidly advancing medical technologies (1).

Undergraduate education in laboratory medicine in Taiwan was established since then, initially through programs closely linked to teaching hospitals, where faculty combined clinical service with academic instruction. This model ensured that education was deeply rooted in clinical practice. Over time, dedicated teaching and research facilities were established, allowing programs to expand their academic scope and diversify faculty expertise.

At present, there are seventeen undergraduate programs in clinical laboratory sciences across major universities and medical schools in Taiwan. Students complete a four-year curriculum leading to a Bachelor of Science degree, which combines general education, foundational sciences, and specialized clinical laboratory training. The programs typically culminate in a minimun of 20 week's intensive, hospital-based internship that provides hands-on experience in areas such as microscopy, clinical chemistry, hematology, blood banking, clinical physiology, microbiology, virology, immunology, and molecular diagnostics. Around 2005, in response to the expanding biotechnology industry, several programs adopted the name "Clinical Laboratory Sciences and Medical Biotechnology" to better reflect their broadened academic and professional scope.

Graduate education in laboratory medicine began in the late 1980s with the launch of master's programs, which later expanded into multiple research tracks to address emerging scientific and clinical needs. By the early 2000s, several institutions had established doctoral programs, enabling advanced research training and fostering interdisciplinary collaboration. The expansion into graduate education reflects a broader trend toward integrating biotechnology, molecular medicine, and translational research into laboratory medicine training, preparing graduates for leadership roles in clinical practice, academia, industry, and public health.

Career Pathways for Clinical Laboratory Sciences Graduates

Graduates of the clinical laboratory sciences programs in Taiwan have a wide range of career options. Many pursue licensure as medical technologists and work in hospitals, clinics, or diagnostic laboratories, performing hematology, chemistry, microbiology, and molecular testing that directly supports patient care. Others join public health and regulatory agencies—such as the Taiwan CDC, local health bureaus, and environmental protection departments—where they contribute to disease control, environmental monitoring, and policy implementation.

In recent years, an increasing number of graduates have entered the biotechnology sector as R&D scientists, quality control engineers, technical marketing specialists, or clinical trial coordinators, with strong demand in emerging areas like laboratory-developed tests (LDTs), cell and gene therapy, and biopharmaceutical manufacturing. Their dual background in medical and biotechnological sciences offers strong growth potential. As precision medicine and artificial intelligence become more integrated into healthcare, these professionals are expected to take on expanding roles in interdisciplinary collaboration, innovation, and the development of advanced diagnostic and therapeutic solutions.

Accreditation and Certification Frameworks

Professional Licensing

To practice as a licensed medical technologist in Taiwan, candidates must pass the Higher Examination for Examination of Specialized Professionals and Technicians administered by the Examination Yuan. Eligibility requires a bachelor's degree in clinical laboratory sciences (or related fields) and completion of required clinical internships. The examination, written in Traditional Chinese, covers six domains: clinical physiology, hematology, molecular diagnostics, microbiology, biochemistry, and immunology (2, 3).

Workforce Development and Continuing Education Strategies

Following licensure, practitioners must register to practice and renew their license every six years. Renewal requires completion of at least 120 continuing education credits within the license period, covering professional knowledge, quality management, medical ethics, relevant regulations, infection control, and gender equality. Continuing education activities may include hospital-based training, professional society meetings, government-sponsored programs, academic publishing, and teaching (2, 4).

Laboratory Accreditation

To ensure the reliability and accuracy of diagnostic results, most clinical laboratories in Taiwan pursue accreditation based on ISO 15189 standards, administered by the Taiwan Accreditation Foundation (TAF) (5). In addition to TAF accreditation, some laboratories also seek:

· **CAP Accreditation**: Awarded by the College of American Pathologists, recognized internationally for stringent quality requirements.

· **TFDA Precision Medicine Laboratory Accreditation**: Managed by Taiwan's Food and Drug Administration (TFDA), targeting molecular testing laboratories engaged in clinical trials and precision medicine applications (6, 7).

Within these frameworks, medical technologists serve not only as test performers but also as key contributors to quality management systems, instrument calibration, internal audits, and continuous process improvement using frameworks such as the PDCA (Plan–Do–Check–Act) cycle.

Integration of New Technologies and Competencies

The rapid advancement of biomedical science has driven continuous curriculum updates in Taiwan's laboratory medicine education. Programs now incorporate molecular diagnostics, next-generation sequencing (NGS), bioinformatics, multi-omics analysis, and the development of LDTs for applications such as genetic testing, cancer screening, and cell therapy.

In addition, artificial intelligence (AI) and big data analytics are increasingly integrated into diagnostic processes and research projects. Students are encouraged to participate in international exchange programs, overseas internships, and interdisciplinary research collaborations to foster global perspectives and innovation capacity. Faculty recruitment prioritizes expertise in emerging biomedical fields, thereby bridging academic research with clinical and industrial applications.

Future Directions

Taiwan's laboratory medicine education is poised to expand in both scope and depth, with an emphasis on integrating precision medicine and precision health through genomics, multi-omics, and personalized diagnostics. Training programs are expected to broaden into areas such as genetic counseling and regenerative medicine, preparing professionals for specialized roles in emerging healthcare sectors. At the same time, artificial intelligence and big data applications are anticipated to enhance diagnostic accuracy and efficiency, while strengthened industry–academia collaboration will drive innovation in diagnostic reagents, medical devices, and biopharmaceuticals. Furthermore, greater support for entrepreneurship and international engagement will encourage the development of biotechnology startups and foster global research partnerships, thereby enhancing Taiwan's competitiveness in the global healthcare landscape.

Graduates of Clinical Laboratory Sciences programs across Taiwan contribute significantly to clinical medicine, academia, biotechnology, and public health both domestically and internationally. These programs continue to produce highly skilled professionals who are poised to play increasingly vital roles in the evolving global healthcare landscape.

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Conflict of Interest Statement

The authors declare that they have no conflict of interest.

Abbreviations

CAP: College of American Pathologists, CDC: Center for Disease Control and Prevention, CLSMB: Department of Clinical Laboratory Sciences and Medical Biotechnology, FDA: Food and Drug Administration, LDTs: Laboratory-Developed Tests, NGS: Next-Generation Sequencing, NTU: National Taiwan University, PDCA: Plan–Do–Check–Act cycle, R&D: Research and Development, TAF: Taiwan Accreditation Foundation, TFDA: Taiwan's Food and Drug Administration

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