An Integrated Curriculum Approach to Develop Industry-ready Biomedical Engineering Graduates

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ABSTRACT

This paper presents the new applied learning track for Quality and Processes in Biomedical Manufacturing that is built specifically on CDIO Standard 3 – Integrated Curriculum. The key feature of this new curriculum is the progressive building up of students' knowledge and working skills via contextual learning and a 24-week structured internship. The paper shares our experience in designing the integrated curriculum and developing the 24-week structured internship program with partnership from the biomedical manufacturing sector. Results of the implementation and measures to address the gaps identified during the implementation are also discussed.

KEYWORDS

Integrated and experiential learning, integrated curriculum, competency-based assessment, contextualized learning, Biomedical Engineering, Standards: 3, 7

Note – In the context of Nanyang Polytechnic, the term 'course' refers to a 'program' while the term 'module' refers to a 'course'. For example, *Diploma in Biomedical Engineering* is a course; *Biomedical Project* is a module.

INTRODUCTION

The biomedical manufacturing sector in Singapore is growing fast, supported by output expansions in both the pharmaceutical and medical technology segments (Ministry of Trade and Industry Singapore, 2016). The pharmaceutical segment was boosted by the increase in production of existing and newly-introduced active pharmaceuticals ingredients and biological products. The medical technology segment, on the other hand, continued to benefit from robust export demand for medical devices. The demand for industry-ready workforce is set to grow in this sector.

In response to this demand, the Diploma in Biomedical Engineering (DBE) at Nanyang Polytechnic offered a new applied learning track in 2014 focusing on quality management and manufacturing processes in biomedical industry. The new applied learning track was developed using the CDIO principles and guidelines (Crawley, Malmqvist, Östlund, & Brodeur, 2007) and the contextual teaching and learning pedagogical approach (Berns & Erickson, 2001). In particular, the curriculum was designed using CDIO Standard 3 – Integrated Curriculum to better reflect the multidisciplinary nature of biomedical engineering. The focus was on providing an integrated learning experiences for students to take an active role in their learning and discover for themselves the relevance of training to their future career needs.

In this paper, we first share the environment scan that was carried out to gather the training needs, then we present the process of designing the integrated curriculum and some examples of those integrated learning opportunities. Finally we present the results of the implementation and discuss measures to address the gaps identified during the implementation.

INTEGRATED CURRICULUM DESIGN

Relevance of DBE Curriculum

The first step was to perform an environmental scan in the current biomedical industry landscape and manpower needs in Singapore. This was done by conducting surveys with companies and alumni, and interviews with faculty and Singapore government agencies. The outcomes of the environmental scan were summarised as follows:

- Industry feedback had indicated that the current DBE curriculum remained relevant to the biomedical industry for skillsets in the areas of medical device design & development, and regulatory compliance. However, skillsets to support latest biomedical manufacturing technology, process validation, automation & control could be further enhanced into the curriculum.
- Information gathered from interviews with government agencies and studies on the biomedical landscape also pointed to the emerging manpower needs on skillsets to support the governments push towards higher productivity and high-value added manufacturing in the biomedical industry.
- Feedback received from the alumni showed that the current curriculum had equipped them with strong foundation knowledge and skills in medical device design and regulatory compliance. However, more employment opportunities were found in the manufacturing sector which required different skillsets in manufacturing technology,

process control and quality compliance.

- Feedback received from faculty members, through interaction with industry partners and literature review, showed that students should be prepared to manage the changing technology in biomedical manufacturing activities such as the use of robotic automation in reducing reliance no human labour. In addition, students should be introduced to the biomedical industry landscape in Singapore starting from Year 1 so that they could have a head start for their future career planning.

These feedbacks served as the basis for the review and enhancement to the existing DBE curriculum.

Integrated Curriculum

The key strategy in designing this new applied learning track was based on the CDIO Standard 3 – Integrated Curriculum. In another words, the curriculum should be designed with mutually supporting disciplinary modules, and with an explicit plan to integrate personal, interpersonal, and product, process, and system building skills.

Following the design process recommended by Malmqvist and his co-workers (2006), we defined the objective of the applied learning track in quality management & biomedical manufacturing technology (see Figure 1). The objective of the new applied learning track is to train a pool of graduates who are technically competent, professionally proficient and socially responsible in quality management, regulatory compliance and manufacturing processes in the biomedical sector. This was followed by an iterative process of developing the learning outcomes, aligning the learning outcomes, designing the learning activities and applying the assessment methods of the modules offered in this track in an integrated manner to meet the biomedical sector's needs.

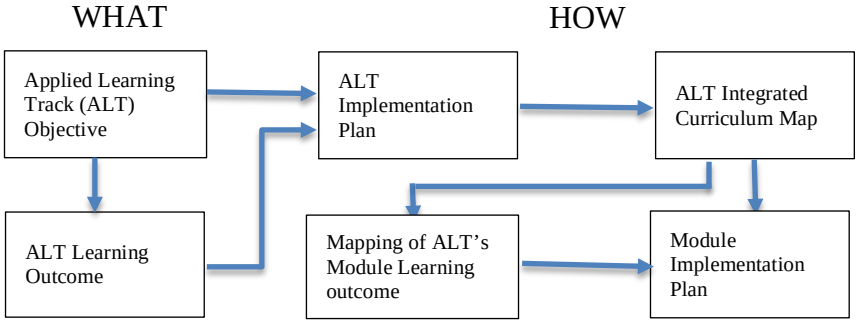

Figure 1: An integrated Applied Learning Track Design Process

This process led us to design a new module in year 1 to introduce students to the biomedical manufacturing processes. This was followed by another new module in year 2 to strengthen students' knowledge and skills in good manufacturing practices. Finally, specialised modules were introduced in year 3 to allow students to deepen their knowledge and skills, as well as gain working experience through a 24-week structured internship program. The old and the

revised DBE integrated curriculum maps with the new applied learning track are shown in Figure 2a and 2b respectively.

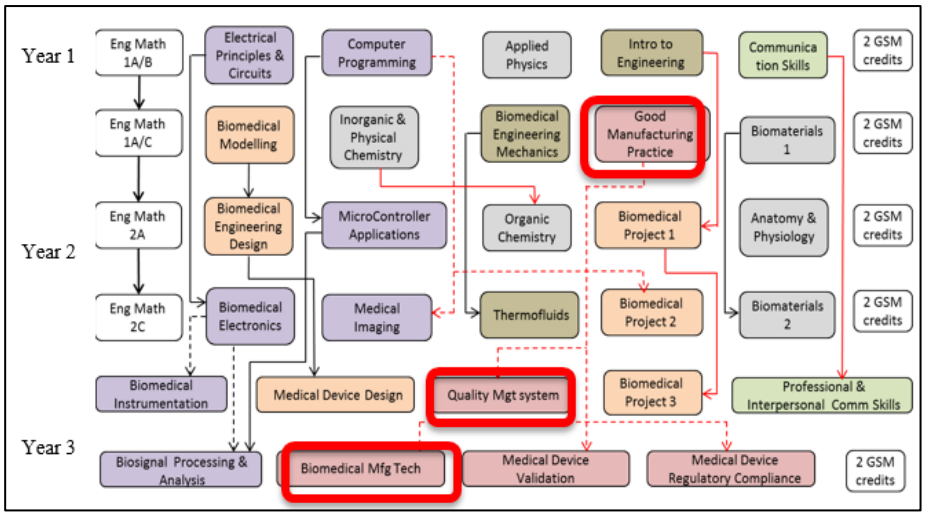

Figure 2a. The Old Integrated Curriculum Map of the Diploma in Biomedical Engineering (biomedical manufacturing related modules are highlighted in red boxes)

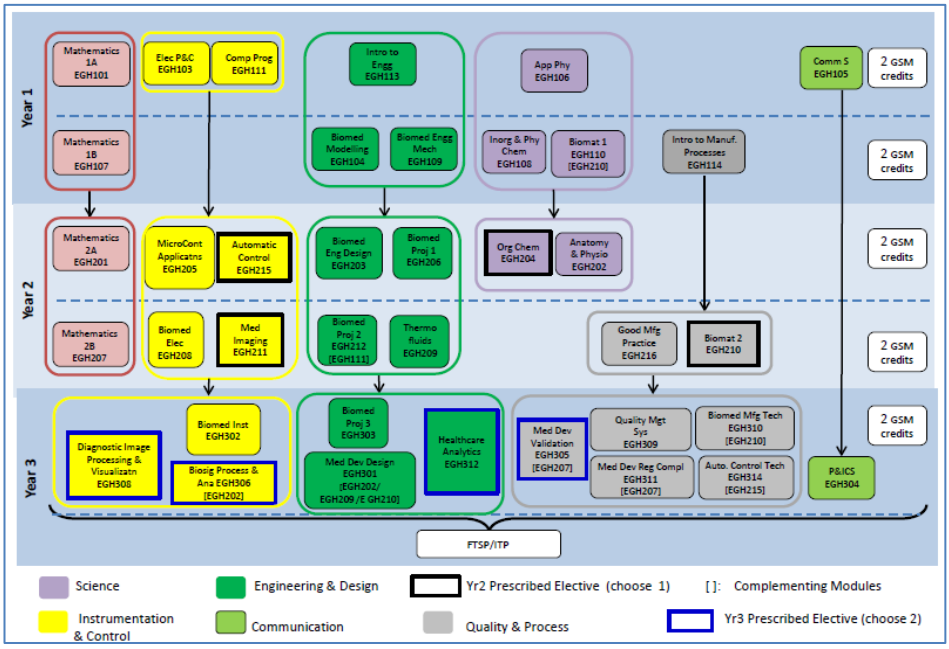

Figure 2b. The Revised Integrated Curriculum Map of the Diploma in Biomedical Engineering (the new applied learning track are highlighted in grey boxes)

Integrated Learning Experiences

Training Facilities for Integrated Learning Activities

To provide our year 1 and year 2 DBE students with contextualised learning experience and hands-on training in a real-life good manufacturing practice working environment, a secondary pharmaceutical teaching facility was set up to train them for the biomedical manufacturing industry. This facility, as shown in Figure 3, trained students on industry-related equipment and processes. It allowed students to acquire skills and knowledge in application of good manufacturing practice which included manufacturing operations, documentation and requirement of production batch records, cleanroom monitoring, clean utilities, validation and facility management.

Figure 3. Secondary pharmaceutical teaching facility for integrated learning experience

Learning Journey

To further enhance the learning experience, learning journeys were organized to related biomedical industries for year 2 and year 3 DBE students (see Figure 4). Through these learning journeys, students were exposed to the real-life working environment in the industry and had the opportunities to explore the requirements of various job functions available for biomedical engineering graduates. Through reflection on these learning journeys and applying the personal career strategy, students were able to recognize their strengths, interests, personality and values that influenced their education and career decision making.

Figure 4. Industry experiential learning trip to Novartis Singapore & Alcon Singapore

Structured Internship Program

Structured internship program is a program that NYP co-designs and develops with our industry partners to meet the training need of an industry sector. This well-structured on-the-job or work-based learning program aims to provide a real-life work environment and facilitate a structured and integrated learning experiences for our Year 3 students before they graduate and join the work force. Through the structured internship program, students further deepen their competencies for occupational skills, transferable workplace skills and personal effectiveness skills. With this structured internship program put in place, our DBE students were able to carry out internships in several related quality and process management departments within the biomedical manufacturing industry and gained valuable experience. Two examples of the structure internship program in a production department of a biopharmaceutical company and a quality control department of a medical device company can be found in Annex 1.

Results and Discussion

Since the launch of the new applied learning track in the Quality Management & Biomedical Manufacturing Technology in 2014, a total of 31 DBE students completed this applied learning track and the structured internship program in various job functions in the biomedical companies. The effectiveness of the integrated curriculum in this applied learning track was measured through the feedback received from the industry partners on students' performance in the internship program and the graduate employment rate.

Positive comments were received from the industry partners on the students' performance. For examples, it was highlighted that our students demonstrated an excellent attitude in approaching the tasks assigned to them and they took the initiative to contribute new ideas and gave their best efforts to all tasks that were assigned to them. It was also highlighted that our students were competent in performing good manufacturing practice checks and review, and they were able to complete their assignment prior to the given deadlines with high quality outcomes.

From the graduate employment survey that was conducted annually by the Singapore's Ministry of Education, the employment rate for students who graduated from the DBE has improved by 12.5% in 2016 when compared with the employment rate obtained in 2013. In the same survey, students also reflected positively to the revised integrated curriculum and more students (an increment of 50% from 2013) found the training to be relevant to the job they were doing.

Conclusion

The revised integrated curriculum where an applied learning track was created to meet the need of the biomedical manufacturing industry has effectively met our curriculum review objectives as well as the intended learning outcomes for our biomedical engineering students. Graduate employment survey has improved significantly and the industries recognise that our graduates are more industry-ready and confident in facing the complex, highly regulated and challenging biomedical manufacturing industry.

However, through interaction with recent graduates and industry partners, there are still gaps in our graduates' skill sets. They expressed that extended period of structured internship program would be needed to deepen the skills that were required for students contribute efficiently in a broad range of products and processes in this industry. To address these gaps, plans have been put in place in developing a 12-month integrated work-study program for graduates who wish to develop their careers in the biomedical manufacturing sector. The proposed work-study program will comprise an on-campus study, self-directed e-Learning as well as the on-the-job training components. This program will allow the students to further acquire the needed domain-specific knowledge and deepen their skills and experience in this industry.

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BIOGRAPHICAL INFORMATION

Kallen Chong is a Senior Lecturer in the School of Engineering, Nanyang Polytechnic. She leads the establishment of enhanced internship with biomedical science and engineering industry. Kallen held several non-academic portfolios such as Quality Manager for an ISO17025 accredited laboratory and capital project leader in setting up a GMP pharmaceutical pilot plant training facility at NYP. Prior to joining NYP, Kallen worked in chemical and pharmaceutical industry in the functions of technical development and quality management for about 10 years.

Ong Hui Yng is a Lecturer in the School of Engineering, Nanyang Polytechnic. She graduated with a Master of Science (Mechanical Engineering) from Nanyang Technological University in Singapore. She is actively involved in industry project development and the delivery of biomedical manufacturing technology related modules.

Liang Kwong is a Senior Lecturer in the School of Engineering, Nanyang Polytechnic. He graduated with a Master of Science (MicroSys & Nano) and Mater of Science (Statistics). He is actively involved in industry project development and management of internship program for DBE. Liang Kwong also conducts CET courses in Precision Engineering at Nanyang Polytechnic.

Dr Choo Keng Wah is a Deputy Director in the School of Engineering, Nanyang Polytechnic. He is actively involved in industry project development and management, biomedical research and development projects, protection and commercialization of IPs, engineering education benchmarking, education quality assurance and accreditation.

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Annex 1: Examples of structured internship program

a) Blueprint for Structured Internship Program in the production department of a biopharmaceutical company

Main Task	Task Elements	Key Points	Task Standards	Skills & Knowledge	Training Guidelines
Good Manufacturing Practice (GMP)	• Introduction to current Good Manufacturing Practice (cGMP) • Introduction to Good Distribution Practice (GDP) • Read & Understand Zoning Classification in BiopharmOps • Read & Understand Gowning Procedures • Read & Understand Material flow & Personnel Flow in Process Unit	• Understand the fundamentals of GMP & its consequences if not followed • Understand GDP and the meaning of signature and understand the importance of Data Integrity • Understand zoning concepts and its rationale • Ability to follow gowning procedures • Understand the basics of facility flow	• Pass the cGMP test • Pass the GDP test • Ability to differentiate the various zones in Process Unit • Ability to gown correctly to various suites • Ability to move material from one area to another correctly	• GMP trained • GDP trained • Ability to perform gowning correctly • Ability to perform material flow and personnel flow correctly • Fulfilled basic requirements to work in clean room environment	**Part 1** – Practicum. Trainees learn on the job **Part 2** – Supervision. Trainees expected to carry out tasks under direct supervision **Part 3** – Assessment. Trainees will be assessed on whether they are competent in task

b) Blueprint for Structured Internship Program in a quality department of a medical device company

JOB TITLE Quality Lab Technician		UNIT QC Lab	DEPARTMENT Quality	TOTAL TASKS 3	Page 1 of 1	
SN	Main Task	Task Elements	Task Standards	Skills & Knowledge	Training Guidelines	OJT Time
1	Complete the new hired orientation program	a) Understand company business activities on site b) Comply to WSH policy on site c) Understand company HR Policy d) Comply to Quality Management System (QMS)	• Test result shall meet acceptance criteria in raw material specifications for reference standards	Knowledge • GMP • GDP • GLP • Singapore WSH Act Skills • Compliance to company HR policy, QMS & WSH	• Info sharing • Demonstration	5 work-days
2	Perform at least three raw material test methods as per SOP using reference standards within 8 weeks	a) Analyse assay of process nitrogen according to SOP-QC-018 b) Analyse water content of PVA according to SOP-QC-023 c) Test microbial count of WFI according to SOP-QC-100	• Test result shall meet acceptance criteria in raw material specifications for reference standards	Knowledge • GMP • GDP • GLP • Biosafety • Aseptic operation Skills • Testing according to SOP • Aseptic sampling • Instrumental	• Demonstration • Practical (on the job)	15 work-days
3	Perform at least 10 quality test records checking according to GDP requirements within 4 weeks	a) Checking quality test record for compliance to GDP requirements	• Passing relevant online SOP competency assessment • Meeting GDP standard	Knowledge • GMP • GDP Skills • Document checking according to GDP requirements • Raising of Deviation Form	• Reading of SOP on document Control (SDL via company training portal) • Reading of SOP on deviation & CAPA management	10 work-day