



The School of Mechanical and Manufacturing Engineering of The University of New South Wales, offers a Graduate Certificate in Good Manufacturing Practices in collaboration with the Australian Self Medication industry (ASMI), the Advanced Manufacturing Centre (AMC), the School of Medical Science, the Australian Therapeutic Goods Administration, the Royal Australian Chemical Institute, Medicines Australia and the Medical Industry Association of Australia. A sound understanding of Good Manufacturing Practices (GMP), regulatory and legal requirements for industry is essential to meet not only industry's needs for legal and safety issues but also to be better placed in global markets to ensure adherence to international standards. This would enable the Authorised Persons in Australia and in New Zealand (the Qualified Person in Europe) who is responsible for verifying, certifying and releasing for sale every manufactured product in accordance with GMP and regulatory and legal requirements. It will also enable industries to move towards achieving high quality, timely delivery, minimum cost and flexible manufacturing.

ADMISSION REQUIREMENTS:

Either a 4 year undergraduate degree equivalent to a standard Australian Bachelor's degree,

OR a 3 year undergraduate degree equivalent to a standard Australian Bachelor's degree AND formal technical work in a related industry or engineering of more than a year,

OR a 2 year formal technical training equivalent to a standard Australian TAFE degree in a related industry AND formal technical work in a related industry or engineering of more than FIVE years,

OR applicants with no formal qualification but substantial experience might be considered for admission on a case by case basis.

PROGRAM OF STUDY:*

This program consists of four courses, each of 6 Units of Credit and offered via part-time distance learning. It takes a minimum of one year to complete the program. Regular communication and interaction with the students is maintained via e-mail, fax, telephone and WebCT Vista with access to UNSW facilities. A brief outline of the courses that comprise the Graduate Certificate are as follows:

MANF8420 Managing Manufacturing Operations – Principles of Quality management. Designing products for quality. Concurrent product and process design. Strategic quality planning. Lean manufacturing. Just in time manufacturing. Human resources in operations management. Reengineering. The voice of the customer. The voice of the market. Benchmarking. Failure modes and effect analysis. Statistical tools for quality management. Statistical process control. Six Sigma. Process capability. Process stability. Quality costs. Acceptance sampling and inspection. Preventive maintenance. Project management. Risk assessment and cost effective validation.

MANF8430 Understanding Good Manufacturing Practice – Understanding the basic processes of product manufacture. Basic principles of analytical approaches, Analysis of products, principles of sterility testing, principles of scale-up. Product quality review. Process planning, analysis and testing. Change control. Variation analysis. Batch record review. Product release procedures. Good distribution practice. The audit process. Certification and supplier audits. Documentation management. Good laboratory practice, Analytical certificates compliance. Implementing and validating the quality system.

MANF8471 Manufacturing Strategy – Sustainable competitive strategies in manufacturing. Core competencies. Corporate, business, operational strategies. Process planning and technology decisions. Value-added manufacturing. Customer Relationship Management (CRM). Supplier development programs. Logistics. Material requirements planning. Inventory management. Scheduling. Design for manufacture. Design for reuse/disposal. Capacity planning and production planning. Supply chain management. Understanding the importance of premises, plant, starting materials, packing. Effective documentation and validation.

PHPH9104 Law, Ethics And Regulations Of Medicines – Pharmaceutical regulations, administration and law in Australia, New Zealand and overseas. Prescription medicine, non-prescription medicine, complementary medicine, medical devices regulations, traceability, links with the other agencies such as Customs, cosmetics industry and the food standards. Duties and responsibilities of the Authorised Person, role of sponsors, manufacturers and contract manufacturing. Importance of drug master files. The marketing authorisation. Analysis of biologics. Commercial agreements.

* website: <http://www.gmp.unsw.edu.au/>