




**GRADUATE
CERTIFICATE
IN GOOD
MANUFACTURING
PRACTICE (GMP)**

Plan your career for tomorrow and you
will be ahead of your competitors



This course is a distance-learning program that will culminate in a Graduate Certificate in GMP. The GMP graduate certificate degree offers you the knowledge to understand and manage complex operational and logistical interactions common to the manufacture operations of medicines and medical devices.

The program is supported by the Australian Self Medication Industry (ASMI); the peak body for the OTC and Complementary Medicines Industry, the Advanced Manufacturing Centre (AMC) and the University of New South Wales (UNSW), the Australian Therapeutic Goods Administration, the Royal Australian Chemical Institute, Medicines Australia and the Medical Industry Association of Australia and has been introduced as a response to changes to the application of regulatory requirements in Australia and New Zealand.

Students completing the program will gain an understanding of global GMP management requirements.

This course is designed for management personnel acting as Qualified Persons (QP) within the therapeutics goods industry. The course material encompasses all the diverse elements required to ensure that each batch of a medicinal or therapeutic good meets the quality requirements as stipulated by manufacturing and marketing licences and GMP. Stringent application of GMP requires people not only with experience from the therapeutic goods industry but also people who have a good understanding of the manufacturing, quality and regulatory principles underpinning the GMP management philosophy.

Enrolled students can complete the GMP program which covers four modules in one year.

The Course is coordinated through the School of Mechanical and Manufacturing Engineering at the University of NSW with participation from the School of Medical Science Postgraduate Studies in the Drug Development at the University of NSW.

Students will be provided with comprehensive course material for self-paced learning with exercises and case studies.



COURSE OUTLINE

The program encourages application of the following key themes of learning outcomes:

- Understanding the key concepts and methodologies of GMP through the supply chain of the therapeutic goods industry.
- Applying the principles of GMP to facility design and operation, product development and process and product evaluation.
- Understanding global therapeutic goods manufacturing operations and related regulatory management practices.
- Applying the knowledge and skills acquired to real-life projects.



WHO SHOULD CONSIDER THE COURSE?

The course is suitable for those professionals wanting to pursue and develop their career in technical and regulatory management within the therapeutic goods industry.



ADMISSION REQUIREMENTS

- 4-year undergraduate degree
- 3-year undergraduate degree & more than 1-year formal technical work in the therapeutic goods industry
- 2-year formal college technical training in areas of the therapeutic goods industry
- 5 years experience in technical aspects of the therapeutic goods industry



LAW, ETHICS AND REGULATIONS OF MEDICINES

- Government Acts and Regulations, the role of the EMEA in Europe the FDA and ICH
- Regulatory procedures relevant to the manufacture and supply of Therapeutic Goods (Prescription Medicines, OTC Medicines, Medical Devices, Biologics, Veterinary Medicines and Complementary Medicines)
- Traceability, links with the other agencies such as Customs, Cosmetics industry and the Food Standards
- The responsibilities of the Qualified Person, sponsors, manufacturers and contract manufacturing, functions of master files, marketing authorisations, GMP contracts and commercial agreements



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, and packing
- Effective documentation and validation, hazard analysis and risk assessment in the manufacturing and regulatory arena



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 mode and effect analysis
- Statistical tools for quality management
- Statistical process control
- Six Sigma and other quality management philosophies
- Process capability
- Process stability
- Quality costs
- Acceptance sampling and inspection
- Preventive maintenance
- Project management
- Risk assessment and cost effective validation
- Validation of the manufacturing processes



GOOD MANUFACTURING PRACTICE IN THE THERAPEUTIC GOODS INDUSTRY

- Pharmaceutical operations, the organization and the facility
- Understanding processes from scale up to production of scale-up
- Overview of API Code of GMP and especially interaction of API suppliers and finished dose manufacturers

- Analytical test methodology development, optimisation and validation
- Use and performance of analytical “Reference Standards”
- Setting of raw material, packaging component and product specifications
- Sampling procedures for raw material, packaging component and product
- Rework criteria and performance
- Setting and performance of stability protocols
- Evaluation of stability data and determination of storage conditions/shelf life
- Evaluation of complaints
- Use of computers in process, documentation and calculations
- Validations – plant, equipment, process, analytical, microbiology, electronic data collection
- Product quality review
- Process planning, analysis and testing
- Change control and Deviations
- Stability
- Batch record review
- Product release procedures
- Vendor certification process
- Documentation management
- Good laboratory practice
- Good distribution practice
- Good agricultural practice (for the complementary industry)
- Quality awards, ISO 9000/2000 and HACCP concepts
- Certificates of analysis, compliance and manufacturing certificates



FEE STRUCTURE

Currently, the enrolment into each module is approximately AUD \$2000 for local students. For non-Australian residents the cost of each module is approximately AUD \$2640. The GMP program is comprised of four modules and take a minimum of one year to complete. Applications from anywhere in the world are welcome.

Applications for Semester 2, 2005 close 8 July 2005.

Enrolled students will be supplied with course notes in hard copy and cases and readings in CD format.

Students will also have access to links to the UNSW Library and other learning facilities. **Students must have access to a computer and Internet connections.**



FURTHER INFORMATION:

Please send me further information

NAME _____

ADDRESS _____

PHONE _____

FAX _____

EMAIL _____

Fax or post this form to

Mrs. Sharon Turnbull

External Studies Coordinator

School of Mechanical and Manufacturing Engineering

The University of NSW

Sydney NSW 2052

Tel: 61 2 9385 4085

Fax +61 2 9663 1222

Do you know anyone else who might be interested in the GMP program?

NAME _____

ADDRESS _____

PHONE _____

FAX _____

EMAIL _____



THE UNIVERSITY OF
NEW SOUTH WALES



Advanced
Manufacturing Centre