APPROVED

# MNUF S7001: Pharmaceutical Manufacturing

## Module Details

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|---|---|
| **Module Code:** | MNUF S7001 |
| **Full Title:** | Pharmaceutical Manufacturing APPROVED |
| **Valid From::** | Semester 1 - 2018/19 ( September 2018 ) |
| **Language of Instruction:** | English |
| **Duration:** | 1 Semester |
| **Credits::** | 5 |
| **Module Owner::** | Arjan van Rossum |
| **Departments:** | Unknown |
| **Module Description:** | Provide the student with the necessary knowledge and understanding of the manufacturing processes, equipment, tools and control systems needed to function effectively in a highly regulated and controlled pharmaceutical manufacturing environment. |

| Module Learning Outcome | |
|---|---|
| *On successful completion of this module the learner will be able to:* | |
| **#** | **Module Learning Outcome Description** |
| MLO1 | Categorise the manufacturing activities, inputs, outputs etc. using a Generic Process Approach model. |
| MLO2 | Explain how cGMP and the regulatory landscape impacts on the design, layout, construction and operation of manufacturing Facilities and Premises. |
| MLO3 | Describe the basic concepts associated with the design, layout, operation and control of clean rooms, how they are applied and used to maintain regulatory conformance. |
| MLO4 | Examine and discuss the principles of tablet /capsule production systems and the associated control/measurement systems i.e. Manual, CLAS and CMMS. |
| MLO5 | Explain how the principles of Cleaning, Decontamination and Sanitation (CDS), Cleaning In Place (CIP), Fogging are applied and how to provide and distribute Purified Water, Water for Injection and Clean Steam. |

| Pre-requisite learning |
|---|
| ***Module Recommendations***<br>*This is prior learning (or a practical skill) that is strongly recommended before enrolment in this module. You may enrol in this module if you have not acquired the recommended learning but you will have considerable difficulty in passing (i.e. achieving the learning outcomes of) the module. While the prior learning is expressed as named DkIT module(s) it also allows for learning (in another module or modules) which is equivalent to the learning specified in the named module(s).* |
| No recommendations listed |

| Module Indicative Content |
|---|
| **Manufacturing Process Approach -**<br>Definitions, transformation process diagrams i.e.inputs, outputs, activities, deliverables etc. Flow Charts and Process Flow Diagrams |
| **Patents**<br>Novelty, obviousness, disclosure and utility. Product, process and use |
| **Regulatory Authorities**<br>FDA, EMEA, PAB, organisational structure, purpose/objectives, processes and areas of responsibility. The need for and application of cGMP. |
| **Site Selection and Premises Design**<br>Criterion, decision and ranking matrix. Material, process and people flow. Weighing & Dispensing area design and environmental control |
| **Premise and Regulatory GMP**<br>Impact on and design of Ancillary, Storage, Production and Quality Assurance areas |
| **Manufacturing GMP and regulatory requirements**<br>How regulatory requirements impact personnel , premise and equipment, |
| **Clean Rooms**<br>Definitions and standards. Turbulent and Laminar flows. Layouts and design, including air locks, air showers and stepover benchs. Factors affecting effectiveness i.e. rest and occupancy. Air supply, distribution and filtration. Zone control and clean room clothing. |
| **Water purification and distribution**<br>Classification types and uses of water. Multistep purification process, Distillation and Reverse Osmosis, Distribution systems for WFI and PW. |
| **Principles of steam generation – steam equipment, boilers.**<br>Utility and Cleam steam. Generation and distribution of Clean Steam |
| **CDS – Cleaning, Decontamination and sanitation**<br>Cleaning, Decontamination and Sanitation (CDS). Clean In Place (CIP) and Fogging |
| **Tablet Production Systems**<br>Tablet forms and formulations, Physical propertie i.e. shape, size and strength. Granual an Dry compression mixes. Wet and Dry cranulation. Eccentric and Rotary presses. powder and granual delivery systems. Weight control systems i.e. Manual, CLAS and CMMS. Correlation betwen compaction force and weight. |
| **Tablet Coating systems**<br>Acid resistant v non resistant coatings. Types of coating processes |
| **Capsule Filling Systems**<br>Generic Filling steps. Filling methodologies, Plate, Auger, Tamping, Compression and Drug-pack |

## Module Assessment

| Assessment Breakdown | % |
|---|---|
| Course Work | 20.00% |
| Project | 30.00% |
| Final Examination | 50.00% |

| Module Special Regulation |
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### Assessments

## Full Time On Campus

**Course Work**

| | | | |
|---|---|---|---|
| **Assessment Type** | Class Test | **% of Total Mark** | 20 |
| **Marks Out Of** | 0 | **Pass Mark** | 0 |
| **Timing** | n/a | **Learning Outcome** | 1,2 |
| **Duration in minutes** | 0 | | |

**Assessment Description**
The test will evaluate knowledge, understanding and application of the subject matter covered in lectures and tutorials

**Project**

| | | | |
|---|---|---|---|
| **Assessment Type** | Group Project | **% of Total Mark** | 30 |
| **Marks Out Of** | 0 | **Pass Mark** | 0 |
| **Timing** | n/a | **Learning Outcome** | 5 |
| **Duration in minutes** | 0 | | |

**Assessment Description**
At a minimum the project will cover one of the following learning outcomes.

No Practical

**Final Examination**

| | | | |
|---|---|---|---|
| **Assessment Type** | Formal Exam | **% of Total Mark** | 50 |
| **Marks Out Of** | 0 | **Pass Mark** | 0 |
| **Timing** | End-of-Semester | **Learning Outcome** | 1,2,3,4 |
| **Duration in minutes** | 0 | | |

**Assessment Description**
End-of-Semester Final Examination

## Module Workload

| Workload: Full Time On Campus | | | | | |
|---|---|---|---|---|---|
| *Workload Type* | *Contact Type* | *Workload Description* | *Frequency* | *Average Weekly Learner Workload* | *Hours* |
| Lecture | Contact | No Description | Every Week | 2.00 | 2 |
| Tutorial | Contact | No Description | Every Week | 1.00 | 1 |
| Directed Reading | Non Contact | No Description | Once per semester | 2.00 | 30 |
| Independent Study | Non Contact | No Description | Once per semester | 2.00 | 30 |
| | | | | Total Weekly Learner Workload | 7.00 |
| | | | | Total Weekly Contact Hours | 3.00 |

**This module has no Part Time On Campus workload.**

## Module Resources

*Recommended Book Resources*


**Augsburger L. Larry, Hoag W, Stephen. (2008), Pharmaceutical Dosage Forms- Tablets: Manufacturing and Process Control, 3. Informa healthcare, [ISBN: 978-0849390166].**

**Haider, Imtiaz Syed. (2006), Validation Standard Operating Procedures: Achieving Compliance in Pharmaceutical, Medical Devices and Biotech Industries, 2nd. Informa Healthcare, [ISBN: 978-0849395291].**

**Buckbee George, Alford Joseph. Automation Applications in Bio Pharmaceuticals, 2008. ISA, [ISBN: 978-1934394250].**

**LeBlanc L. Destin. (2000), Validated Cleaning Technologies for Pharmaceutical Manufacturing, Informa Healthcare, [ISBN: 978-1574911169].**

**Paikh, D.M.. (1997), Handbook of pharmaceutical granulation technology, Marcel Dekker Inc, [ISBN: 978-0824798826].**

**Allport-Settle J. Mindy. (2009), Current GMP Practices, Create Space Indep Publishing Platform., [ISBN: 978-144955236].**

**Whyte William. (2010), Cleanroom Technology: Fundsmentals nof Design, Testing and Operation, 2nd. Wiley, [ISBN: 978-0470748060].**

**Collentro V. William. (2010), Pharmaceutical Water: System: Design, Operation, and Validation, 2nd. CRC Press, [ISBN: 1420077821].**

**Lachman Leon. (2010), The theory an practice of industrial pharmacy, CBS Publishing and Distributors P Ltd, [ISBN: 978-8123916798].**

**Walsh, G. (2003), Biopharmaceuticals: Biochemistry and Biotechnology, Wiley.**

**Lachman Leon, Lieberman A. Herbert, Kanig L. Joseph. (1986), The Theory and Practice of Industrial Pharmacy, 3rd. Lea & Febiger, [ISBN: 978-0812109771].**


*This module does not have any article/paper resources*

*Other Resources*

**Link, Library Catalogue,**
**http://tinyurl.com/o3adncv**

**Link, Library Catalogue,**
**http://tinyurl.com/ke55lv2**

**Link, Library Catalogue,**
**http://tinyurl.com/lvl4bqg**