

<b>Full Title:</b>	Pharmaceutical Biotechnology
<b>Module Code:</b>	BITC S7012
<b>Credits:</b>	7.5
<b>Valid From:</b>	Semester 1 - 2013/14 ( September 2013 )
<b>Module Delivered in</b>	<a href="#">1 programme(s)</a>
<b>Module Description:</b>	The aims of this module are to provide an understanding of the applications, problems and uses of microorganisms in the pharmaceutical industry and to allow students the opportunity to acquire laboratory skills in the manipulation of industrially significant microbes and their products.
<b>Learning Outcomes:</b>	
<i>On successful completion of this module the learner should be able to</i>	
<ol style="list-style-type: none"> <li>1. Explain how micro-organisms and mammalian cells can be cultured on a large scale.</li> <li>2. Identify and differentiate between different expression systems for the production of biopharmaceuticals.</li> <li>3. Discuss bioprocessing and pharmaceutical products of microbial origin.</li> <li>4. Recognise microbial contamination and choose appropriate testing measures to avoid contamination in the pharmaceutical industry.</li> </ol>	

**Module Content & Assessment**

Indicative Content
<p><b>Introduction</b> Review of the structure, growth and metabolism of microbial cells. Beneficial use of microorganisms in industry. Properties of an Industrial Microorganism. Factors affecting the growth of Industrial Microorganisms.</p>
<p><b>Fermentation Technology</b> Modes of fermentation, reactor types, process control, scale-up.</p>
<p><b>Upstream Processing</b> A review of recombinant product generation. Recombinant E. coli and other recombinant prokaryotic systems. Yeast and fungal cell culture systems. Insect cells as expression systems. Recombinant animal cell lines and hybridoma cell lines. Transgenic plants and animals.</p>
<p><b>Downstream Processing</b> Cell harvesting, cell disruption, product recovery and protein purification.</p>
<p><b>Microbial contamination in the Pharmaceutical Industry</b> Microbial contamination in the pharmaceutical industry. Endotoxin and pyrogen detection and identification. Approaches to avoiding contamination, focus on sterilisation and cleanrooms.</p>
<p><b>Production of Pharmaceutical products</b> Selected Case studies: Production of antibiotics, vaccines and therapeutic enzymes.</p>
<p><b>Sample practical exercises</b> Yeast fermentation, GFP purification, Antibiotic production, Endotoxin testing, Industrial visits</p>

Assessment Breakdown	%
Course Work	10.00%
Practical	40.00%
End of Module Formal Examination	50.00%

**Full Time**

Course Work							
Assessment Type	Assessment Description	Outcome addressed	% of total	Marks Out Of	Pass Marks	Assessment Date	Duration
Short Answer Questions	There will be a 1-hour short question written examination half-way through the semester, the student will be required to answer 20 out of 20 questions.	1,2	10.00	0	0	Week 8	0

No Project
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Practical							
Assessment Type	Assessment Description	Outcome addressed	% of total	Marks Out Of	Pass Marks	Assessment Date	Duration
Practical/Skills Evaluation	A 3-hour practical session each week will provide the student with the opportunity to back up the theory covered in formal lectures with practical experience. Students must submit a written report of a professional standard on each laboratory session.	3,4	40.00	0	0	n/a	0

End of Module Formal Examination							
Assessment Type	Assessment Description	Outcome addressed	% of total	Marks Out Of	Pass Marks	Assessment Date	Duration
Formal Exam	End-of-Semester Final Examination	1,2,3,4	50.00	0	0	End-of-Semester	0

**DKIT reserves the right to alter the nature and timings of assessment**

**Module Workload & Resources**

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**Workload: Full Time**

Workload Type	Workload Description	Hours	Frequency	Average Weekly Learner Workload
		Total Weekly Learner Workload		00
		Total Weekly Contact Hours		00

This course has no Part Time workload.

Resources
<i>Recommended Book Resources</i>
<p>S. Denyer, N.A. Hodges and S.P. Gorman 2011, <i>Hugo and Russell's Pharmaceutical Microbiology</i>, 8th Ed., Wiley-Blackwell</p> <p>M. Waites, N.L. Morgan, J.S. Rockey and G. Higton 2009, <i>Industrial Microbiology</i>, Wiley-Blackwell (available on DkIT Dawsonera online collection)</p> <p>G. Walsh 2003, <i>Biopharmaceuticals: Biochemistry and biotechnology</i>, 2nd Ed., Wiley</p> <p>J.E. Smith 2009, <i>Biotechnology</i>, 5th Ed., Cambridge University Press</p> <p>N.J. Hoboken 2007, <i>Handbook of pharmaceutical biotechnology</i>, Wiley-Interscience</p>
<i>Supplementary Book Resources</i>
<p>Madigan et al. 2011, <i>Brock Biology of Microorganisms</i>, 13th Ed., Pearson education</p> <p>L.M. Prescott 2005, <i>Microbiology</i>, McGraw-Hill</p>
<i>Recommended Article/Paper Resources</i>
<p>A. Demain 2000, <i>Small bugs, big business: The economic power of the microbe</i>, <i>Biotechnology Advances</i>, 18, 499-514</p> <p>N. Ferrer-Miralles, J. Domingo-Espin, J.L. Corchero, E. Vazquez, A. Villaverde 2009, <i>Microbial factories for recombinant pharmaceuticals</i>, <i>Microbial Cell Factories</i>, 8 (17), 1-8</p>
<i>Other Resources</i>
<p>Website: <i>European Biopharmaceutical Enterprises</i>, <a href="http://www.ebe-biopharma.org/">http://www.ebe-biopharma.org/</a></p> <p>Website: <i>FDA/Center for Drug Evaluation and Research</i>, <a href="http://www.fda.gov/">http://www.fda.gov/</a></p> <p>Website: <i>United States Food and Drug Administration</i> <a href="http://www.fda.gov/CDER">http://www.fda.gov/CDER</a></p> <p>Website: <i>British Pharmacopoeia</i> <a href="http://www.pharmacopoeia.co.uk">http://www.pharmacopoeia.co.uk</a></p> <p>Journal search database: <i>Entrez PubMed</i>, <a href="http://www.ncbi.nlm.nih.gov/entrez">http://www.ncbi.nlm.nih.gov/entrez</a></p> <p>Journal search database: <i>Science Direct</i> <a href="http://www.sciencedirect.com">http://www.sciencedirect.com</a></p> <p>Link: <i>Library Catalogue</i> <a href="http://tinyurl.com/ma8ghwb">http://tinyurl.com/ma8ghwb</a></p>

### Module Delivered in

Programme Code	Programme	Semester	Delivery
DK_SPHAR_7	<a href="#">Bachelor of Science in Pharmaceutical Science</a>	5	Mandatory