



University
of Worcester

Institute of Science
and the Environment

Postgraduate Certificate (PgCert) Medical Communications



Welcome to the PgCert in Medical Communications

This handbook is designed to provide you with a basic outline of how the PgCert Medical Communications course operates, to answer any questions that you have and to provide study guides for assessment criteria. It contains useful and important information; please take the time to read it carefully.

The field of Medical Communications has expanded alongside the explosion of novel pharmacotherapies being profiled and marketed by pharmaceutical and biotechnology companies. As a result, Medical Writers are currently in high demand in the UK and internationally within the pharmaceutical industry, at Clinical Research Organisations and with Medical Communications companies. However, specific vocational training for Medical Writers is currently not available and as a result graduates of Biosciences struggle to gain the editorial experience needed to make them attractive to employers in the field. The aim of the PgCert in Medical Communications is to prepare bioscience graduates for a career as a Medical Writer by covering areas where candidates currently lack training.

The specific aims of the PgCert in Medical Communications are:

- To develop awareness of the role of a Medical Writer
- To enable students to identify specific healthcare audiences and to raise awareness via different modes of effective communications
- To develop data interpretation techniques
- To provide an understanding of legislation involved with medical communications
- To train students in client relations
- To introduce students to clinical trial documentation and processes
- To enable students to apply publication planning processes

We want you to have an enjoyable and successful time at the University of Worcester. If you have any queries or concerns, however minor they may seem, please contact me.

Dr Shelley Davies
s.davies@worc.ac.uk
(01905) 542372

This course is offered subject to sufficient recruitment figures.

The University of Worcester is committed to ensuring that disabled people, including those with specific learning difficulties and/or mental health difficulties are treated fairly. Reasonable adjustments to provision will be made to ensure that disabled students and other disabled people are not disadvantaged. This handbook can be provided in a variety of formats upon request.

This handbook is for advice and guidance only and is not a substitute for the formal Academic Regulations and Procedures of the University of Worcester. In case of any conflict these formal statements and requirements take precedence over the handbook.

Every effort has been made to ensure the accuracy of the information contained in the handbook at the time of publication. The University reserves the right to change the information given at any time.

Awarding institution/body: University of Worcester

Final award: PG Cert Medical Communications

Entry requirements:

- A minimum 2nd class BSc (Hons) in a Bioscience, Life Science or Biomedical Science related subject area.
- Evidence of publications and/or relevant professional working experience is desirable.
- If English is not your first language, you will be expected to have reached a sufficient standard on admission to the course (minimum IELTS 7.5)
- Shortlisted applicants will normally be invited for a telephone interview.
- For further advice, please contact the Course Leader Dr Shelley Davies directly on 01905 542372 or on s.davies@worc.ac.uk.
- Students are required to have access to a home PC, office software and internet facilities for this course, due to the element of distance learning involved.

Modules: This PgCert will encompass 3x 20 credit modules (specific module specifications are included in the Appendix):

- Clinical development of Medicines
- Medical publication and promotion processes
- Fundamentals of Medical Writing

Each module will have its own individual assessment components. The assessment strategy is designed to provide students with the knowledge and skills that are required to work as a Medical Writer in the professional environment of a Medical Communications company.

Course structure and scheduling:

- This course is part-time over 1 year
 - October – December: Clinical development of Medicines
 - January – April: Medical publication and promotion processes
 - May – August: Fundamentals of Medical Writing
- There will be a standard taught programme held over weekends (one weekend per month – this may be a Saturday only or a Saturday and a Sunday; prior notice will be given in advance)
- Taught sessions usually run from 10am – 5pm, with breaks incorporated
- There will be additional on-line material, support and discussion as distance learning will be a major element of this course.
- While the university cannot provide accommodation for weekend sessions we can advise you about local accommodation, which, if booked up in advance, can be very cost-effective.

Where will you be studying?:

- This course involves a large proportion of distance learning, therefore, the majority of the time you will be studying from the comfort of your own home!
- When you have taught sessions, lectures and workshops will be held at the University's brand new 'City Campus' with state of the art teaching facilities, IT facilities and wireless internet access.
 - Address: University of Worcester City Site, Infirmary Walk (corner of Castle Street), Worcester, WR1 3AS.
 - This location is a very short walk from Worcester Foregate Street train station (on the main line from London Paddington, Oxford and Birmingham New Street) and a short drive from the M5 (exit at junction 6 or 7).

Course fees (for 2011/12 study): £500 per module (fees for international students may differ, please enquire for further details)

How to apply: Go to 'How to apply' at the bottom of the course webpage (<http://www.worc.ac.uk/courses/13964.html>) and follow the instructions.

Appendix: Module Specifications

*Module Title:	Clinical development of Medicines
*Department:	Institute of Science and the Environment
*Subject:	Institute of Science and the Environment – Biological Sciences
Module Leader:	Dr. Shelley Davies
*Module Type and Restrictions:	Postgraduate degree (PgCert) Closed module.
*Level:	Levels 7 (M)
*Module Credits:	20 Credits
*Module Status in relation to courses:	Mandatory
*Pre-requisites:	n/a
*Co-requisites:	n/a
*Excluded combinations:	n/a
*Location of Teaching:	University of Worcester
Short Module Descriptor:	A key element of drug development is the progress from preclinical investigations to clinical trials. This involves careful trial design to investigate predetermined efficacy and safety outcomes via appropriate data analysis techniques. Such trials require review and approval from Health Authority/Ethics Committee. This module will involve lecture and distance learning material to provide training in the clinical development and approval process.
*Rationale:	A Medical Writer plays a key role in the construction of approval documentation and works with the pharmaceutical team to draw out key educational messages from the clinical data for publication and marketing purposes. A clear understanding of the processes and regulations surrounding the clinical development of medicines is essential to generate accurate documentation and to advise clients effectively.
*Intended Learning Outcomes	On successful completion of the module, students should be able to: <ul style="list-style-type: none"> • Demonstrate originality and professionalism in the generation of effective communication strategies targeted to specialist and non-specialist audiences • Demonstrate an advanced knowledge of the importance of concise and accurate presentation and data interpretation • Demonstrate an understanding of, and an ability to, critically evaluate clinical trial protocols, reports, outcome measures and variables • Appraise statistical analysis techniques applicable to clinical trial data. • Apply scientific knowledge to Medical Communications scenarios

Indicative Content	<ul style="list-style-type: none"> • Clinical trial design • Informed consent • Variables and measurements – pharmacokinetics/pharmacodynamics, efficacy and safety measures, quality of life • Content and structure of clinical trial documentation • Statistical analyses for the health sciences • Regulatory procedures/bodies in clinical development • Transforming data • From Clinical Study Report (CSR) to publication • Poster presentation 									
*Mode of Module Delivery	<p>A mixture of lectures, tutorials and distance learning. Students will be required to attend a maximum of four mandatory contact sessions, held on weekends; a maximum total of 30 hours.</p> <p>Students will be expected to commit 170 hours to distance learning. This will be split in to 3 distinct activities:</p> <ol style="list-style-type: none"> 1. Summative assessment work 2. Study in an e-learning environment 3. Independent and directed study 									
Learning and Teaching Activities	<p>Mandatory contact sessions will be delivered in the form of lectures and tutorials.</p> <p>e-learning will be delivered via material added to the University of Worcester Blackboard site specific to this module and will include discussions boards and formative assignments.</p>									
Use of learning technologies	<p>e-learning will be delivered via material added to the University of Worcester Blackboard site specific to this module and will include discussions boards and online tests. All students registered on the module will be supplied with their own log-in details for the e-learning facilities. e-learning will be incorporated into the 170 hours of distance learning allocated to the module and will support the 30 hours of face-to-face contact time.</p>									
*Attendance Policy /Requirement	<p>Mandatory attendance for timetabled contact time (lectures, tutorials). Many students are expected to reside outside the locality. Contact time is thus essential to ensure progression and that students receive appropriate support and complete assessment criteria, which may be timetabled.</p>									
*Assessment Details	<p>Students must pass all assessments to pass the module:</p> <table border="1" data-bbox="496 1664 1425 2004"> <thead> <tr> <th data-bbox="496 1664 805 1756">Summative Assessment Items</th> <th data-bbox="805 1664 1115 1756">Indicative Word Limit or equivalent (e.g. time)</th> <th data-bbox="1115 1664 1425 1756">Weighting</th> </tr> </thead> <tbody> <tr> <td data-bbox="496 1756 805 1881">Individual poster presentation</td> <td data-bbox="805 1756 1115 1881">2000 words</td> <td data-bbox="1115 1756 1425 1881">50%</td> </tr> <tr> <td data-bbox="496 1881 805 2004">Problem-based learning coursework</td> <td data-bbox="805 1881 1115 2004">1500 words</td> <td data-bbox="1115 1881 1425 2004">50%</td> </tr> </tbody> </table>	Summative Assessment Items	Indicative Word Limit or equivalent (e.g. time)	Weighting	Individual poster presentation	2000 words	50%	Problem-based learning coursework	1500 words	50%
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Individual poster presentation	2000 words	50%								
Problem-based learning coursework	1500 words	50%								

Sample Assignments	<p>Individual poster presentation: 'Using excerpts from a clinical study report generate a poster presentation highlighting the key educational messages'</p> <p>Problem-based learning coursework: 'Clinical safety outcomes from a clinical trial have demonstrated some concerning adverse events. Students should critically evaluate the impact of these data on the development of this particular agent'.</p>
Key Texts	<ul style="list-style-type: none"> • Chin, R. & Lee BY. Principles and Practice of Clinical Trial Medicine. Academic Press; 1 edition (28 July 2008) <ul style="list-style-type: none"> ○ ISBN-10: 0123736951 ○ ISBN-13: 978-0123736956 • Petrie A. & Sabin C. Medical Statistics at a Glance. WileyBlackwell; 3rd Edition edition (10 July 2009) <ul style="list-style-type: none"> ○ ISBN-10: 140518051X ○ ISBN-13: 978-1405180511
Indicative Bibliography and other learning resources	<p>http://www.icr-global.org/</p> <p>http://www.icr.ac.uk/research/research_sections/clinical_trials/index.shtml</p>
Date Module Specification Validated	June 2010

*Module Title:	Medical publication and promotion processes
*Department:	Institute of Science and the Environment
Module Leader:	Dr. Shelley Davies
*Module Type and Restrictions:	Postgraduate degree (PgCert) Closed module.
*Level:	Levels 7 (M)
*Module Credits:	20 Credits
*Module Status in relation to courses:	Mandatory
*Pre-requisites:	n/a
*Co-requisites:	n/a
*Excluded combinations:	n/a
*Location of Teaching:	University of Worcester
Short Module Descriptor:	A Medical Writer can be involved in the development of a drug from its preclinical to clinical stages. The dissemination of data from drug studies is crucial to progress a drug to approval stages. Publication and marketing processes play a key role in this; generated material must adhere to the regulations set out by international governing bodies. Students will be trained in the codes of practice applicable.
*Rationale:	The implementation of medical publications and drug promotion processes is essential for the progression of a drug to approval status; however it is tightly regulated. Students will be trained in the codes of practice applicable.
*Intended Learning Outcomes	<p>On successful completion of the module, students should be able to:</p> <ul style="list-style-type: none"> • Display an ability to systematically and creatively deal with client and strategic issues • Demonstrate an understanding of, and an ability to, critically evaluate clinical trial protocols, reports, outcome measures and variables • Show sound judgement in designing, constructing and executing a publication plan • Demonstrate an ability to implement good publication practice (GPP) guidelines • Reflect upon compliance issues via Good Clinical Practice, FDA Regulations, EU Directives and ICH Guidelines.

Indicative Content	<ul style="list-style-type: none"> • Publication planning strategies • Good publication practice (GPP) • Revisiting the teams involved in publications and drug promotion • Branding • OTC treatments • Identifying and working with Key Thought Leaders (KTLs) • Good Clinical Practices (GCP) 									
*Mode of Module Delivery	<p>A mixture of lectures, tutorials and distance learning. Students will be required to attend a maximum of four mandatory contact sessions, held on weekends; a maximum total of 30 hours.</p> <p>Students will be expected to commit 170 hours to distance learning. This will be split in to 3 distinct activities:</p> <ol style="list-style-type: none"> 1. Summative assessment work 2. Study in an e-learning environment 3. Independent and directed study 									
Learning and Teaching Activities	<p>Mandatory contact sessions will be delivered in the form of lectures and tutorials. e-learning will be delivered via material added to the University of Worcester Blackboard site specific to this module and will include discussions boards and formative assignments.</p>									
Use of learning technologies	<p>e-learning will be delivered via material added to the University of Worcester Blackboard site specific to this module and will include discussions boards and online tests. All students registered on the module will be supplied with their own log-in details for the e-learning facilities. e-learning will be incorporated into the 170 hours of distance learning allocated to the module and will support the 30 hours of face-to-face contact time.</p>									
*Attendance Policy /Requirement	<p>Mandatory attendance for timetabled contact time (lectures, tutorials). Many students are expected to reside outside the locality. Contact time is thus essential to ensure progression and that students receive appropriate support and complete assessment criteria, which may be timetabled.</p>									
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Summative Assessment Items	Indicative Word Limit or equivalent (e.g. time)	Weighting								
Case study	2000 words	50%								
Report	1500 words	50%								
Sample Assessments	<p>Case study: 'Review clinical study documents and informed consent forms for completeness and compliance. Adhere to GCP'</p> <p>Report: 'Generate a publication plan for a client brief, adhering to GPP'</p>									

Key Texts	<p>Miller FP, Vandome AF., McBrewster J. Pharmaceutical Industry: Drug discovery, Drug development, Food and Drug Administration (United States), Orphan drug, Pharmaceutical marketing, Prescription Drug Marketing Act. Alphascript Publishing (8 Oct 2009)</p> <ul style="list-style-type: none"> • ISBN-10: 6130046162 • ISBN-13: 978-6130046163
Indicative Bibliography and other learning resources	<p>http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/index.htm</p> <p>http://www.ich.org/LOB/media/MEDIA482.pdf</p> <p>http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416</p> <p>http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm</p> <p>http://www.ema.europa.eu/pdfs/human/ich/013595en.pdf</p> <p>http://www.nice.org.uk/aboutnice/whatwedo/aboutclinicalguidelines/about_clinical_guidelines.jsp</p> <p>http://apps.who.int/medicinedocs/en/d/Js8109e/7.1.html</p> <p>http://www.thepublicationplan.com/</p>
Date Module Specification Validated	June 2010

*Module Title:	Fundamentals of Medical Writing
*Department:	Institute of Science and the Environment
Module Leader:	Dr. Shelley Davies
*Module Type and Restrictions:	Postgraduate degree (PgCert) Closed module.
*Level:	Levels 7 (M)
*Module Credits:	20 Credits
*Module Status in relation to courses:	Mandatory
*Pre-requisites:	n/a
*Co-requisites:	n/a
*Excluded combinations:	n/a
*Location of Teaching:	University of Worcester
Short Module Descriptor:	The purpose of this module is to prepare students for their role as a Medical Writer. This will encompass an exploration of the responsibilities of a Medical Writer and the writing and communication skills applicable to their role in a Medical Communications company. This module will involve standard seminar-based lecture material along with the expectation that students can transfer their knowledge to specific case study scenarios linked to the role.
*Rationale:	The role of a Medical writer requires excellent team work, strategic/creative thinking, client liaison and extensive attention to detail. The aim of this module is to expose students to the real-life role of a Medical Writer in a Medical Communications company, and to provide training in key elements of this role.
*Intended Learning Outcomes	On successful completion of the module, students should be able to: <ul style="list-style-type: none"> • Reflect on the professional role of a Medical Writer in practice and contribute effectively to a team-based problem solving exercise • Demonstrate originality and professionalism in the generation of effective communication strategies targeted to specialist and non-specialist audiences • Display an ability to systematically and creatively deal with client and strategic issues • Demonstrate an advanced knowledge of the importance of concise and accurate presentation and data interpretation • Apply scientific knowledge to Medical Communications scenarios

Indicative Content	<ul style="list-style-type: none"> • The diverse role of a Medical Writer • Structure and organisation of Medical Communications • Methods of communication • How to generate different and effective communication materials • Targeting your Audience • Key educational messaging • Abstract generation and summarising • Referencing techniques and software packages • Client liaison • Thinking strategically for your client • Writing skills • Proofreading • Group presentation skills
*Mode of Module Delivery	<p>A mixture of lectures, tutorials and distance learning. Students will be required to attend four mandatory contact sessions, held on weekends; a total of 30 hours.</p> <p>Students will be expected to commit 170 hours to distance learning. This will be split in to 3 distinct activities:</p> <ol style="list-style-type: none"> 1. Study in an e-learning environment 2. Independent and directed study 3. Summative assessment work
Learning and Teaching Activities	<p>Mandatory contact sessions will be delivered in the form of lectures and tutorials.</p> <p>e-learning will be delivered via material added to the University of Worcester Blackboard site specific to this module and will include discussions boards and formative assignments.</p>
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Assignment	1000 words	40%											
Group oral presentation	20 minutes	40%											
Contribution to group work	300 words with supporting evidence	20%											
<p>Sample Assignments</p>	<p>Assignment: ‘Critically evaluate a data table provided by your client and develop two pieces of marketing material based on the brief included – one for a specialist audience and one for a non-specialist audience.’</p> <p>Group oral presentation: ‘Based on the marketing materials generated from your client brief, present the logic behind the development of these and future product development possibilities for your client’</p> <p>Contribution to group work: ‘Submit a formal statement of the responsibilities and contributions of the group members agreed by the group, signed by all. This should be accompanied by minutes of group meetings.’</p>												
<p>Key Texts</p>	<ul style="list-style-type: none"> • Goodman N. W., Edwards M.B., Black A. Medical writing: a prescription for clarity. Cambridge University Press; 3 edition (26 Oct 2006) • Wager E. Getting Research Published: An A to Z of Publication Strategy. Radcliffe Publishing Ltd; 2nd Revised edition (24 Mar 2010) 												
<p>Indicative Bibliography and other learning resources</p>	<ul style="list-style-type: none"> • Stuart, M. The Complete Guide to Medical Writing. Pharmaceutical Press; 1 edition (16 April 2007) • Fraser, J. How to Publish in Biomedicine. Radcliffe Publishing Ltd; 2Rev Ed edition (26 April 2008) • Seeley, J. Oxford A-Z of Grammar and Punctuation. OUP Oxford; 2 edition (27 Aug 2009) 												
<p>Date Module Specification Validated</p>	<p>June 2010</p>												