

Documentation/Configuration Management for Biomedical Industry

Certificate Program 2011-2012

Program Requirements	15
Additional Requirements	3
TOTAL CREDITS.....	18

PROGRAM INFORMATION:

This certificate program prepares students to work in positions involved with documentation/configuration management within the biomedical device and products industry. Graduates will work in developing and managing documentation and configuration. Classes include specific biomedical coursework in storing, managing and retrieving medical device documentation. For additional information about our biomedical programs, visit our Web site at <http://www.AnokaRamsey.edu>.

PROGRAM GOALS:

By completing this certificate, students will achieve the following learning goals:

- 1) demonstrate an understanding of the elements of configuration management including design and development of a document change control system;
- 2) demonstrate a global understanding of the governmental regulations and implications in establishing and maintaining a configuration management system;
- 3) demonstrate an understanding of the benefits, scope and elements of medical device documents and configuration management control system;
- 4) demonstrate an understanding of management responsibilities as they relate to document/configuration management.

APPLICATION

To receive this certificate, submit a Certificate Application to the Records and Registration Office. Applications are available in Academic Advising Services, or the Records and Registration Offices on either campus.

GENERAL INFORMATION:

College-level competence in English, writing, mathematics, and computer competency should be acquired before entering the BMED programs. All BMED Program requirements are offered at the Coon Rapids campus.

DEVELOPMENTAL COURSES:

Some students may need preparatory courses in the areas of English, reading, or mathematics. Courses numbered below 1000 will not apply toward this certificate program.

COMPLETION REQUIREMENTS:

- A minimum of 12 semester credits must be completed at ARCC.
- A minimum cumulative grade point average (GPA) of 2.0 in courses numbered 1000 or above at ARCC.
- BMED 1100 is strongly recommended as a first class for those with no previous biomedical device industry experience.
- A minimum grade of C must be earned in all Program requirements.
- All Program requirements must be completed through Anoka-Ramsey Community College.
- All course requirements must be completed before a certificate will be awarded.

Program Requirements: 15 credits

- BMED 2100 Design & Manufacturing in the Medical Device Industry 3
- BMED 2200 Introduction to Medical Device Regulations/Ethics 3
- BMED 2500 Introduction to Documentation/Configuration Management 3
- BMED 2510* Introduction to Database Management for Medical Device Industry..... 3
- BMED 2520* Technical Writing for Regulated Industries 3

Additional Requirements 3 credits

- BUS 1119* Introduction to Relational Databases..... 3

Program Sequence:

The sequence that follows is suggested for full-time students. Part-time students may need more time to complete this program; many courses are offered in the evening.

FIRST YEAR	Fall Semester	Spring Semester
	BMED 2100.....3	BMED 2520.....3
BMED 2200.....3	BMED 2510*3	
BUS 1119*3	BMED 2500.....3	
TOTAL 9	TOTAL 9	

GAINFUL EMPLOYMENT DISCLOSURE REPORT

* Course has a prerequisite. Prerequisites are listed on the course schedule and in the ARCC Catalog Course Descriptions pages.

NOTE: The requirements of this program are subject to change without notice. You are encouraged to contact an academic advisor, Cambridge Campus 763.433.1840 or Coon Rapids Campus 763.433.1240, for course planning assistance and information about transfer credit evaluation.

