

Quality Systems for Biomedical Industry

Certificate Program 2012-2013

Program Requirements..... 18
TOTAL CREDITS.....18

PROGRAM INFORMATION:

This certificate program prepares students to meet the critical industry-specific educational needs in quality assurance and present the regulatory and quality standards that are required for the medical device industry. Graduates will work in quality assurance and compliance, manufacturing and production. Classes include specific biomedical coursework in medical device design and manufacturing, regulatory environment risk and management for medical devices. 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. Evaluate a quality management system as it conforms to Food and Drug Administration (FDA) regulatory requirements.
2. Demonstrate an understanding of medical device-related risk assessment and evaluation through written course assessments.
3. Show how FDA regulations and compliance pertain to the design and manufacturing of medical devices.
4. Communicate understanding of the change control procedures, including documentation, communication, and quality assurance through written examples.

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.

COMPLETION REQUIREMENTS:

- BMED 1100 is strongly recommended as a first class for those with no previous biomedical device industry experience.
- BMED 2300 should be taken prior to or concurrent with BMED 2310, 2320.
- A minimum grade of C must be earned in all BMED program requirements.
- All program requirements must be completed through Anoka-Ramsey Community College.
- A minimum of 12 semester credits must be completed at ARCC.
- All course requirements must be completed before a certificate will be awarded.
- All course requirements must be completed before a certificate will be awarded.

Program Requirements:

18 credits

- | | | | |
|--------------------------|-----------|---|---|
| <input type="checkbox"/> | BMED 2100 | Design & Manufacturing in the Medical Device Industry..... | 3 |
| <input type="checkbox"/> | BMED 2200 | Introduction to Medical Device Regulations/Ethics | 3 |
| <input type="checkbox"/> | BMED 2300 | Introduction to Quality Assurance for Medical Devices | 3 |
| <input type="checkbox"/> | BMED 2310 | Risk Management and Assessment for Medical Devices | 3 |
| <input type="checkbox"/> | BMED 2320 | Quality Management for Medical Devices..... | 3 |
| <input type="checkbox"/> | BMED 2500 | Intro to Documentation/Configuration Management..... | 3 |

For more information about our program graduation rates, the median debt of students who completed the program, and other important information, please visit our Web Site at <http://anokaramsey.edu/classes/Certificates/Quality%20Systems%20-%20Certificate.aspx> and click on the "Gainful Employment Disclosure Report" link at the bottom of the page.

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.

