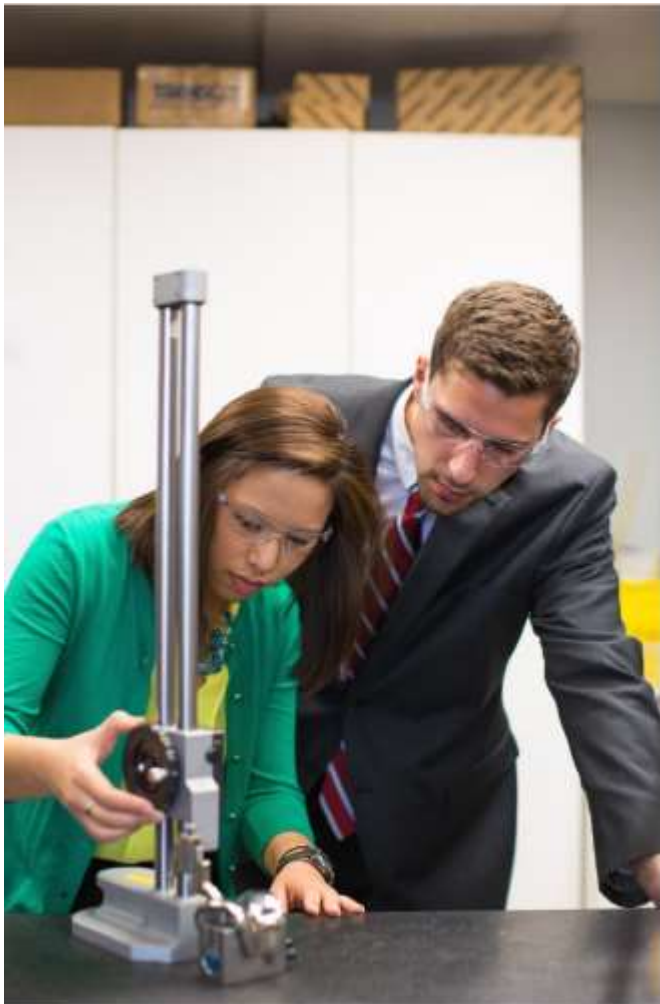


## GRACE COLLEGE AND SEMINARY CATALOG | 2016-2017

### Medical Device Quality Management (MDQM)



#### Faculty

Stephen Grill, Ed.D., Program Director

#### Guest Professors

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## **Medical Device Quality Management Program (MDQM)**

The Medical Device Quality Management (MDQM) program is a three-track program leading to either a certificate (15 credit hours), a Bachelor of Science degree-completion (60 credit hours), or a Master of Science degree (36 credit hours). On-ground courses are offered in a non-traditional format to accommodate working adults and are web-assisted.

The MDQM Program targets the following student clientele:

1. Existing Quality Affairs (QA) employees who desire career advancement/enrichment.
2. New managers to Quality.
3. Medical device professionals in other fields who desire to launch a career in Quality Management.
4. Recent college graduates from programs such as business management, engineering/manufacturing, pre-law, and pre-medicine who want to enter the medical device industry.

Classes are taught by industry leaders selected for their technical and educational expertise, working on real-life quality-control projects, and selected for not only their education and expertise, but also their exceptional teaching abilities.

### **Program Purpose**

The Medical Device Quality Management (MDQM) program exists to train and develop individuals who are currently employed in, or wish to enter the medical device industry or related industries. The five courses in this program can be applied to a certificate, bachelor's degree, or master's degree, depending on the student's academic background and educational goals. The MDQM program focuses on the critical elements in quality management, including quality systems, post-market surveillance, design control and assurance, manufacturing quality and supply chain management, and statistical processes that ensure excellence at key stages of the medical device life cycle.

The MDQM program is part of the OrthoWorx Center of Excellence at Grace College and exists to support the talent development needs of the multi-billion dollar orthopaedic industry. Warsaw, Indiana, is adjacent to Grace College in Winona Lake, and is considered "The Orthopaedic Capital of the World."

Industry and educational leaders were consulted during the program's development and will continue to provide oversight for this dynamic and evolving field of study.

### **Program Co-Requisites**

Accepted students coming directly from college or from a non-related industry may be required to complete an industry practicum in addition to the required coursework.

### **Schedule and Delivery Format**

Certificate classes are conducted in a one-night-a-week format January through July;

Bachelor's classes are also offered year-'round in an evening and weekend format, starting each fall.

Master's classes are a mix of evening and weekend formats, with weekend classes running Friday afternoons and Saturday mornings, two weekends per month over a fifteen month timeframe, beginning in the spring. An additional 12-15 hours per course of independent study related to content, readings, and projects are facilitated through Grace College's online learning management system.

Please contact [deckerap@grace.edu](mailto:deckerap@grace.edu) for more information regarding the academic calendar.

All students must have regular access to a computer. Information regarding the technology and user-skill requirements is available on the technology support page of the institution's website. The MDQM program is also designed to accommodate distance learning through videoconferencing technology. *Note:* strictly distance learners may be assessed an additional resource fee.

## Admission Requirements

**Certificate, Bachelor's and Master's Tracks:** A completed application for admission. See [www.grace.edu/mdqm](http://www.grace.edu/mdqm) to complete an application online.

### Bachelor's Degree-Completion Admission Requirements

1. Adult Degree Completion Application
2. All transcripts of previous college coursework.
3. If applicable, a portfolio detailing experiential learning (information on how to produce an acceptable portfolio will be provided).
4. Personal reference
5. See the GOAL Program section of the catalog for other admissions requirements.

### Master's Degree Admission Requirements

1. A completed bachelor's degree from an accredited institution with a cumulative grade point average of at least 2.75. Transcripts from all post-secondary schools attended will be required as part of the student's application file.

*Note:* In some cases, qualified applicants may be able to complete a bachelor's degree and this graduate program concurrently.

2. A positive professional reference.
3. A personal resume/vitae that reflects the appropriate level of scholarship and/or experience required to be successful in an accelerated graduate program.
4. At this time, the Graduate Records Exam (GRE) is **not** required for admission.

## Tuition Costs and Refunds

For information about tuition costs and refunds please view the [tuition pricing sheet](#).

## Grading Procedures

For information about grading policies and procedures, please view the institution's [Academic Policy Manual](#).

## Notice of Nondiscrimination

Grace College and Seminary is a private, not-for-profit, faith-based exempt organization as described in Section 501 (c) 3 of the Internal Revenue code. In compliance with applicable federal and state laws, Grace College and Seminary does not discriminate on the basis of race, color, national origin, age, sex, or disability in its administration of its educational policies, admissions policies, scholarship and loan programs, and athletic and other school-administered programs and activities, or in employment.

The following person has been designated to handle inquiries regarding the Notice of Nondiscrimination:

Carrie Yocum, Title IX Coordinator and VP of Administration and Compliance  
Grace College and Seminary  
McClain 104  
200 Seminary Drive  
Winona Lake, IN 46590  
[yocumca@grace.edu](mailto:yocumca@grace.edu)  
574-372-5100 x6491

Inquiries may also be addressed to the U.S. Department of Education's Office for Civil Rights at 400 Maryland Avenue, SW, Washington, DC 20202-1100.

## Community Lifestyle Pledge

Students agree to show respect for the faith commitment that Grace practices and agree to abide by certain of the institution's community guidelines (avoidance of disrespecting others, sexual misconduct, illegal drugs, gambling, coarse or obscene language, tobacco, alcoholic beverages, and such conduct) while on campus or engaged in Grace activities. The student understands that this extends to any advocacy initiatives in which the individual might participate while a Grace student.

## Contact

For additional information about admission requirements or course enrollment and completion, please contact the School of Professional and Online Education, Prof. Allyn Decker, Director, OrthoWorx Center of Excellence at Grace College, 200 Seminary Drive, Winona Lake, IN 46590; telephone: 574-372-5100, ext. 6509 or 855-267-6722; fax: 574-372-5120; email: [deckerap@grace.edu](mailto:deckerap@grace.edu); or visit: [www.grace.edu/mdqm](http://www.grace.edu/mdqm)

## Course Descriptions

Note:

- MDQM Certificate track consists of only QMD 1000, 1100, 1200, 1300 and 1400.
- The Bachelor's track substitutes QMD 3000-3400 courses for five courses in the GOAL degree-completion curriculum.
- Master's track consists of all courses listed below.
- RCA courses meet in a one-month weekend format;
- QMD courses meet in a five-week, evening format.

### **RCA 4900 Orthopaedic Foundations**

The student will be introduced to the ORCA and MDQM programs and staff, as well as the larger campus community and the resources available to them. Additionally, the history of orthopaedic medical device manufacturing will be discussed, as well as current industry issues and the economic implications of being located in the "Orthopaedic Capital of the World". Students will follow the life of an orthopedic product from concept to obsolescence. Along the way, the role of the FDA and regulatory and clinical affairs will be showcased and careers paths will be explored. Three hours.

### **RCA 5000 Orthopaedic Anatomy and Physiology**

This course is an introduction to the general anatomy and physiology of the musculoskeletal system and related structures. This course includes structural make-up, group composition, relationships, and location of each bone. Common types of fractures and treatments will be discussed. Also covered will be common pathologies and treatment options relevant to the orthopaedic medical device industry in general. Three hours.

### **RCA 5100 Introduction to Medical Device Law**

This course will examine the role of the law in the orthopaedic medical device industry and in the American health care system. The course will provide an understanding of the laws, statues, and regulations affecting the orthopaedic medical device industry. The course will include discussion of the interplay between ethics and law. The role of government in the regulation of the medical device industry will be examined. Three hours.

### **RCA 5300 Writing for Regulatory and Clinical Affairs**

This course will review the elements of effective technical writing. The course will identify the types and nature of documents created by medical device professionals and will provide the student with the opportunities to develop skills needed to successfully author and edit such documents. Three hours.

**RCA 5500 Regulation of Medical Devices: Submissions**

This course covers the regulation of medical devices by government and the requirements to demonstrate safety and efficacy to the government prior to the device being allowed by them on the market. This demonstration is called a "submission". This course focuses strictly on medical devices, with an emphasis on the orthopaedic industry. Three hours.

**RCA 5700 Regulation of Medical Devices: Compliance**

This course prepares the student to understand the history and scope of the FDA's oversight of the medical device industry. Students will also learn best practices for building internal compliance systems and working with the FDA through the entire examination process. Three hours.

**QMD 1000, 3000, 5000 Quality Systems**

Students will receive a comprehensive overview to quality management in general, with specific applications made to the medical device industry. Case histories and in-class exercises will help demonstrate these critically important concepts. Students will also be introduced to key regulations that guide quality management efforts. Three hours.

**QMD 1400, 3400, 5400 Survey in Statistics**

Statistical information is used extensively in quality management and students will be exposed to the core concepts, formulas, and applications used in statistical analysis. Software tools will be explored and students will have an opportunity to apply conceptual information to real-world medical device scenarios. Three hours.

**QMD 1200, 3200, 5200 Design Control and Assurance**

Quality management begins at the design stage. Engineers must know how to build and manage the design history file so that key decisions and findings are recorded accurately. Students will build a DHF in a team environment and will apply project management principles over the span of this course. Three hours.

**QMD 1100, 3100, 5100 Post Market Surveillance**

Once a device is released to the market, some of the most challenging quality management work is required. Students will be exposed to situations that require close monitoring and ongoing communication with manufacturing partners, physicians, patients, and regulating bodies so that issues can be resolved effectively. Three hours.

**QMD 1300, 3300, 5300 Manufacturing Quality & Supply Chain Management**

Quality management must extend to external partners including vendors, suppliers, and contract manufacturers. This course explores those critically important external relationships and the safeguards that must be in place for maintaining the highest levels of quality across the entire supply chain. Three hours.

**QMD 5400 Applied Project (Master's Students Only)**

This capstone course is comprised of five unit projects representing the subject matter covered in the previous five quality (QMD) courses in the curriculum. Each student's unit project proposal must be approved by the respective instructor. A final presentation and portfolio are required. Three hours.