This graduate program is targeted to professionals who desire a thorough knowledge of the laws and regulations mandated by the federal government, especially the FDA, as they apply to the development, testing, approval, manufacturing, and commercialization of orthopaedic products.
Two Options

• 24 hour graduate certificate in Regulatory or Clinical Affairs
• 36 hour master’s degree in Regulatory and Clinical Affairs
Professors

They are experts in the industry, working on real-life regulatory projects and clinical studies.
Let’s meet some of them.
RCA 540 Acquiring and Managing Clinical Data

Director, WW Biostatistics & Data Management, DePuy Orthopaedics

M.B.A. State University of New York at Albany; M.S. Biostatistics, Western Michigan University; B.A. Mathematics, Hope College.
Dr. Jordan Lee

RCA 550 Regulation of Medical Devices: Submissions

Regulatory Affairs Manager, DePuy Orthopaedics

Ph.D. Philosophy, University of Wisconsin at Madison; M.S., University of Wisconsin at Madison; M.S. University of Alabama; Bachelor of Engineering Science and Mechanics, Georgia Institute of Technology. Jordan has four patents in the field of orthopaedics, and continues work on an additional seventeen patent applications.
Other Professors in ORCA

Mark T. Piazza
Principal, Mark T. Piazza, LLC; Retired Assistant General Counsel/Corporate Counsel/Vice President, Law and Secretary, DePuy Orthopaedics
RCA510 Introduction to Medical Device Law

Dr. Theodore Wendt
Consultant in Regulatory Affairs, Compliance and Quality Assurance (retired from Zimmer); V.P. Regulatory Affairs and Compliance for Zimmer
RCA520 Practical Ethics for Regulatory and Clinical Affairs

Dr. Pamela Plouhar
Vice President, Worldwide Clinical Affairs, DePuy Orthopaedics
RCA530 Medical and Scientific Writing
Tell me More

• Students complete the entire program with a cohort of approximately 30.
• Complete program in one year.
• Classes are held on the campus of Grace College in the Orthopaedic Capital Center.
• The next cohort begins May 2013.
The Graduate Program in
Orthopaedic Regulatory & Clinical Affairs
What does the coursework look like online?
When is class?

• Two weekend sessions per month, with half days on Friday 1:00 – 6:00 p.m., and Saturday 8:00 a.m. – 1:00 p.m.

• Additional content, readings, and projects completed online.
Are you a prospective student?

• Existing Regulatory Clinical Affair (RCA) employees who desire career advancement.
• New managers to RCA.
• Existing orthopaedic professionals who want to launch a career in RCA.
• Recent college graduates and individuals who want to enter the orthopaedic industry.
The Graduate Program in Orthopaedic Regulatory & Clinical Affairs
TO SCHEDULE A MEETING OR ASK MORE QUESTIONS, CALL

Allyn Decker
Program Director
(574) 372-5100 ext. 6509
To Apply for the May 2013 cohort, go to www.grace.edu/orca.