Master of Science in Regulatory Science and Medical Devices, School of Engineering

Suggested introductory courses for MBA students with no medical background:

1. As an intro and overview: ETLS 520: Design & Manufacturing in the Medical Device Industry. Students who do not have a medical background should take this class first.
2. To help students learn the language of health care, diseases and devices: ETLS 720: Anatomy and Physiology for Medical Devices and/or ETLS 730: Cardiovascular Anatomy, Physiology and Medical Devices
3. Clinical studies that will help to evaluate new products in medical research. Very good for marketing students: ETLS 724: Medical Device Clinical Studies

Course Descriptions:

ETLS 601: Program/Project/Team Management
Focusing on the applications of project management, students gain insight and understanding of the day-to-day activities of project management (including cost-analysis and scheduling techniques) and exposure to software options. A significant portion of the course focuses on conflict resolution, time management, leadership, and other personnel-related topics with the goal that engineers might effectively carry out the requirements of their companies without paying a penalty in lost good will or personnel.

ETLS 670: Masterful Leaders and Leadership
This course challenges the learner to make a fundamental decision to refocus their minds in a leadership way of thinking which is about personal maturity and its impact on the bottom line. The focus is on emotional intelligence, culture and leadership greatness.

ETLS 671: Human Aspects of Tech Management
Managers use written, oral and non-verbal communication to accomplish many purposes. This course teaches the student techniques and practice skills for targeting your audience, coaching and supporting employees, interviewing, salesmanship, performance management, personnel selection and employee development, conflict management, running meetings, problem solving and decision making, teamwork, networking and customer and vendor relationships.

ETLS 721: Medical Device Regulatory Submissions
This course teaches the student about submissions for regulatory approval of medical devices. Topics include: medical device law, custom and research devices, significant and non-significant risk devices, FDA investigational device exemption, 510(k) substantial equivalence determination, pre-market approval, PMA supplements, third party review, combination devices, European economic area CE mark, international harmonization, MDR, device tracking, post market surveillance, annual post approval reporting. Depending upon the degree of class interest medical device submissions in Canada, Australia, and Japan may be covered.

ETLS 724: Medical Device Clinical Studies
This course teaches clinical study design, research hypotheses, statistical considerations, clinical study planning and execution. Students are trained to apply this information to include clinical studies that encompass a wide variety of clinical objectives: prototype evaluation, pivotal studies, FDA approval requirements, marketing claims, customer acceptance, reimbursement, etc. Other topics include data form design, databases, applicable U.S. and International Regulations and selected topics of interest.

ETLS 851: Enterprise Information Systems
This course examines the requirements and needs of companies and other organizations for operating information and, in particular, the capabilities of automated systems to manage, analyze and deliver this
information. A review will be made of information system vendors that provide an integrated approach to information management including software features and equipment requirements. Systems that provide these features are typically referred to as an Enterprise Resource Planning (ERP) or Enterprise Resource Management (ERM) system. The process and techniques of assessing, designing, evaluating, selecting and implementing enterprise information systems in order to develop and establish a repeatable organization methodology for this process is actively studied and applied. The importance of process flow documentation and change management are studied in relation to successful enterprise information system implementation. Preparing requests for vendor proposals and analyzing vendor responses to choose a supplier is also studied. Topics include sales quotation and order processing, purchasing, manufacturing resource planning, shop floor control, inventory control, capacity planning, job shop and repetitive manufacturing, quality control, master scheduling, financial accounting and cost control, human resource management, logistics, engineering operations, and E-commerce as they relate to automated information systems.