BMEN 6333 - Quality Management Systems and Compliance

BMEN 6333 Quality Management Systems and Compliance (3 semester credit hours) A good Quality Management System (QMS) assures that products meet specifications efficiently and effectively to gain customer satisfaction, and as a result, gain profitability. This course will cover pre/post market QMS requirements and expectations of performance, best practices in QMS development, QMS evaluation for different audiences, the cost of poor quality, and the role this plays on how to meet customer satisfaction. This course will also engage students in quality system internal audits and regulatory external audit facilitation and negotiation, writing responses to allegations of non-conformance for the regulatory agencies, and the consequences that can be expected when regulatory enforcement ensues. Department consent required. (3-0) Y