**Research Development Fund – FY17 Cover Page**

**Application Title:** Core pharmaceutical laboratories and cGMP facility for product development

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**Key Participating Units:** Irma Lerma Rangel College of Pharmacy, College of Medicine, Agriculture and Life Sciences (Department of Biochemistry and Biophysics) and Engineering

**Anticipated Request Amount ($): $1,800,000**

**Executive summary of the intended application to utilize Research Development Funds.**

Despite enormous strength of outstanding programs at Texas A&M University, our pharmaceutical product development pipeline needs improvement. It requires an integration of chemistry, engineering, life sciences, and clinical sciences for development of small as well as biotech molecules for human, veterinary, and Agri-life products. Too many valuable TAMU discoveries have been hindered or delayed for a practical development from bench to bedside or have gone unnoticed. Patients do not take our discovered drugs as chemicals; they take dosage forms or delivery systems such as tablets, injections, or transdermal patches, among others. At the present time, TAMU has no provisions for formulations development research to promote successful development of our chemical discoveries for clinical studies and FDA filing. However, an important milestone has recently been achieved at TAMU by the recent expansion of the Rangel College of Pharmacy to College Station and development of cGMP facility for pharmaceutical product development. However, we need **cGMP** compliant equipment (FDA requirement) to be able to develop pharmaceutical product that can be administered to human in a clinical studies. We have the knowledge to comprehensively understand and link the essential components of all dosage forms and delivery systems from various Colleges and components across TAMU. Development of dosage forms requires the most modern understanding of drugs, excipients, processes, products, environment and stability, bioavailability and bioequivalence, and finished dosage form quality with all applicable laws and regulatory considerations. Additionally, pharmaceutical product development requires process scale-up and modernization of all unit operations with process analytical technologies, quality-by-design, and continuous manufacturing through collaborations. Together, with our capabilities in Engineering, Veterinary, and AgriLife Programs, we have the potential to be nationally and internationally recognized for pharmaceutical and biopharmaceutical product development for human and animal use and to serve the State and Federal Governments as advisors on policy development with targeted research. Another critical need is to help establish a pharmaceutics core laboratory to help develop dosage forms and carry out all analytical validations, quality development and monitoring, performance evaluation by *in vitro* and *in vivo* methods, and eventual bioavailability and bioequivalence for **pre-market research**. This will allow TAMU faculty to receive internal support for development of their discoveries with practical INDs, NDAs, BLAs, and ANDAs. It will also dramatically increase the chances of patentability of their inventions and help prepare students for job markets with high competence and entrepreneurial skills. This set-up will present new opportunities from FDA, NIH, NSF, DoD, BARDA/DARPA, and several industrial and state sponsors. Pharmaceutics core laboratories would also be critical for **post-market product evaluation**. When serious adverse events or fatalities of patients in hospitals in Texas occur, it is critical that we evaluate the product failure modes in addition to other possible metabolic and genomic reasons for the lack of performance. When such critical events occur, TAMU can identify the root cause of dosage form failures and correct them.