

Pharmaceutics core laboratory to facilitate dosage form development and evaluation

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Collaborators: College of Medicine, College of Agriculture and Life Sciences, Dwight Look College of Engineering, AgriLife Research, TEES, College of Veterinary Medicine and Biomedical Sciences

Total Amount Requested: \$1,850,000 (Matching additional funds available from College of Pharmacy: \$500,000)

Summary:

Despite enormous strength of outstanding programs at TAMU, our pharmaceutical product development pipeline needs improvement. It requires an integration of chemistry, engineering, life sciences, and clinical sciences for small as well as biotech molecules for human, veterinary, and agri-life products. Too many of our valuable TAMU discoveries have been hindered 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 such as tablets, injections, transdermal patches among others. At the present time, Texas A&M has no provisions for formulations development research to promote successful development of our chemical discoveries.

An important milestone has recently been achieved at TAMU by the recent expansion of our Pharmacy School in College Station, with an emphasis on pharmaceutical product development. We now have the knowledge to comprehensively understand and link the essential components of all dosage forms and delivery systems from various colleges across TAMU. Development of dosage forms require the most modern understanding of drugs, excipients, processes, products, environment and stability, bioavailability and bioequivalence, and finished dosage form quality with all applicable laws. Additionally the 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 Engineering, Veterinary, and Agri-Life 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.

The need right now 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 get 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 today's and tomorrow's job markets with high-tech entrepreneurship.

Pharmaceutics core laboratories would also be critical for **post-market product evaluation**. When there are serious adverse events or fatalities of patients in hospitals in Texas, it is critical that we evaluate the product failure modes in addition to other possible metabolic and genomic reasons for the lack of performance. Medications are chemicals that degrade, especially under unfavorable conditions of temperature, humidity, light, uncontrolled manufacturing conditions, or less than desirable excipients and process factors in the development of dosage forms. When such critical events occur, we at Texas A&M can identify the root cause of dosage form failures and correct them.

Equipment to be purchased: Pharmaceutical manufacturing equipment with on-line, at-line, or in-line process analytical technologies (PAT) approaches for mixing, milling, granulation, compression, coating, lyophilization; analytical equipment such as USP dissolution apparatus with fiber optic cables, UPLC/MS, texture analyzers, state-of-the-art rheometers, and 3D printers for tablet dosage forms. On-line processors include fbrm, particulate visualization microscopy (pvm), Near-IR, Raman, and FT-NIR, and TDLAS spectroscopies.

Note: Since pharmaceutical sciences is a new program in College Station, most equipment needed is not available on campus for immediate collaboration. This work will open up new opportunities from FDA, NIH, NSF, DoD, BARDA/DARPA, industry, and several industrial and state sponsors.