Research question: Is it possible to create a tool that can help companies statistically determine acceptable theoretical batch parameters?

**Introduction**

1. Many medical devices utilize degradable drug-eluting microspheres to improve control over drug release and minimize systemic drug effects [1]. However, manufactured batches typically do not have size uniformity, which leads to a nonuniformity in drug release [2].
2. FDA strictly regulates drug dosing [3]. Companies must prove that their drug amounts deliver therapeutic effects, but it is difficult to control exact drug dosage in a nonuniform particle batch.
3. Solution: a computational template that statistically models the effects of mean and percent standard deviation on drug release
   - Conserve time, money, and material resources of companies and the FDA.

**Methods**

1. Mathcad File
   - Inputs: mean, % standard deviation
   - Outputs: Time for 60% drug release, Slope and Intercept (log scale)

2. JMP14: Design of Experiments and Statistical Analysis
   - 2n factorial experimental design

3. Excel: Data Comparison
   - Graph for percent drug release until point of 60% drug release
   - 3D visualization of dimensionalized drug release over time and radius

**Assumptions:**

1. Radius Distribution: Log-normal Probability Function
   \[ PDF = \frac{1}{\sqrt{2\pi}} e^{-\frac{(\ln x - \mu)^2}{2\sigma^2}} \]
2. Surface Degradation
   - No drug diffusion
   \[ \frac{dr}{dt} = -b \]
3. Material uniformity: Nonporous, Spherical
4. Boundary Conditions
   - All drug begins inside microparticle with maximum radius
   - As time goes to infinity, all drug environment with radius = 0

**Challenges:**

1. Selected assumptions constrains ability to interpret data
2. Determining range/limits to adequately capture enough data
3. Program Syntax and limitations
4. Selected assumptions constrains ability to interpret data
5. Determining range/limits to adequately capture enough data
6. Program Syntax and limitations

**Future Work**

1. Analysis of other reasonable values for mean and standard deviation
2. Application to other distribution models (both radius distribution and drug release)
3. Application to randomly generated data
4. Comparison of results acquired from Mathcad to experimental data acquired from a wet lab
5. Translation of mathematical logic to other programs (Matlab, Wolfram Mathematica, etc.)

**References**


Acknowledgements:

This report was created under the guidance of Dr. Brent Vernon, who provided explanations for implementing Mathcad syntax and clarifying overarching project themes.
An additional thanks is extended to Jacob Nickle for providing additional insight for the theoretical process.
Thank you to FURI for providing the opportunity to further explore this area of healthcare.