Project #3
Producing layered granules using twin Screw granulation

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Problem Statement

- Twin Screw Wet Granulation (TSG) is a novel, continuous method for wet granulation
- The movement of material axially along the screw offers the possibility of producing layered granules
  - Note previously explored with TSG
- Has the potential to provide an alternate pathway for producing structured granules

Cross-section of a TSG granule with a thin powder coating layer
Perform parametric studies with varied processing and formulation conditions to produce layered granules

- Include variations in screw configuration, powder and liquid addition locations, liquid-to-solid ratio, powder feed rate, and screw rotation speed
- Prior experience using the TSG will be used to efficiently design these parametric studies

Characterize the resulting granules

- Granule size distribution, granule shape, granule porosity, binder distribution, internal microstructure, and granule strength

Offer recommendations for how to efficiently manufacture layered granules with target properties
Materials/Methods

- Thermo Fisher Scientific Eurolab 16 mm twin screw granulator
- Powder formulation to be determined by project partners
- Measurement methods
  - granule size distribution - sieving
  - granule shape - microscopy
  - granule porosity - gas and powder pycnometry
  - binder distribution - UV-Vis absorption spectrometry
  - internal microstructure - XRCT and Raman spectroscopy
  - granule strength - micro-compression tester
Anticipated Impact

- Provide engineers and formulators additional flexibility when designing drug products and processes
  - Produce layered granules
  - Modified release profiles, buffer layers, surface lubricant, or attrition resistance
  - Although layering could be performed via Wurster column coating on excipient beads, for example, the method proposed here would apply the coating in a powder form rather than as a sprayed solution