

## **IFPRI BRIEF TEMPLATE**

**Collaboration** 

## Check One:\Box Project\Box Review\Box Workshop\Box Other

**Descriptive Title Reduced order model development for melt granulation using** twin screw extruder Working Title<sup>1</sup> Melt Granulation Model Technical Area<sup>2</sup> F, M, SE Date 06/27/2019 **Short Description** Twin screw extruder-based melt granulation processes have proven to be a useful enabling technology alternative to manufacture crystalline and/or amorphous solid dispersions consisting of very high (>50%) loadings of active drugs in pharmaceutical formulations, embedded organic salts in molten mass in food industry, or specialty products in process chemical and allied industry, etc. The challenge is to design the process equipment (i.e. screw element design and configuration) and operational parameters (i.e. screw speed and temperature profile) to achieve a uniform dispersion of solids into the melt for a given formulation. **Development of an experimentally validated, reduced order** model for routine use is desired in order to facilitate rapid process development and optimization. **Objectives** Build a reduced order 1-D model based on experimentally validated 3-D modeling and simulation of a co-rotating twin screw extruder to predict the optimal operating conditions, namely the screw element configuration, screw speed, residence time and temperature profile to achieve a uniform solid dispersion. 1. Development of 3-D model for solid dispersion in the melt in the co-rotating twin screw extruder accounting for powder melting and temperature-dependent rheology. 2. Experimental model validation of granule quality (e.g. structure, composition, uniformity) using various loadings and PSD of the active compound.

<sup>&</sup>lt;sup>1</sup> Title used in meeting agendas and file archives

<sup>&</sup>lt;sup>2</sup> One or more from the following list: W = wet systems; D = dry systems; F = particle formation; SR = size reduction; M = modeling; SE = systems engineering

|       | 3. Development of reduced order 1-D model to enable quick prediction of the effect of underlying extruder design and  |  |
|-------|---|--|
|       | operational parameters on the granule quality.  |  |
| Scope | In scope:   |  |
|       | <ul> <li>One mutually agreed twin screw extruder size with specified screw elements.</li> <li>Consideration of multiple 'active' formations with varying mass fractions and PSDs</li> </ul> |  |
|       | Out of scope:<br>• Optimization of various screw designs  |  |

| Recommended Contractors (2 or 3) |                     |                      |  |  |
|----------------------------------|---------------------|----------------------|--|--|
| Name                             | Institution         | Email Address        |  |  |
| Professor Johannes Khinast       | Graz University of  | khinast@tugraz.at    |  |  |
|                                  | Technology, Austria | _                    |  |  |
| Professor Karl Wagner            | University of Bonn, | kgwagner@uni-bonn.de |  |  |
| _                                | Germany             |                      |  |  |
| Professor Stafan Radl            | Graz University of  | radl@tugraz.at       |  |  |
|                                  | Technology, Austria | _                    |  |  |

| Submitted By:    |              |  |  |
|------------------|--------------|--|--|
| Name             | Organization |  |  |
| Joe Bullard      | Vertex       |  |  |
| Bill Ketterhagen | AbbVie       |  |  |
| Fesia Laksmana   | Corbion      |  |  |
| Nandu Nere       | AbbVie       |  |  |