

# A DEEP DIVE INTO THE PHYSICAL MECHANISMS OF GRANULATION: DEVELOPMENT OF 1D-PBM MODEL FOR PHARMACEUTICAL APPLICATIONS.

## Introduction

Recently the pharmaceutical industry has experienced changes in the way of producing solid oral dosages (tablets) from traditional inefficient and expensive batch production to continuous. Recent advances in the pharmaceutical industry include increased use of twin screw wet granulation (TSWG) in the manufacturing of solid dosage and application of advanced modeling tools such as Population Balance Models (PBM). However, improved understanding of the physical process within the TSWG and improvement of current PBM models are necessary for the continuous production process to be successful in practice.

## Methodology

The ConsiGma-25 line is a novel fully continuous production line to make pharmaceutical tablets. This work focuses on the granulation part, where the dry powder is processed to wet granules. In order to speed up the time to market readiness for a new product, we need a predictive model of the particle size. You will work on PBM that describes the mechanisms of aggregation and breakage of particles. Based on the extensive knowledge we have, you will improve the model's mechanisms by incorporating first-principles knowledge on the governing physical processes that are occurring in the granulator.

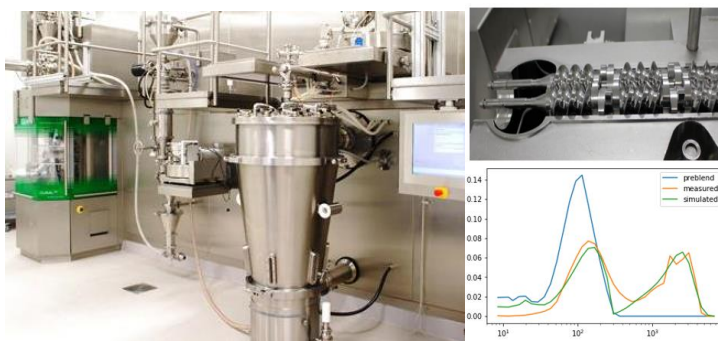


Figure 1 –ConsiGma™ line, TSG and results with current model.

## Objectives of the thesis

The goal is to develop a 1D-PBM mechanistic model to predict the particle size distribution both inside the granulator and just before the next unit operation in function of the critical process parameters. This work is performed in a precompetitive consortium with Janssen Pharmaceuticals, UCB, and Pfizer.

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