

Pharmaceutical Industry

EXCELERATE

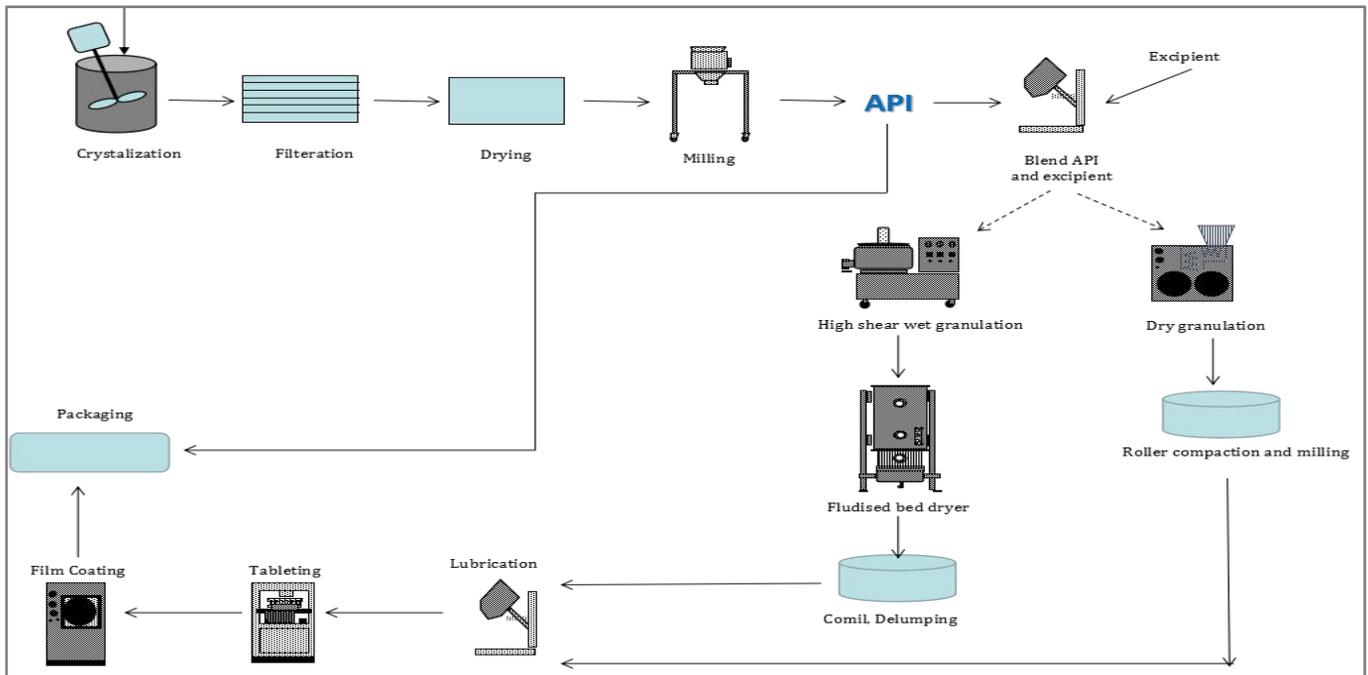


R&D - Scale-up - Operations

Process Scale up and Tech Transfer
Process Improvement and Optimization
Manage Operational Anomalies
Asset Selection

As we know with QbD-based process development being mandated by the FDA, it is important to identify and then optimize critical process parameters (CPP's) for various unit operations. Today, process engineers spend more time in DOE studies and do OFAT/univariate/multivariate analysis, which is cumbersome and time-consuming (especially if non-standard equipment/ multi-phase recipes are involved). The industry puts pressure to look at Asset utilization, Process optimization /first-time-right manufacturing and optimized CPPs for getting the consistent quality product (desired CQA's).

Pharmaceutical Industry- Process flow chart



The Physics-based advanced modeling and validation of equipment/ unit operations assist process engineers in validating Critical Process Parameters (CPPs) and design of Experiments (DOE) studies. Advance Modeling includes CFD, DEM and Analytical Modeling. These predictive (Flow models) models give better insights in terms of process understanding, equipment selection/characterization, and optimizing CPPs.

Reaction:

- Identify all the critical hydrodynamic parameters.
- Improve conversion and yield by studying desired process parameter.
- Compare distinct reactant or solvent feed strategies.
- Helps in optimizing heat and mass transfer and in reducing batch cycle time by knowing all the CPPs and CQA.
- Aids in Reactor Design, Selection and Management.

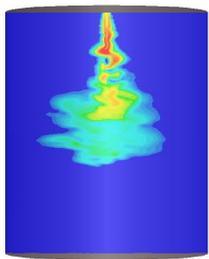
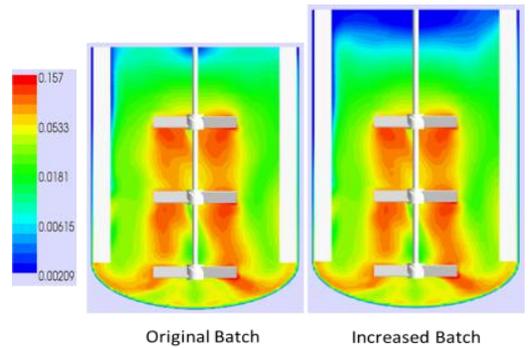


Fig: Contours of density

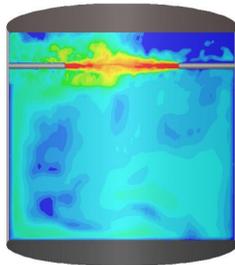


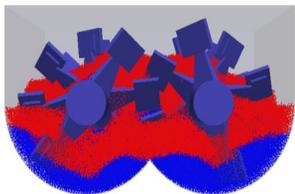
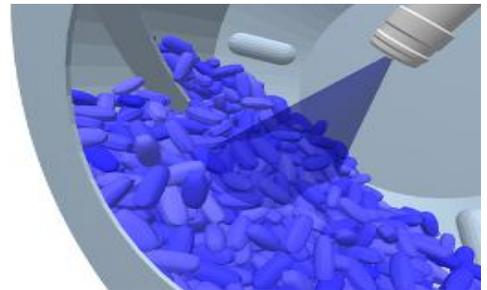
Fig:Contours of velocity for impinging jet system

Crystalization:

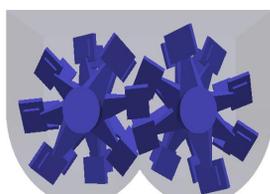
- Identify mass balance, crystallization kinetics, and drying kinetics.
- Helps in controlling particle size distribution and polymorph.
- Helps in process Scale up and optimization through virtual experiments, which further reduce the cost occurring due to multiple trial-n-error.
- Study CPPs and CQAs which helps in getting the desired quality right at first time.

Drying:

- Study drying rate, heat transfer and mass transfer, granular size and granular size distribution to achieve the desired quality.
- Analyze the performance of the dryer before making major structural changes to the dryer.
- Predictive analysis to avoid unnecessary downtime due to change in the dryer.



Front view **Vertical mixing** Front View

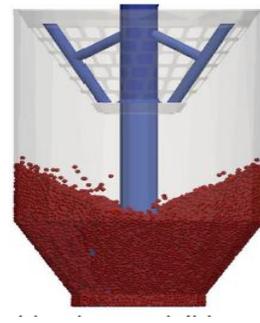


Powder Mixing:

- Helps in getting appropriate blend uniformity by knowing CQA and CMA.
- Helps in batch cycle time reduction as well as scale up by analyzing coefficient of restitution, coefficient of friction, Coefficient of rolling friction, flow field and vessel flow characteristic, and shear stress distribution.
- Examines the performance of mixers and predicts the degree of mixing achieved.
- Study the drug excipient compatibility to minimize unexpected stability failures and maximize the shelf life of the drug product.

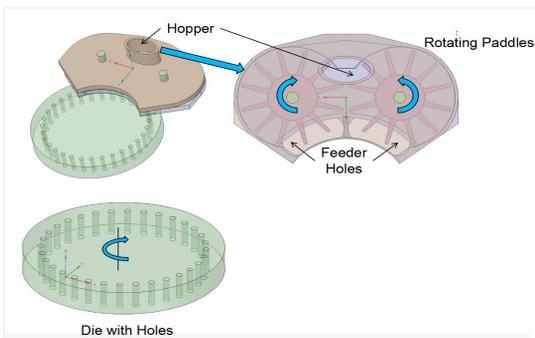
Dry granulation or wet granulation:

- Analyse various input parameters and provides the better insight on the outcome of the system.
- Helps in Batch cycle time reduction and Utility cost cutting.
- Describe and resolve the issues at the grain scale, kiln scale as well as the plant scale.



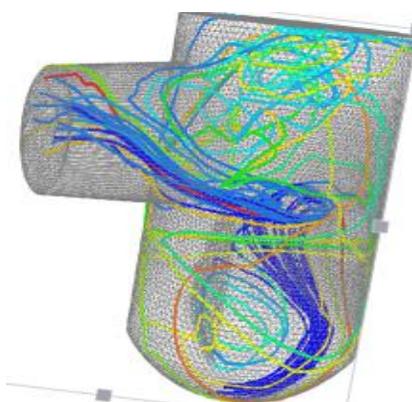
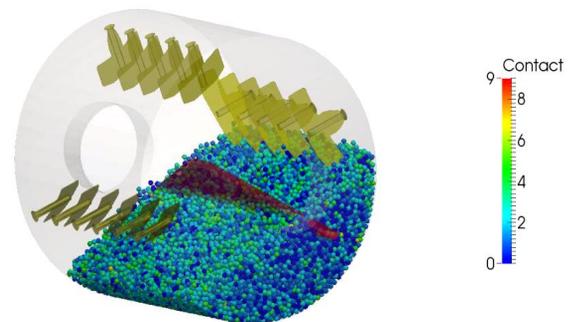
Tablet die filling:

- Study the speed of carousel (rotation rate), fluid flow properties (punch speed), material flow properties, feed frame paddle speed and feed rate to provide the better insights about the process.
- Enables better understanding of powder flow ability impact on process efficiency by studying and analyzing the bulk density, compressibility and tablet hardness.



Tablet Coating:

- Enables the strategies for cycle time reduction, throughput increase and energy optimization by studying coating score distribution, air flow velocity, spray pattern, bed position, contact time distribution and coating thickness.
- Helps to understand principles of the tablet coating process by analyzing various critical process parameters and critical parameter matrix.
- Provides optimal process conditions in regard to the heat and mass transfer.



Drug Delivery devices:

- Provides the ability to predict dissolution and absorption of a drug, in particular, circumstances.
- Provides the optimization of both design and use of medicine required.
- Provides important insight about the flow structure which can help to improve the dosage efficiency.
- Suggest a geometric modification to improve particle delivery efficiency.
- Predict the particle laden flow to obtain better insight about the mixing behavior of such flows.

Freeze technology

- Improve the design by gaining deeper insights about the process.
- Investigate the laboratory-scale freeze apparatus as well as the industrial-scale condenser for easy scale up.
- Investigates the influence of the condenser geometry, flow dynamics and ice deposition on process efficiency.
- Minimize cost of testing and shorten drying time to increase yield

Fluidised bed technology

- Studies the drying rate as well as fluidization profile at different particle sizes to improve the scientific understanding and optimize the drying process.
- Minimize cost of testing and shorten process time to increase yield

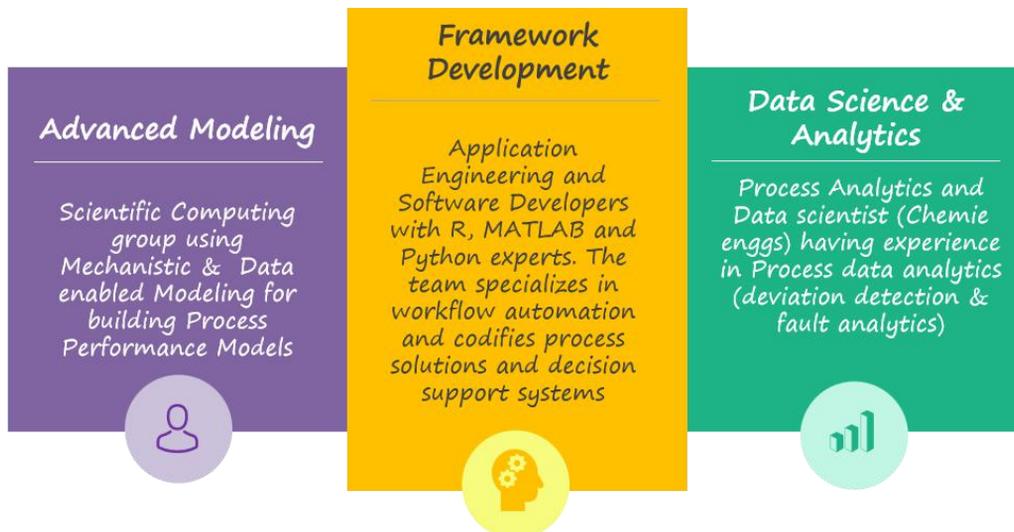
Packaging

- Predictive analysis helps to reduce the time and cost incurred during the Trial-and-error experiment along the filling lines.
- Conduct virtual experiments before changes are made to the filling lines or to the package geometry.
- Allows a wide range of conditions to be tested virtually and leads to an optimized filling process.

Milling

- Model describe the particle breakage and particle sizes phenomina.
- Helps in Process and Energy optimization by understanding process parameter like feed rate, spindle speed, agitator speed, blade design, etc.
- Analyses the performance of Miller before making any major structural changes.

Tridiagonal Solutions provides process performance enhancement as well as product development solution to world wide clients. Tridiagonal team has extensive expertise and experience in utilizing wide range of computational and experimental model to solve challenging problem in Industry. tridiagonal solutions provides solutions and services for various industry segment including Pharmaceuticals, chemical, power generation, oil and gas, food and consumer goods.



Capabilities

CFD modeling and simulation: Thermal and fluid flow analysis, single and multiphase flow with chemical reaction, solid-fluid interaction analysis and on demand resource placement.

DEM simulation: Granular dynamics consulting, simulation of bulk particle and particle laden flow, solids handling process design and scale up/down, DEM-CFD coupled simulations.

Application-specific software development: Customised solver development, GUI and vertical application development, training, support and implementation.

Process engineering: Process scale up, troubleshooting, Pilot experiment, Pilot plant design and manufacturing, software tools for mixing application, convert the batch to continuous processes.

DNA: DNA is Science-based Decision Support System that maps the fundamental process performance characteristics of an asset/ equipment.



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