Joint Event

18th Annual Congress on
Pharmaceutics & Drug Delivery Systems | Diabetes & Nursing Care
June 27-28, 2019 | Amsterdam, Netherlands

Challenges and opportunities in controlling drug substance properties

Peter H Karpinski
Novartis Pharmaceuticals Corp., USA

In order to control drug substance (DS) properties one has to select an optimal form (specific polymorph or hydrate of free form, salt, or co-crystal) and be able to consistently manufacture it with the same particle size (PS), particle size distribution (PSD), and crystal surface attributes. The use of automated and robotic systems in salt/co-crystal and polymorph screening, and in early crystallization development experimentation, facilitates DS form selection. Ultimate properties of DS are largely determined by the way the batch precipitation or crystallization processes are conducted, and to obtain crystalline material of desired properties consistently, these processes must be carefully controlled. This can be accomplished via in-situ seeding that simplifies the design and control of batch precipitation/crystallization and gives the results comparable with the conventional seeding approach. Continuous precipitation/crystallization removes the risk of batch-to-batch variability and ensures an optimal control of PS, PSD, and particle surface attributes.