

Development and Implementation of the Robustness Index

Challenge



Support required to provide success criteria in line with QbD principles

- Implementation of a Robustness Index aiming to translate development goals into objectively measurable success criteria to assess scientific knowledge, development and performance data to promote Quality by Design (QbD) principles in manufacturing

Solution



Used data to provide predictive estimation of future product and process robustness

- Resorted to data-driven approaches at all stages of development process
- Focused on measurement system, long term process performance predictions, and design spaces analyses
- Future prediction of process performance, and computation of the probabilities to pass the specifications

Outcome



Better resources allocation in continuous process improvement

- In-house teams have been fully equipped in order to properly adhere to QbD principles
- All tasks delivered within defined time frame