PHARMA SOLID KNOWLEDGE REPORT

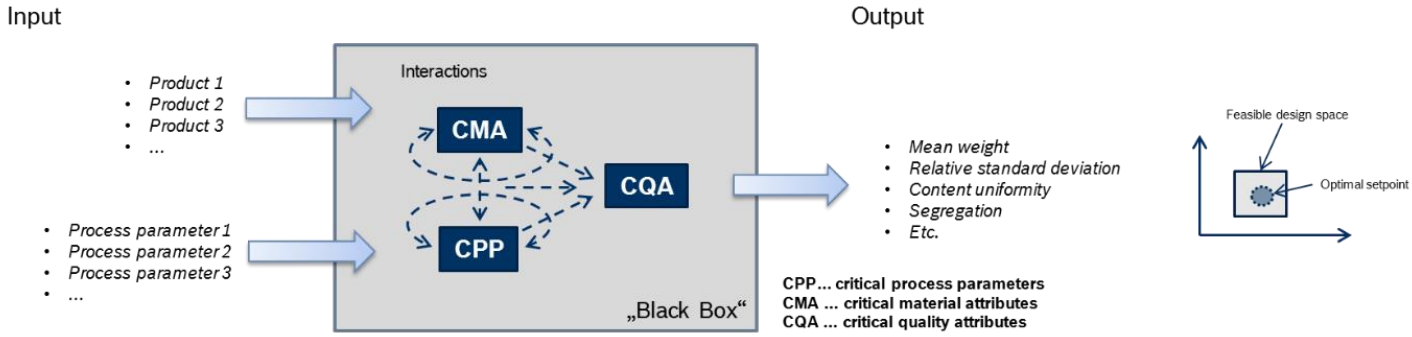
SYNTEGON
PROCESSING & PACKAGING

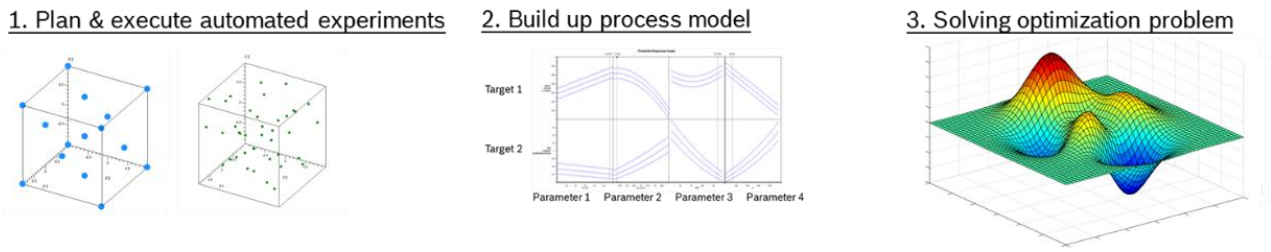
Automated Process Development (APD).

Quality by Design (QbD) was introduced by the American FDA in the ICH Q8 (R2) “as a new paradigm with significant effects on current and future trends in pharmaceutical development (2004). QbD describes good practice for pharmaceutical product development and introduces concepts of design space and flexible regulatory aspects. It is a systematic approach to development, emphasizes product and process understanding, as well as process control.

Changes in formulation and manufacturing processes during development should be looked upon as opportunities to gain additional knowledge and further support establishment of the design space (from ICH Q8 (R2)).

CRITICAL QUALITY ATTRIBUTES AND QUALITY BY DESIGN

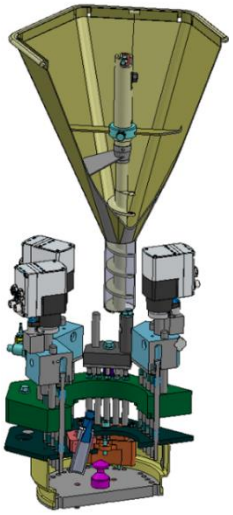




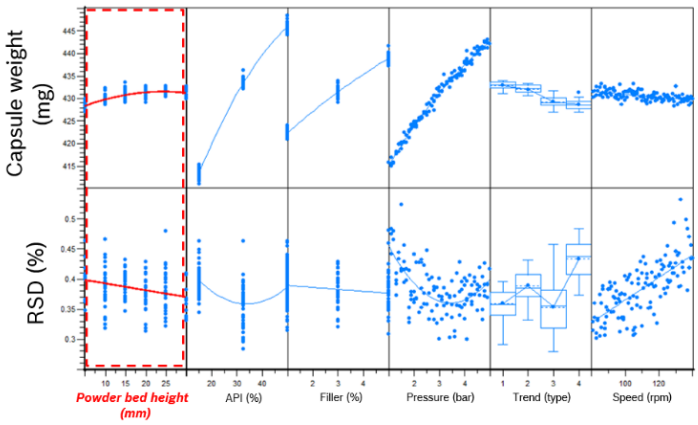
The combination of a systematic planning (DoE) with an automated test setup at a GKF is a unique and patented technology to perform more experiments in a shorter time. The automation allows you a broad screening to identify interactions between process parameters and to optimize yield, quality and robustness. The reproducibility of the tests and the quality of the data analysis is improved by an order of magnitude.

AUTOMATED TESTING GKF AT PHARMA SERVICE WAIBLINGEN

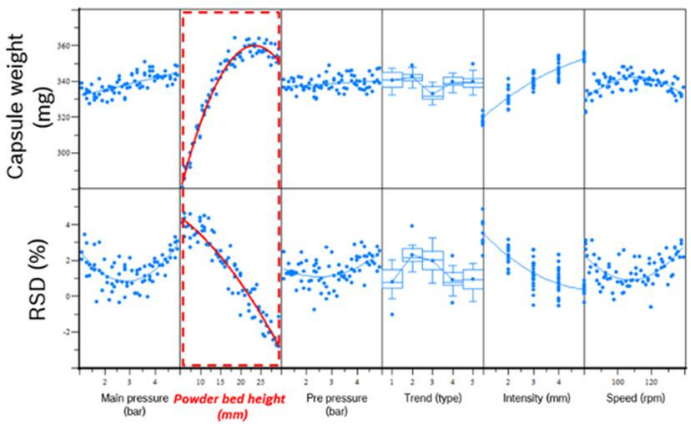
- Automated adjustment of critical process parameters
  - Power bed height
  - Pneumatic spring rate
  - Immersion depth
  - Speed
- Advanced sensor technology
  - Power bed height
  - Transfer force
  - Pressure monitoring
- Robust control
  - Constant power bed level (PID)
  - Machine safety (damage protection)
- Monitoring and logging
  - User warnings
  - Show process details
  - Long-time data



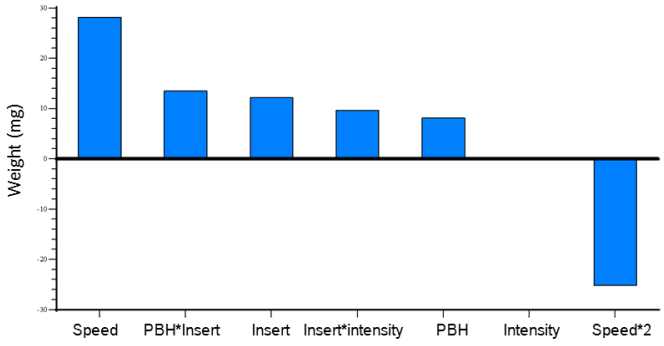
FORMULATION DEVELOPMENT

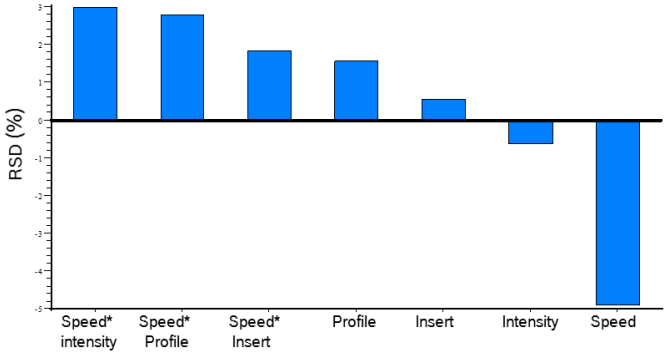


PROCESS DEVELOPMENT



PARETO ANALYSIS OF WEIGHT AND RSD OF FLUFFY POWDER





Conclusion

- The Automated Process Development (APD) allows an efficient and fast determination of the interaction between Critical Material Attributes, Critical Process Parameters and Critical Quality Attributes. Optimum process parameters and robust production can be determined systematically.
- Enhanced process understanding and higher product capability leads to better product quality. It's an investment in the process development phase with a large benefit in commercial manufacturing.
- Automated adjustment and monitoring guarantee less time and material consumption for broad parameter screening.

More Questions?

You also have processes for optimization?
Please contact us. Our "Engineering Pharmaceutical Service" team will be available with all our experience of over 50 years:

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