



Skyepharma

The solution provider for development and manufacturing of high quality and complex oral solid dosage forms

Visit our Website : www.skyepharma.fr



The Number One
Pharma Sourcing
Platform

24 - 26 October 2017

Messe Frankfurt,
Germany

Visit us at stand
41A10
Skyepharma

Quality by Design and Expertise: Accelerating time to market of complex oral solid dosage forms



Lucile KOWALSKI - NPI Project Manager
Guy VERGNAULT - VP R&D



Skyepharma provides de-risked time- and cost-effective services



Extensive project management



Early stage development

Commercial & packaging



Speakers' Corner

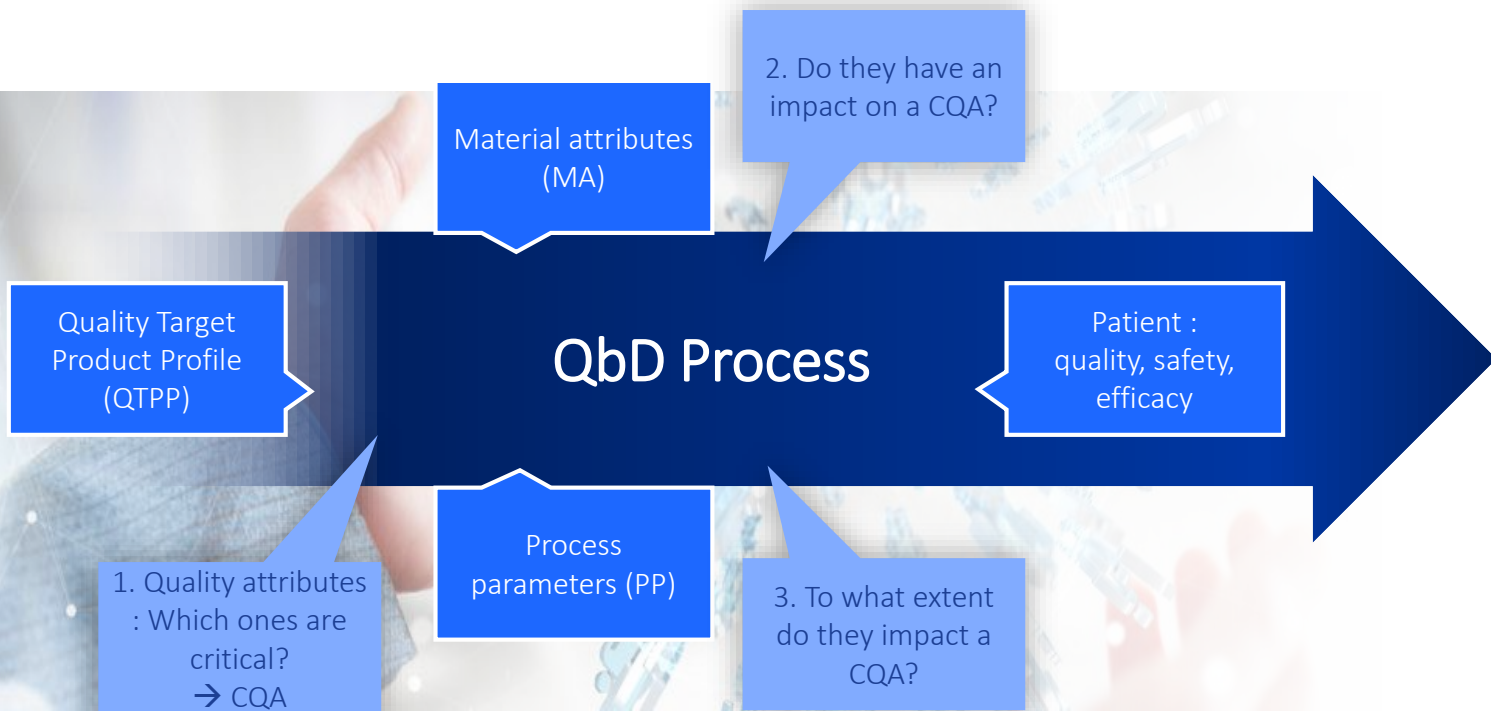
A 'Right First Time' approach creates competitive services

1. Patient-oriented,
Quality by Design
approach

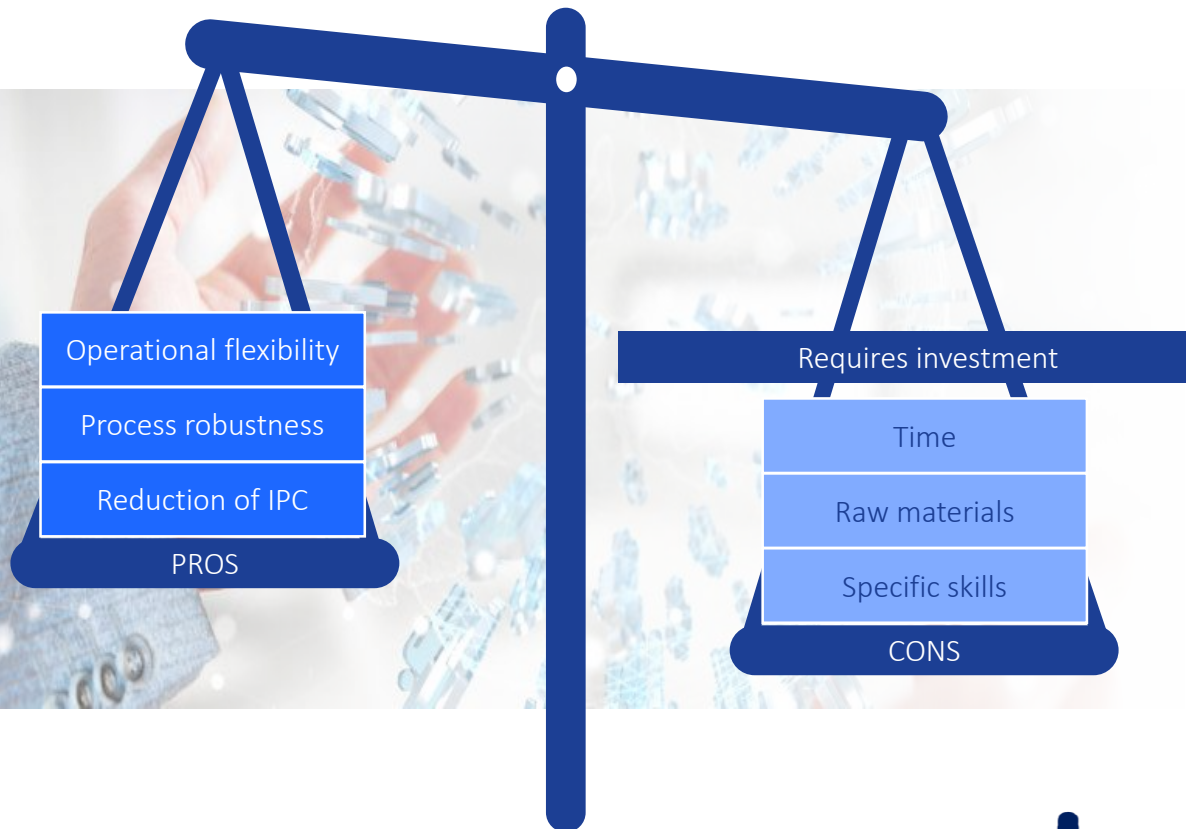
2. Cost reduction and
enhanced time-to-
market



Quality by Design is the Gold standard



QbD : Pros and Cons



Case study : To what extent do PPs impact a CQA? (1/2)

Implementation of design of experiment

Case study: impact of 5 factors and their interactions on crushing strength

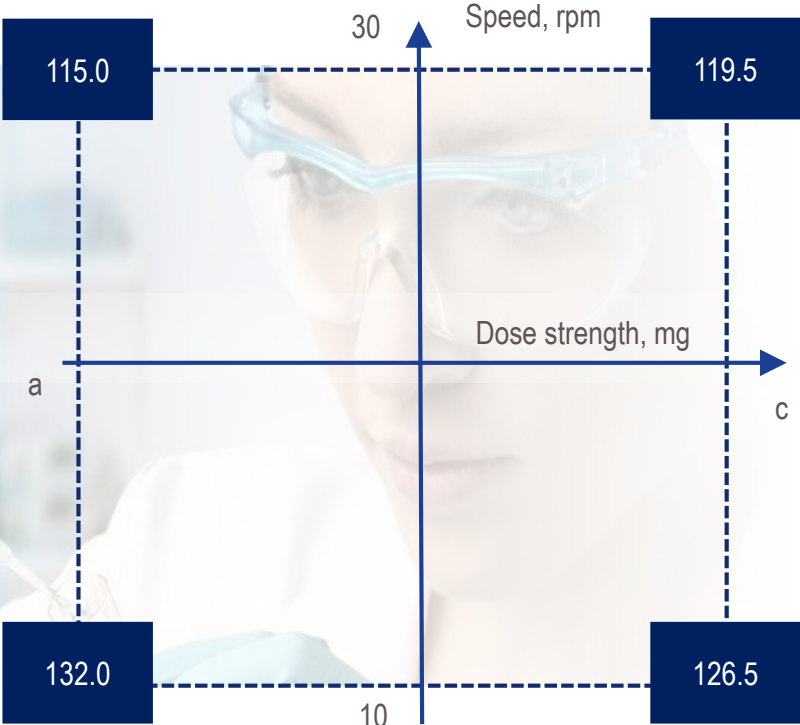
Responses



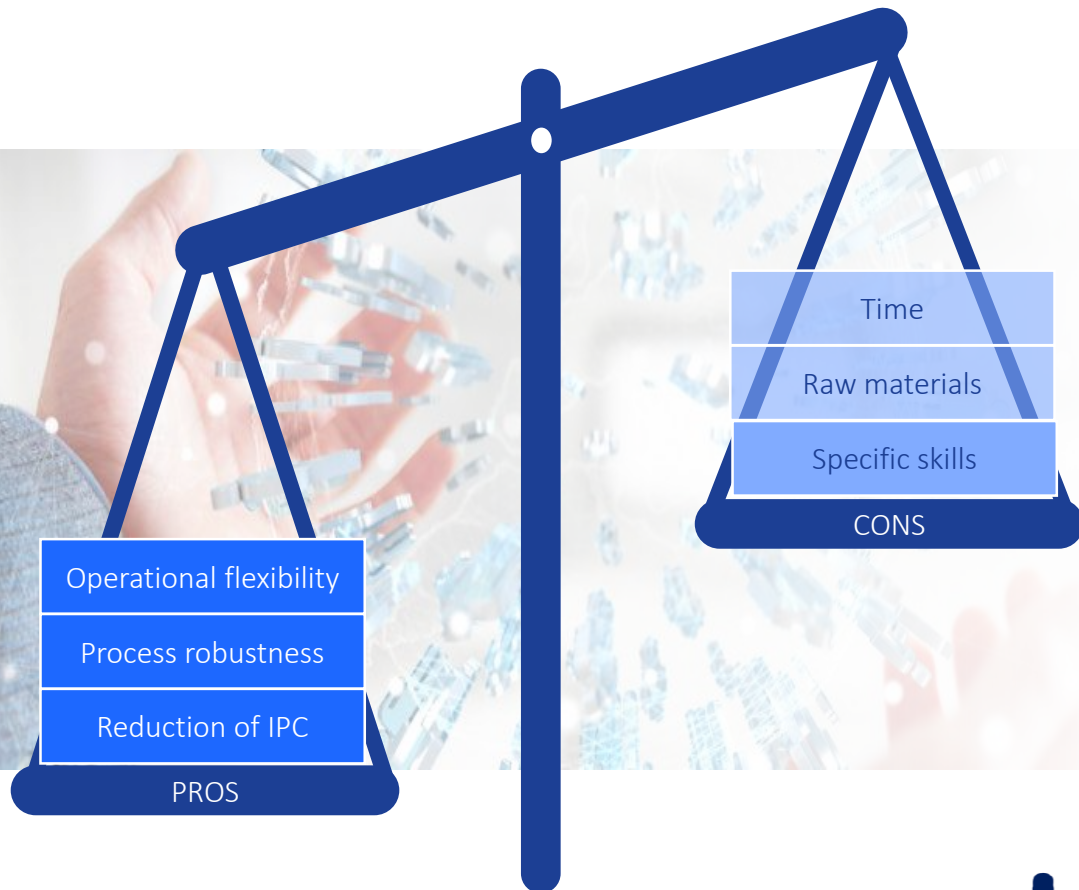
Case study : To what extent do CPPs impact a CQA?

Implementation of design of experiment

Leading science-driven development



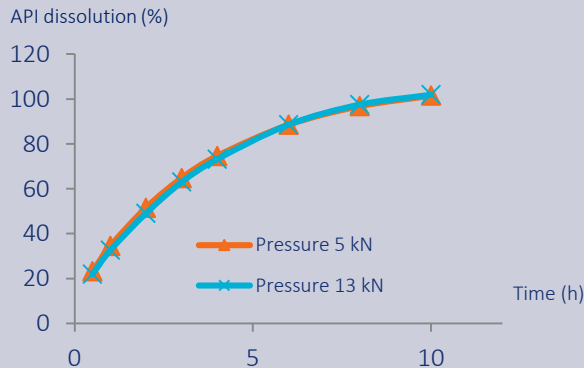
QbD : Pros and Cons



Case study 2 : Do PPs have an impact on a CQA ?

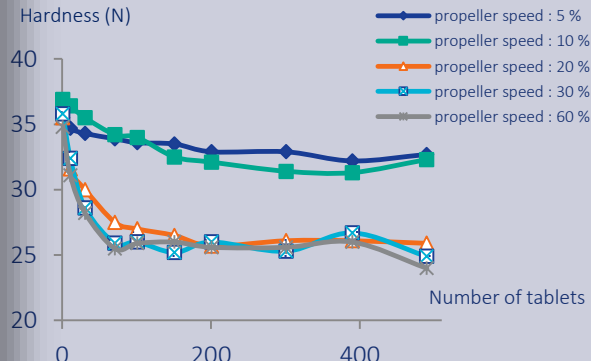
Compression pressure on disso

- 500 mg of API
- 0.5 day



Feeding shoe settings on hardness

→ how improper setting of simulator parameters could be misleading



Competitive advantage: Quick and easy access to key information

- Implementation of state of the art compression simulator
- QbD initiation at early stage of development
- Continuous improvement of commercial product
- Rapid results using minimum amount of powder

Skyepharma special features

- ✓ Piezoelectric sensors
- ✓ Press coating module
- ✓ Roller compactor module

Conclusion #1



A hand in a blue suit sleeve holds a tablet. The tablet screen is mostly obscured by a semi-transparent blue overlay containing white text. The background is a blurred image of a city skyline with blue and white tones.

2. Cost reduction and enhanced time-to-market



Development and scale up: cost and time reduction



By straight to goal development and optimization

Screening of excipients

Compression cycle of API grades
Pressure/hardness relationship

Formulation development

Pressure/hardness relationship
Impact of formulation on dissolution
Compression cycle

RIGHT FIRST TIME

Impact of feeding shoe settings
Impact of pressure on dissolution
Rejection limits determination

Impact of tooling characteristics
Determination of compression parameters

Assessment of critical parameters

Setting of scale-up parameters



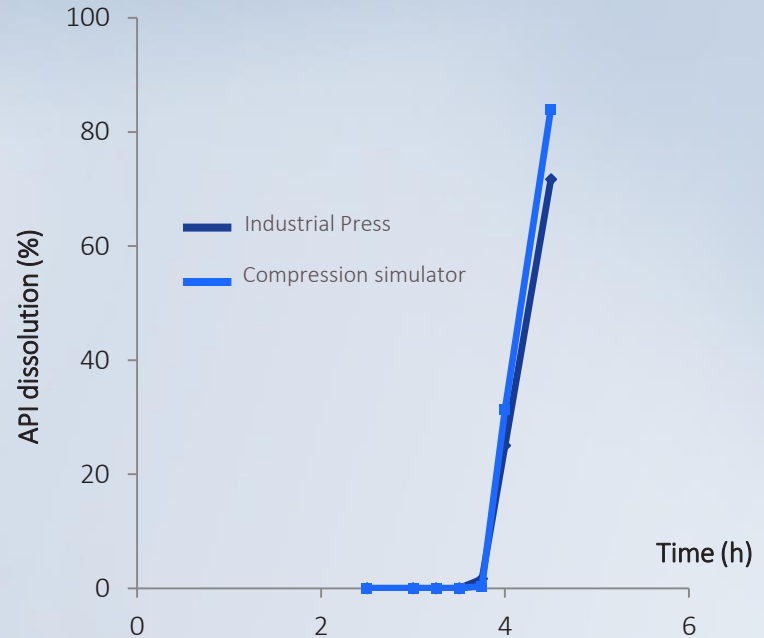
Speakers' Corner

Development and scale up: cost and time reduction



By anticipating scale up using a compression simulator

Comparison of drug delivery on Kilian industrial press and simulator



Example #1: Press coated tablet → Delayed release



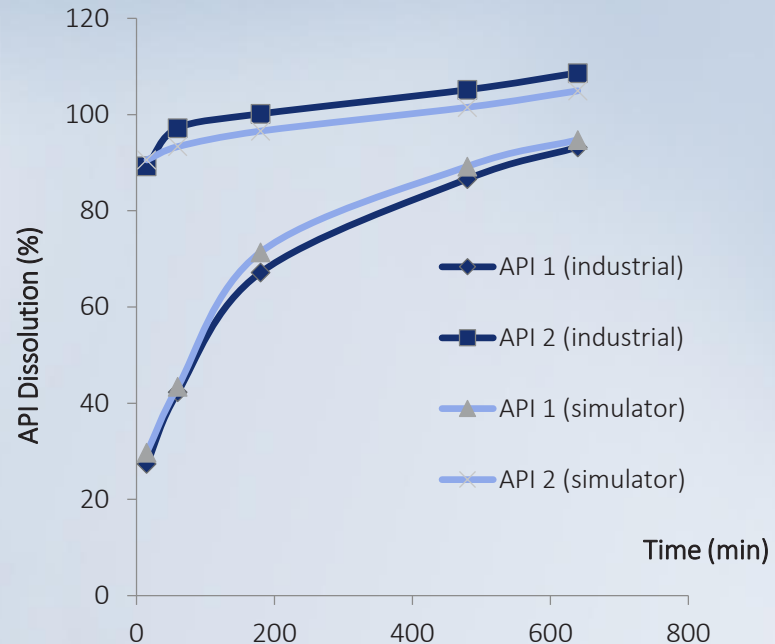
Speakers' Corner

Development and scale up: cost and time reduction



By anticipating scale up using a compression simulator

Comparison of drug delivery on Hata industrial press and simulator



Example #2: Trilayer tablet → Biphasic release

Development and scale up: cost and time reduction



By reducing batch size and shortening timelines

Step	Batch size*		Time*	
	Simulator	Industrial press	Simulator	Industrial press
Tool assembly	-	-	0.5 h	5 h
Setting of comp. parameters	50 g	1 kg	0.5h	1.5 h
Production of trial batch	100 g	33 kg	1 h	2 h
Disassembly + cleaning	-	-	2 h	20 h
SAVINGS	70 – 95 %			

**Skyepharma case study based on a monolayer tablet transfer*



Speakers' Corner

General Conclusion



Expertise
The Right People
Approach

Quality & Excellence
The Right Focus
Solutions Provider

Reduce costs & time
Right First Time
Faster time to market

Reliable & Accurate
The Right Technology
Scale up capable



Visit us and Meet our Team on our booth : 41 A 10

Cheese & wine event on Wednesday October 25th, at 4:00-5:30 pm



