



## COMPACTION SIMULATION AS A POWERFUL QUALITY BY DESIGN (QbD) TOOL

How Skyepharma can help you to shorten the time and reduce the cost of pharmaceutical development programmes

# WHAT IS COMPACTION SIMULATION?

Compaction simulation has been of scientific interest for more than 40 years

- first compression simulator described in 1976<sup>1</sup>

Simulates industrial compression: produces tablets at lab scale, with a process similar to industrial equipment:

- versatility for prototyping
- decreased risk during scale-up
- reduced time to market

→ Time and cost saving all along the pharmaceutical development process

# SKYEPHARMA: COMPACTION SIMULATION EXPERTISE

## Technology

- High-performing compression simulation facilitated by **using the same format as an industrial press**
- We focus on **rigorous reproduction** of compression cycles



Styl'One  
Evolution

## Expertise

- We can apply our methodology and expertise at **ANY step of development** (prototyping, scale-up, manufacturing optimization)
- We are experts in compressing **complex oral solid dosage forms**

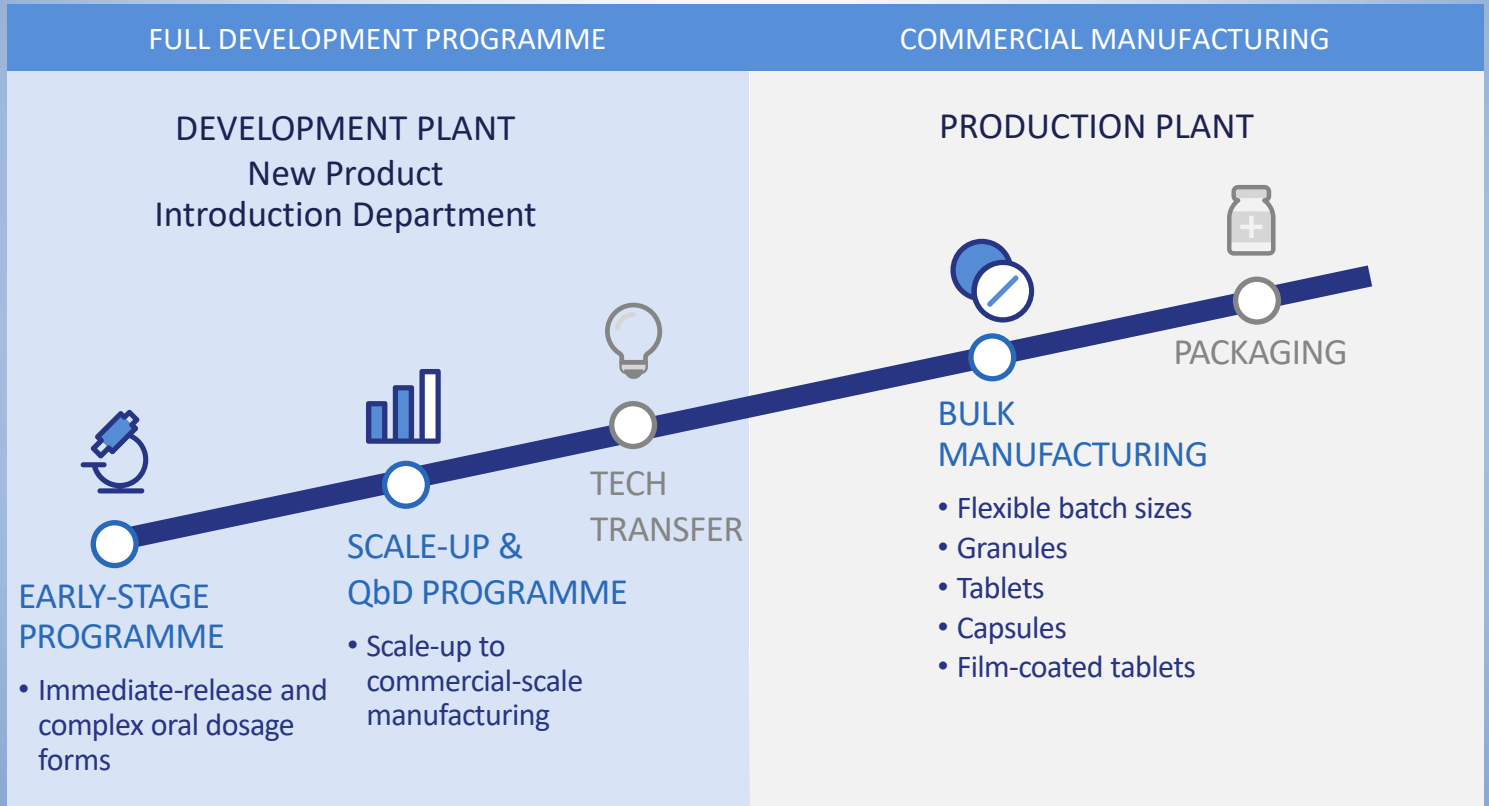


# HOW MUCH TIME AND MATERIALS CAN SKYEPHARMA SAVE YOU PER BATCH?

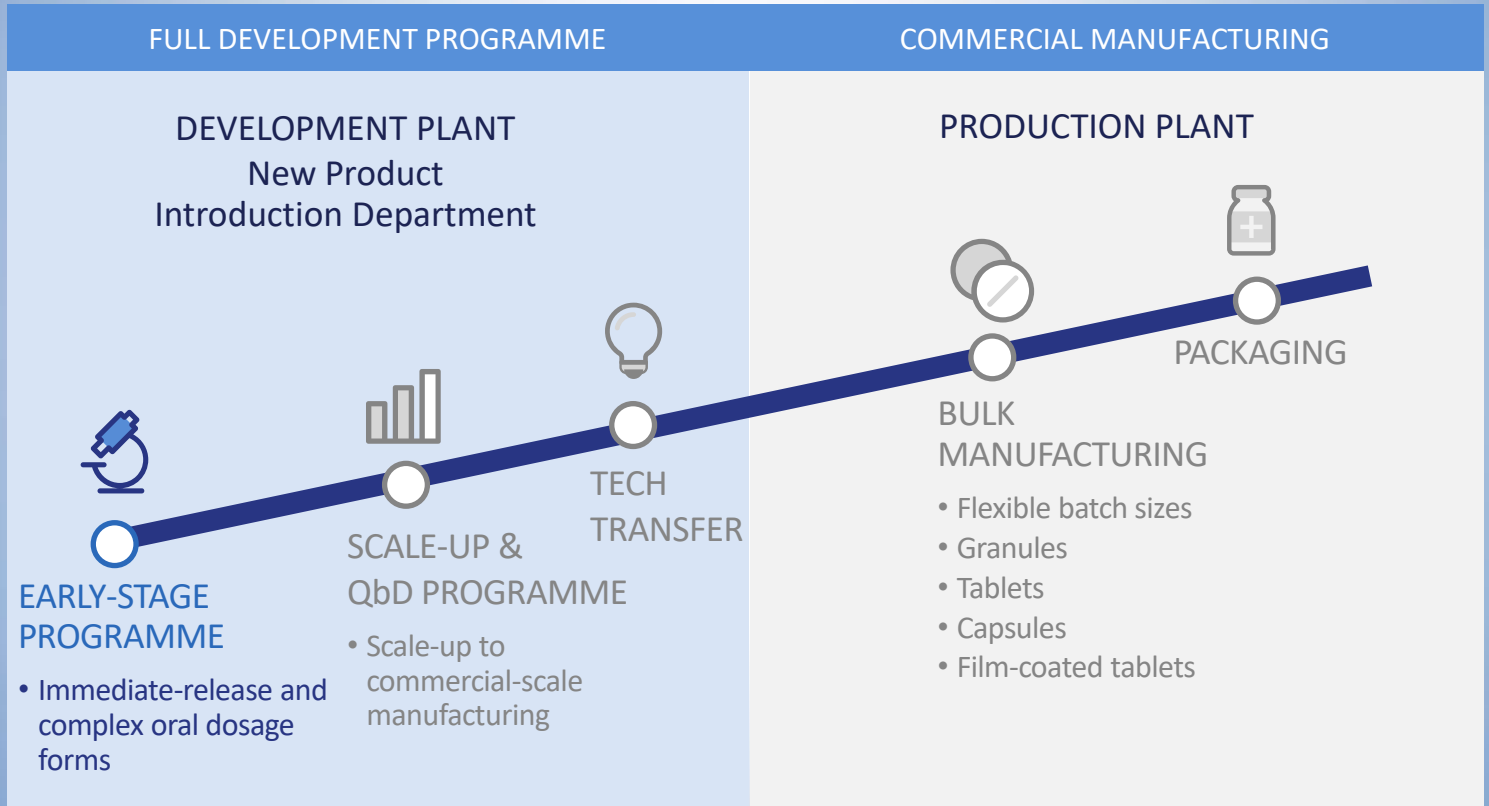
Step	Batch size (kg)		Time (h)	
	Industrial press	Simulator	Industrial press	Simulator
Tool assembly	–	–	5	0.5
Setting of comp. parameters	1	0.05	1	0.5
Production of trial batch	33	0.1	2	1
Disassembly & cleaning	–	–	20	2
<b>Total</b>	34	0.15	28	4
<b>Total savings</b>	<b>33</b>		<b>3 x shifts</b>	

# WORKING IN PARTNERSHIP: WHEN CAN WE HELP YOU?

Skyepharma can help shorten development at three critical stages



# CASE STUDY 1: SKYEPHARMA COMPACTION SIMULATION EXPERTISE APPLIED TO AN EARLY-STAGE PROGRAMME



## EARLY-STAGE PROGRAMMES:

### SKYEPHARMA EXPERTISE IN THE DESIGN OF INNOVATIVE FORMULATIONS

#### Skyepharma team expertise

- Dedicated formulation and analytical development team

#### Partnership with clients

- Dedicated project manager
- Strong implication of technical managers
- Dedicated quality assurance support



Expert utilization of compaction simulation

# AN EXAMPLE OF AN EARLY-STAGE PROGRAMME: 6-BATCH FEASIBILITY STUDY

RAW MATERIAL NEEDED

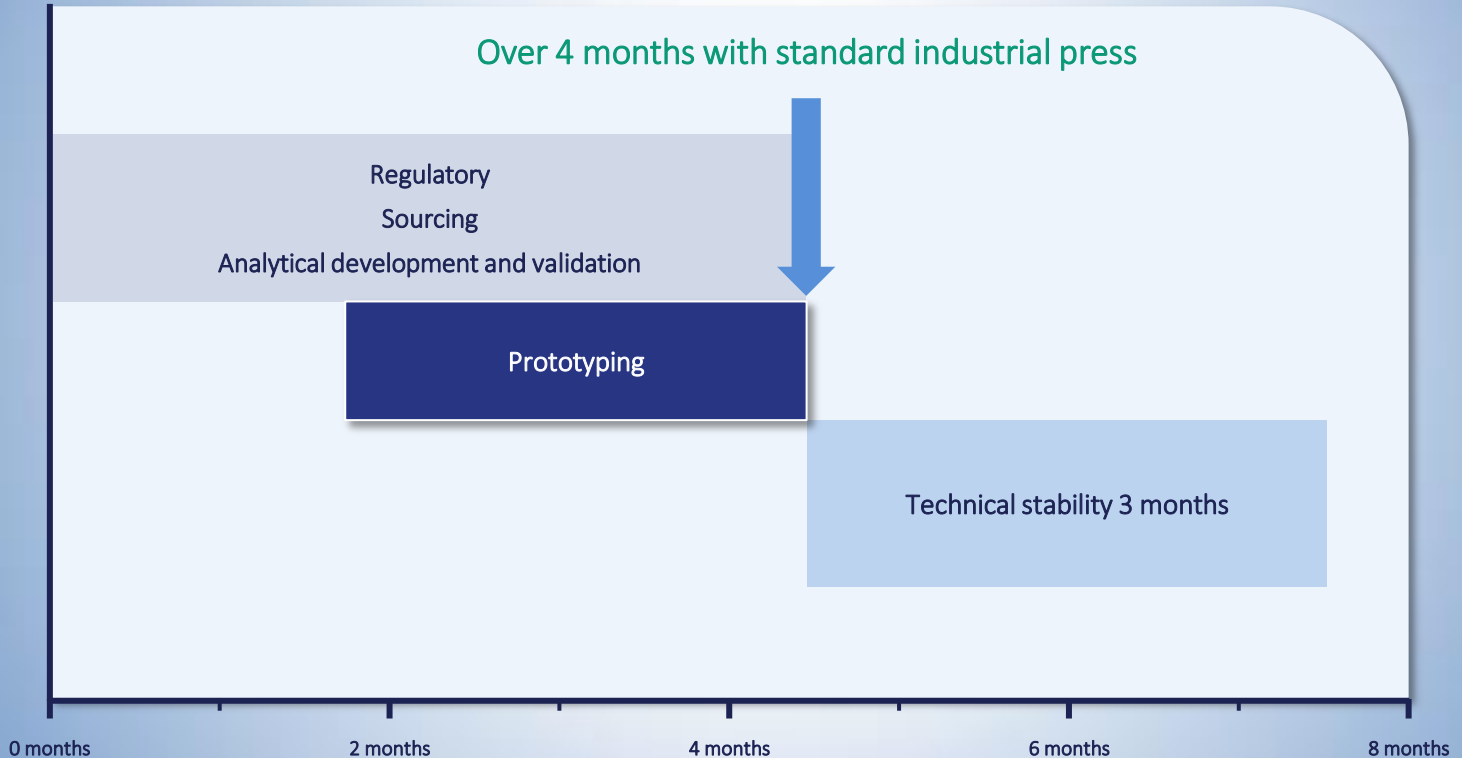
DURATION



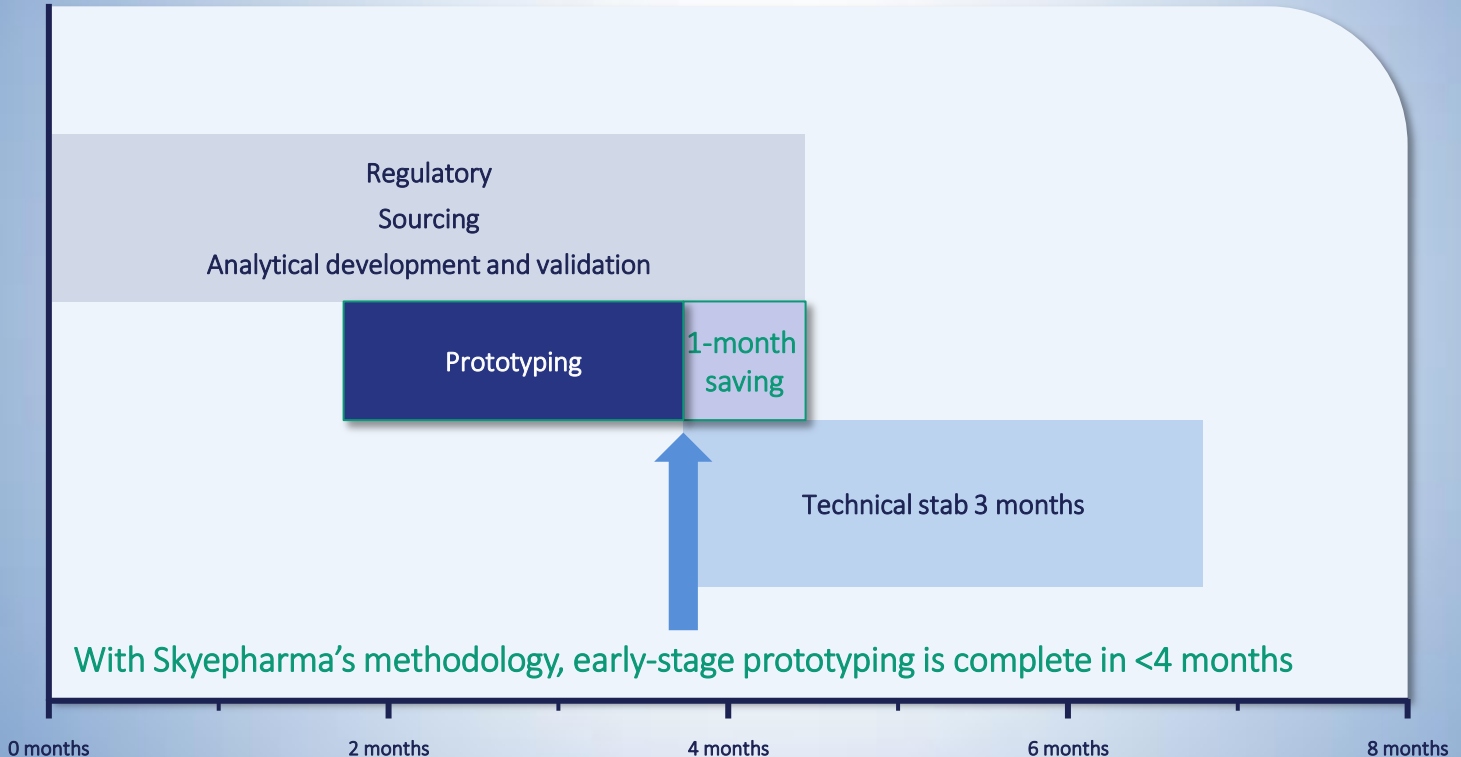
Notable reductions in development time and waste product



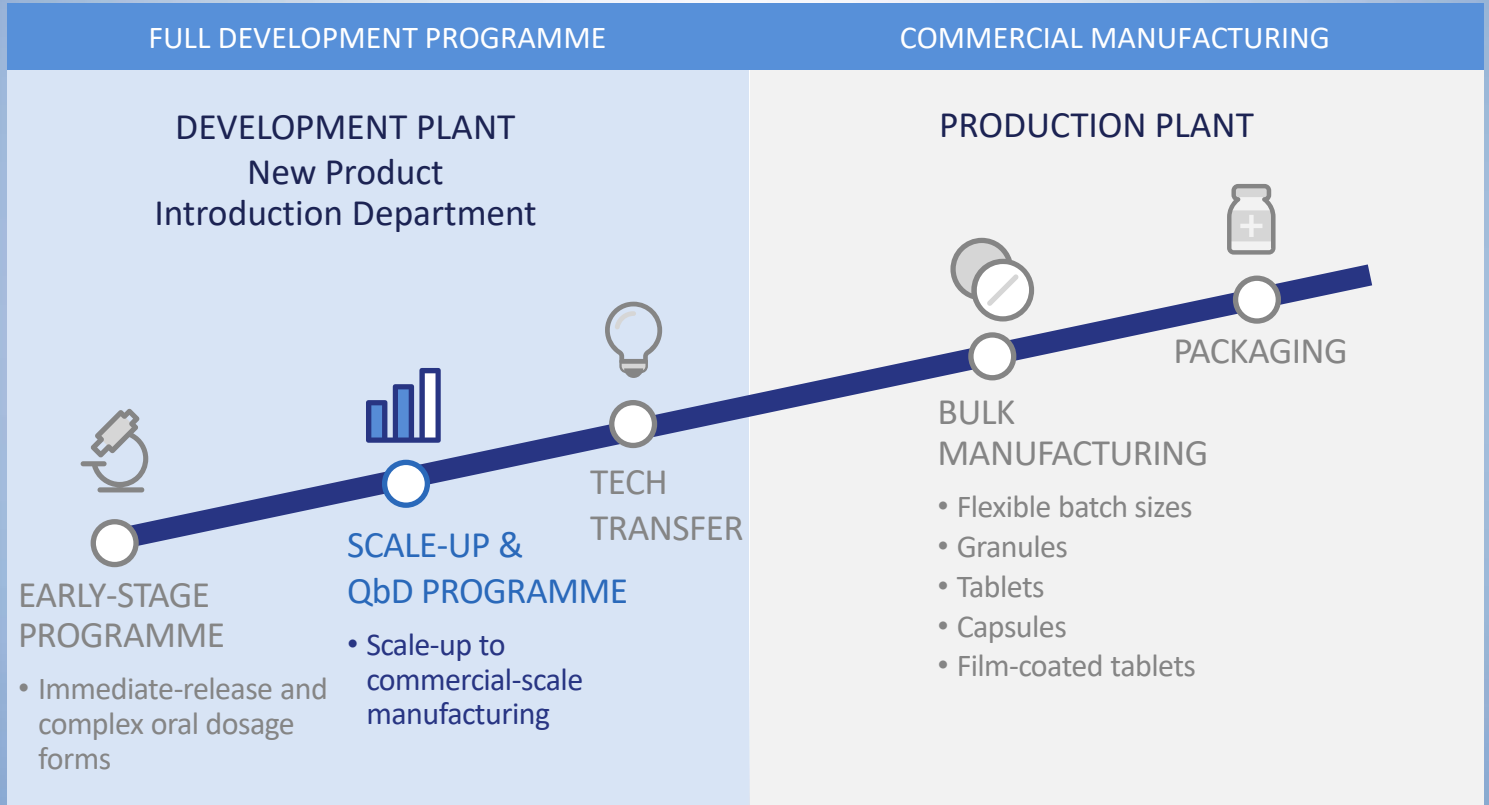
# WHAT IMPACT CAN SKYEPHARMA HAVE ON YOUR GLOBAL EARLY-STAGE PROGRAMME GANTT CHART?



# WHAT IMPACT CAN SKYEPHARMA HAVE ON YOUR GLOBAL GANTT CHART?

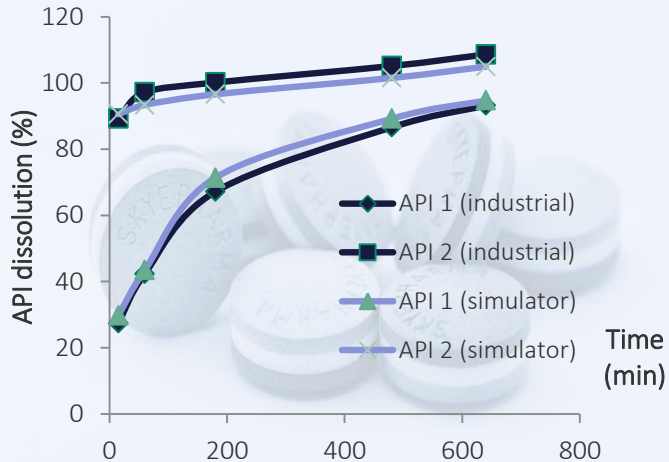


# CASE STUDY 2: SKYEPHARMA COMPACTION SIMULATION EXPERTISE APPLIED TO SCALE-UP AND QbD PROGRAMMES



# OUR RESULTS: CORRELATION BETWEEN COMPACTION SIMULATOR AND INDUSTRIAL PRESS

Comparison of drug delivery on Hata industrial press and simulator: sustained release

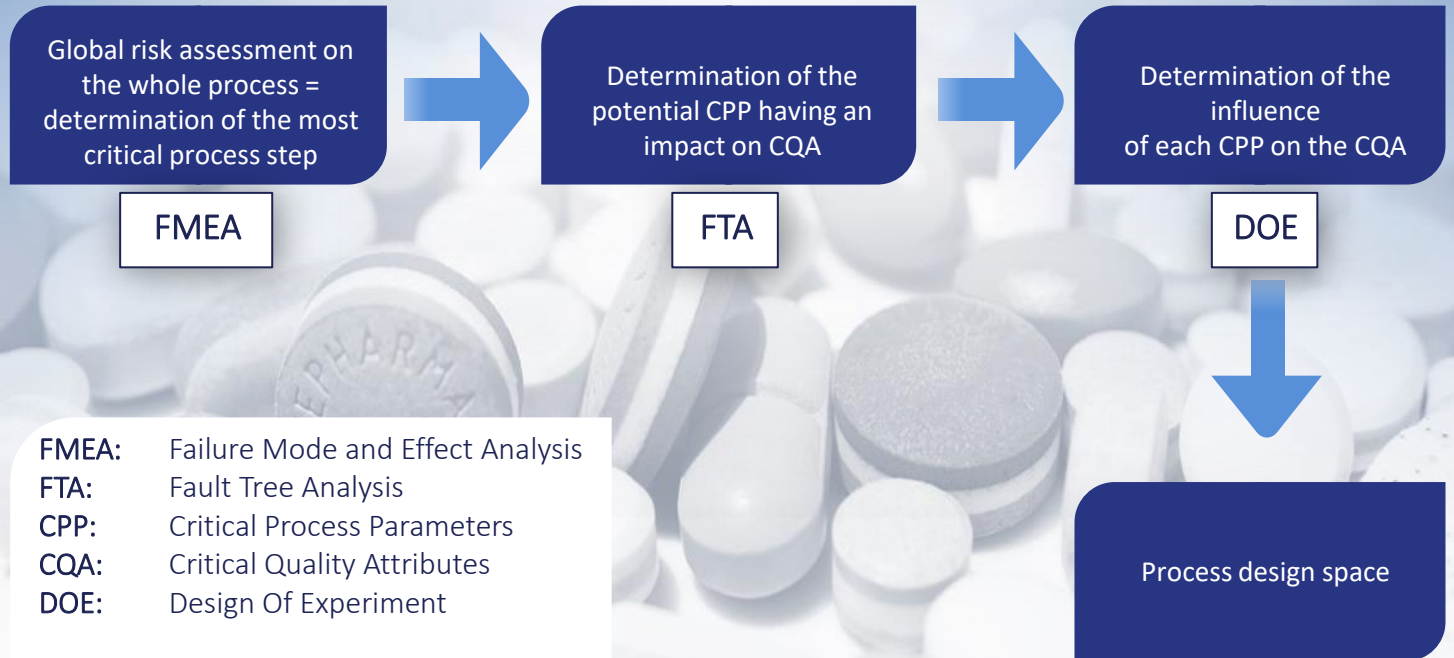


Comparison of drug delivery on Kilian industrial press and simulator: delayed release



Skyepharma expertise: establishment of reliable correlations  
→ Reduced risk during the scale-up process

# SKYEPHARMA'S QUALITY BY DESIGN METHODOLOGY



# SKYEPHARMA QbD PROGRAMMES ARE DESIGNED TO SAVE YOU TIME AND MONEY

Skyepharma case study based on a mono-layer tablet transfer; saving estimation due to compaction simulation

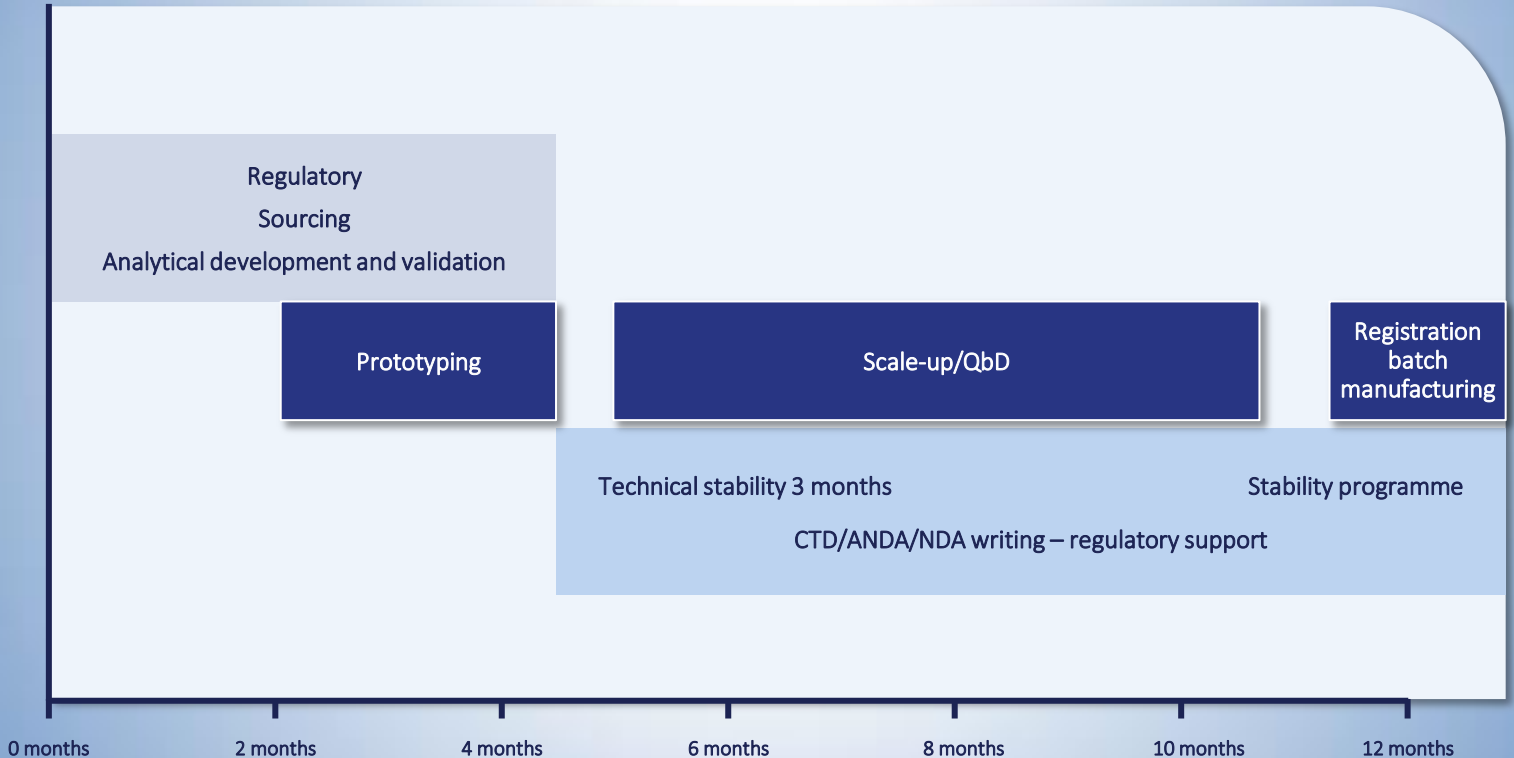
QbD: 11 assay DOE matrix

	Raw material needed (kg)		Time (h)	
	Industrial press	Simulator	Industrial press	Simulator
	374.0	1.7	308	44
Savings	70–95%			

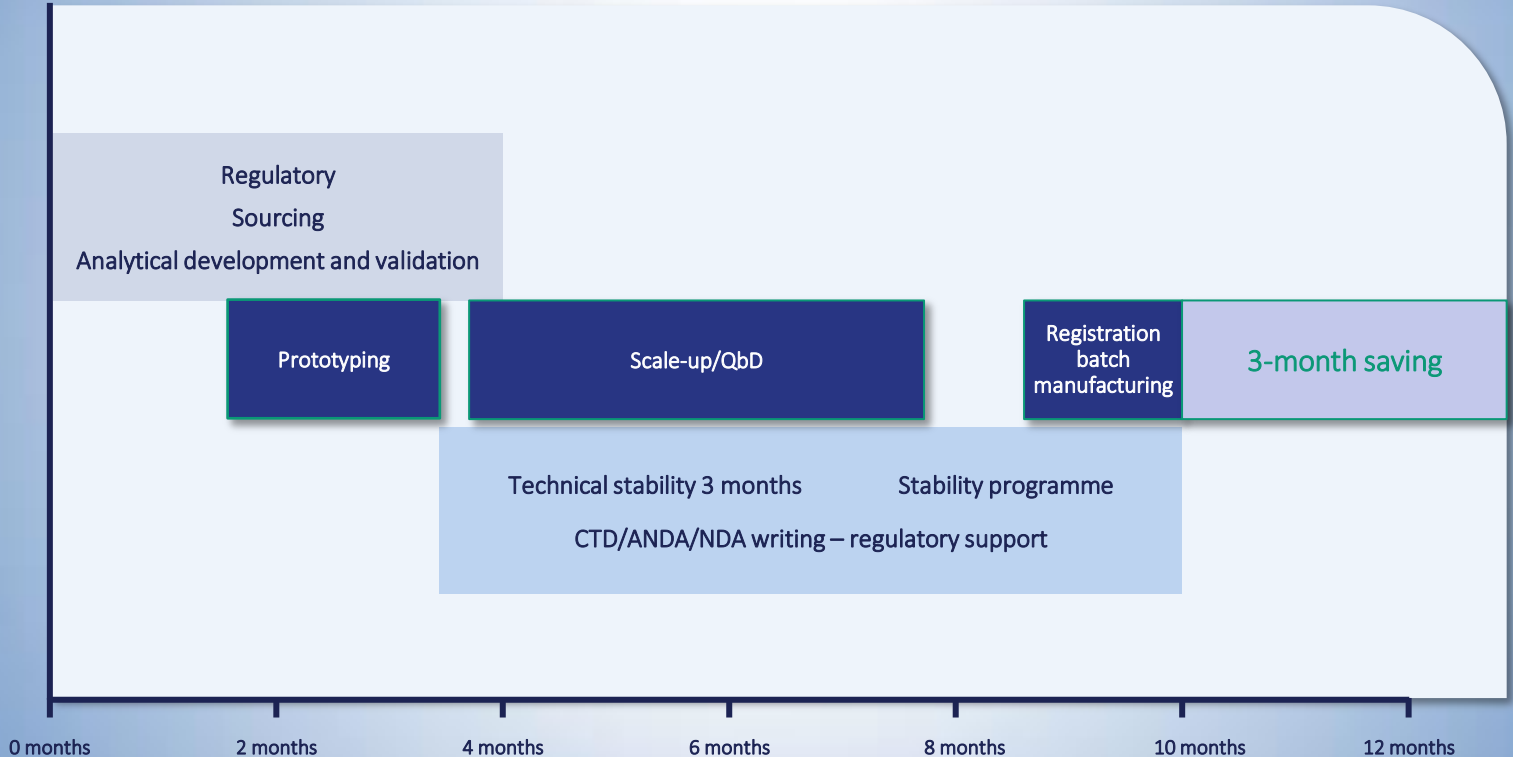
Determination of the influence of each CPP on the CQA

DOE

# WHAT IMPACT CAN SKYEPHARMA HAVE ON YOUR GLOBAL GANTT CHART?

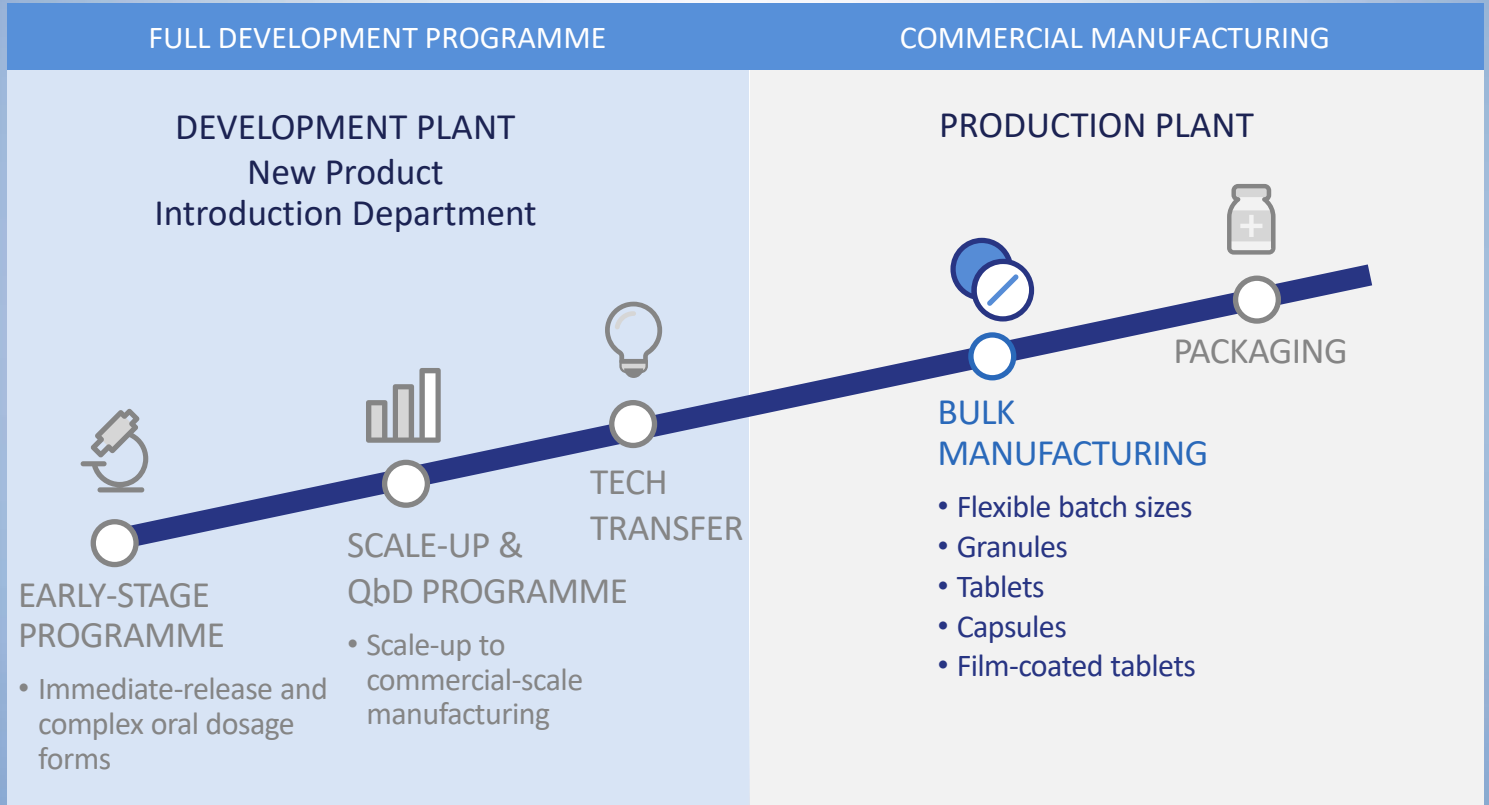


# WHAT IMPACT CAN SKYEPHARMA HAVE ON YOUR GLOBAL GANTT CHART?



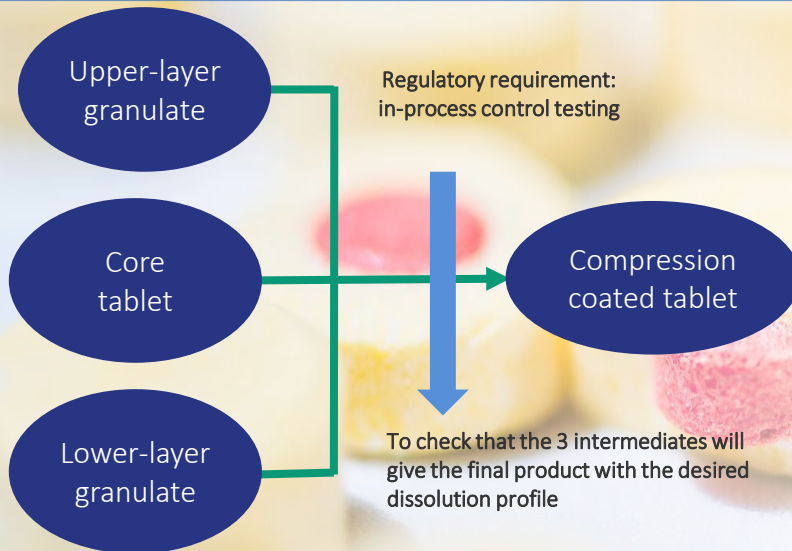


# CASE STUDY 3: SKYEPHARMA COMPACTION SIMULATION EXPERTISE APPLIED TO BULK MANUFACTURING IN PROCESS CONTROL



# SKYEPHARMA COMMERCIAL MANUFACTURING EXPERTISE

Case study 3: complex solid oral dosage forms with extremely tight dissolution specifications manufactured on a commercial scale



Use of compaction simulation:  
17% time saving (4 working days per month)

Balances high standard of quality with cost- and time-saving efficiency, even in a highly complex technical environment and demanding regulatory context

# CONCLUSION: SKYEPHARMA CAN SAVE YOU TIME AND MONEY WITHOUT COMPROMISING ON QUALITY



Reduces risk during scale-up process



Estimated 70% savings on manufacturing cost



Approximately 10 months to registration batch manufacturing

Skyepharma CDMO: agile partner for tailor-made solutions

Helping you to shorten the time and reduce the cost of pharmaceutical development programmes

# Come and meet our team!

Compression simulator live demonstration at our booth 1K12



9–11 October 2018, Madrid