## Skyepharma, a company of the and robustness. In order to Vectura group of companies, has answer ever shorter development a long history of modified release expectations from its clients without dosage forms development. This compromising the overall quality of

WHO IS SKYEPHARMA?

INTRODUCTION

years Skyepharma integrated the need to accelerate the time to market of the products without jeopardizing product quality SKYEPHARMA INVESTS IN

expertise is key in promoting its

CDMO business model. For many

the latest generation of compaction simulator from Medelpharm. STYL'ONE EVOLUTION

proper up scaling to commercial

Last but not least, site change

could also be a challenge as it

often implies equipment change

the deliverables, Skyepharma has

recently invested in the tableting

instrument STYL'One Evolution,

COMPANY INSIGHT

1 / WHAT IS THE SKYEPHARMA

STRATEGY TO DELIVER QUICKER?

## of the formulation of the product, or possible process simplification. its goal is to provide the best Whatever the challenges are, the formulation that will match the STYL'One can contribute to the QTPP as quickly as possible. final performance of the service If involved at a later stage, our provided by Skyepharma.

supply.

STYL'ONE COVERS ALL

As previously explained,

Skyepharma's aim is to be present

for all aspects of CDMO business

and consequently Skyepharma

needed a single equipment that

could cover in a reliable way all

high speed tableting or dry

Moreover, at the request of

granulation studies.

these options.

Skyepharma as a CDMO has

to address various challenges

When Skyepharma is in charge

goal is to study and characterize

the process parameters to ensure

depending on when we are

involved.

CHALLENGES FOR A FASTER

Skyepharma, Medelpharm has

of multilayer and press coated

tablets such as increased scale

sensors or micrometric core

be reactive and flexible for the

satisfaction of its clients.

centering systems.

been able to provide customized

solutions for specific requirements

## Historically Skyepharma has The quality of aftersales service was developed proprietary technologies also an important aspect for the based on multilayer and dry coated final decision, a company such as tablets. STYL'One Evolution has the Skyepharma needs an equipment great advantage to support such fully operational with the highest technologies beside conventional level of maintenance in order to

TO PROVIDE CUSTOMIZED

ANSWERS, SKYEPHARMA

**SKYEPHARMA TO IMPROVE** 

**FORMULATION DEVELOPMENT?** 

2 / WHY HAS SKYEPHARMA SELECTED

STYL'ONE EVOLUTION?

3 / HOW DOES THE STYL'ONE HELP

Skyepharma recognizes the

importance of being able to

produce tablets at very small

scale under highly controlled

conditions. Therefore we perform

study of the inert as well as active

Dissolution profiles of the various

interpreted despite the production

of very small amount of prototypes,

formulations could be reliably

allowing efficient screening of

the target product profile.

formulation candidates to match

Once target profiles have been

matched, QbD on formulation

variables and impact on dissolution

performances is easy and rapid to

conduct thanks to the accuracy of

ingredients tableting characteristics.

NEEDS SUPPLIERS PROVIDING CUSTOMIZED SOLUTIONS

of development the possible

When complex formulations such

as multilayer tablets or press

coated tablets are considered,

the compression pressures are

playing a major role in the final

performance of the system in

as physical characteristics, the

STYL'One allows us to integrate

and to generate invaluable data.

this parameter at a very early stage

terms of dissolution profile as well

Thus, we integrate at early stage impact of the tableting equipment selected for commercial supply. We therefore define a space design that encompasses not only formulation variables but also equipment.

## the compression simulator.

WITH STYL'ONE SMALL SCALE

BECOMES POWERFUL

**HOW DOES SKYEPHARMA** INTEGRATE STYL'ONE EVOLUTION IN ITS QBD APPROACH? Extensive QbD programs on formulation aspects could be carried out with minimal quantities of API or blends and therefore prevents unnecessary costs linked to raw materials and preparation of

blends for compression tests.

Of course, Skyepharma has

acquired its STYL'One with Analis

compliant to be able to produce

clinical material with this press.

Skyepharma has also designed a

Production software that is 21 CFR

Considering the much reduced time required by STYL'One setup (change of tooling, setting of parameters, cleaning) formulation scientists at Skyepharma can concentrate on analysis of the results and plan next tests and finally provide a better service to the client for a similar budget. WE THINK QbD

very small scale GMP lab where robust and reliable clinical material the STYL'One is installed next to being representative of what the processing equipment for providing final commercial product could be very small batch sizes; including is a clear upside for the success of high shear mixer, fluid bed drier, dry clinical programs. "

WELL CONTROLLED CLINICAL

STYL'ONE, THEREFORE YOU

WON'T WASTE YOUR MONEY IN

AT SMALL SCALE USING

CLINICAL STUDIES

**BUSINESS?** 

processes have to be upscaled

and validated. Despite all tests

production, issues could also

happen, for tableting steps

quickly to deliver on time.

Once again Skyepharma has

conducted comparative studies

their behavior on the STYL'One

versus the industrial tablet presses.

carried out ahead of commercial

MATERIAL COULD BE PRODUCED

**DOES SKYEPHARMA USE ITS** 

**CLINICAL MATERIAL SUPPLY?** 

mill, diffusion mixer, side-vented

pan coater. When low amount of

API or costly API are considered,

allows Skyepharma to supply high

this coherent mix of equipment

quality clinical samples for early

clinical phases. The existence of

STYL'ONE EVOLUTION FOR

THE STYL'ONE PROVIDES UNMATCHED ADDED VALUE FROM DEVELOPMENT TO COMMERCIAL SUPPLY CHAIN

7 /

The reliability of the STYL'One

to implement on conventional

press. For instance new punch

investment limited to one set of

design could easily be tested with

tooling. Last but not least, having a

tableting instrument with high level

allows Skyepharma to conduct

intensive test programs without

impacting production planning.

of correlation with industrial presses

FIRST TIME.

allows us to test solutions quickly

that would be expensive and long

6/ WHAT IS THE BENEFIT OF THE STYL'ONE EVOLUTION FOR CDMO Based on the outcome of these A significant part of a CDMO activity is the commercial supply of finished studies, Skyepharma has now products. Before reaching this step, a clear understanding of the correlation level between the tableting instrument used as a simulator and its industrial presses and is in a position to speed-up, scale-up activities and determine future tablet press settings with everybody has in mind capping or tests carried out on the STYL'One. sticking issues that could become a real nightmare and should be fixed Considering the flexibility of the machine, the rapid turnover of the tests and the limited amount of material to be used, this allows more tests to be carried out for on commercial products to assess a better understanding of critical

process parameters.

ON TIME DELIVERY AND RIGHT

WHICH ARE THE BENEFITS OF THIS

With regards to trouble shooting

support if any, Skyepharma can

test rapidly with limited amount

machines. The final yield and

timelines of production are less

to stick to its key performances

and Right First Time.

impacted and allows Skyepharma

indicators that are On Time Delivery

of material different solutions that

could be then applied to production

**NEW TECHNOLOGY?** 

serialization.

A KEY ASSET TO BE A ONE-STOP-SHOP CDMO

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**BUSINESS?** The acquisition of the STYL'One has dramatically changed the way Skyepharma deals with its clients. development and scale up of products. The combination of its unique expertise in the field of complex dosage forms with the versatility offered by the STYL'One makes a package that allows better quality and quicker service for the client without cost inflation. Ultimately Skyepharma can help its client to access market quicker not at the expense of lower product

quality.

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8 / WHAT IS THE INPUT OF THE STYL'ONE TO SKYEPHARMA This tool has created a true win/win situation between Skyepharma and The STYL'One Evolution has been a major asset in the transformation of Skyepharma as a "One Stop Shop" CDMO, offering full coverage from formulation to manufacturing and commercial packaging including