



# FULLY INTEGRATED EXPERT & AGILE CDMO

Complex and classic oral solid dosage forms

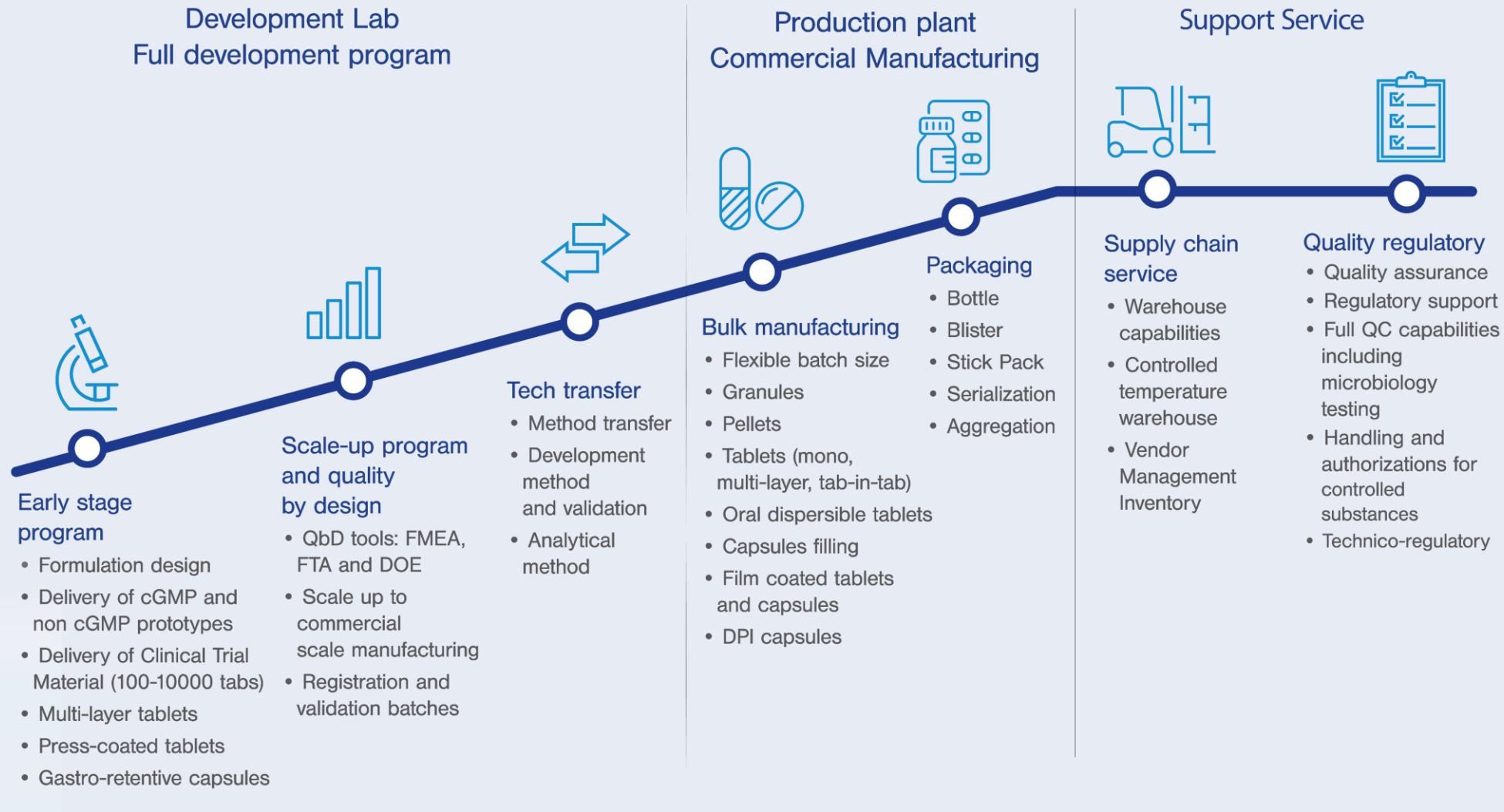


[www.skyepharma.fr](http://www.skyepharma.fr)





Technical teams are involved at the very beginning of your project



## Our Partnership approach

### END-TO-END APPROACH



From development  
to batch certification  
and RTM  
(Release To Market)



FLEXIBILITY  
ADAPTABILITY  
AGILITY

### “A LA CARTE” APPROACH



Select your need  
in our offer of  
services



Skyepharma's partnership approach : Right team, right approach from the start



### IDENTITY

- 1996 : Creation of Skyepharma
- 25 years of experience in oral solid dosage forms
- 150 employees including ¼ in development
- Located near Lyon, France



### GLOBAL MARKET

- Products commercialized in US, EU, Brazil and Asia
- 40% of products exported to the US market
- January 2019: 1st batch serialized and aggregated for the US market



### CERTIFICATIONS

- EU cGMP certified facilities
- FDA approved since 1998, Last inspection in September 2019
- ANVISA approved since 2013
- Registered at South Korean MFDS since 2013



### Available CAPABILITIES/year

- 2 billion tablets
- 300 millions capsules
- 30 millions blisters
- 6 millions bottles
- 20 millions stick-pack
- Fully equipped for early stage development

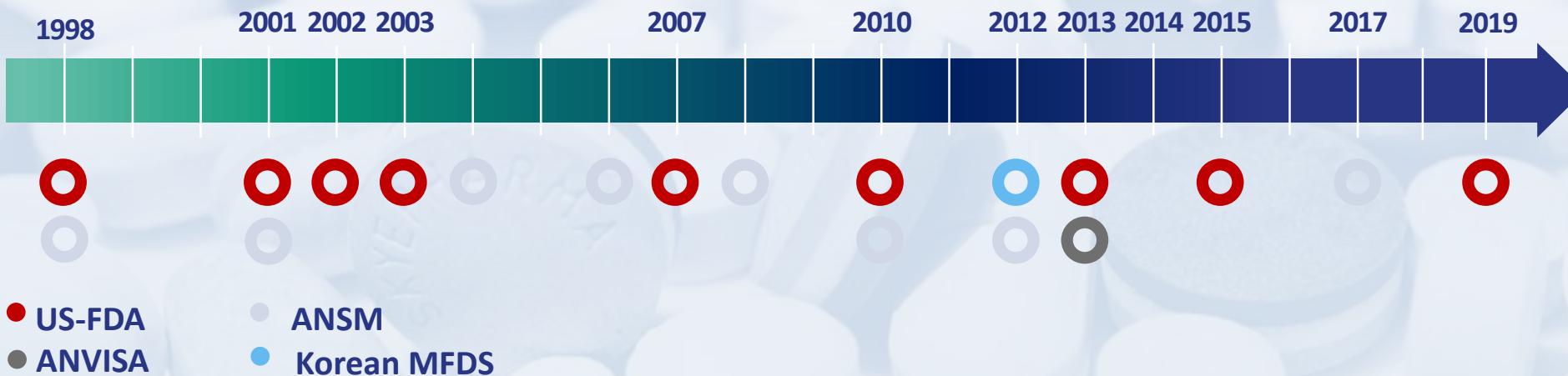


**65, 000m<sup>2</sup>**  
piece of land near  
Lyon France

**22, 000m<sup>2</sup>**  
manufacturing  
facility

We pass the regular inspections carried out by international certification agencies

- EMA-/FDA-approved development and manufacturing facility
- Experience in US and EU regulatory with major pharmaceutical companies
- Data integrity requirements compliance (CFR21 Part 11)





### TABLETS

Mono-layer, multi-layer press-coated and oral disintegrating tablets



### CAPSULES

Filled with tablets, granules, pellets or powder



### GRANULES & PELLETS

Aqueous and organic granulation  
Roller compaction



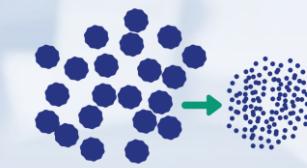
### DPI CAPSULES

Inhalation grade  
100% weight checking



### FILM COATING

Tablets and capsules



### Microfluidizer Technology

Bioavailability enhancement  
Dynamic high pressure processing



### STICK-PACK

Filled with powder & granules



### BLISTER

PVC, PVDC, Aclar, Triplex, Alu/Alu  
Serialization and aggregation



### BOTTLE

Plastic and glass bottle  
Serialization and aggregation

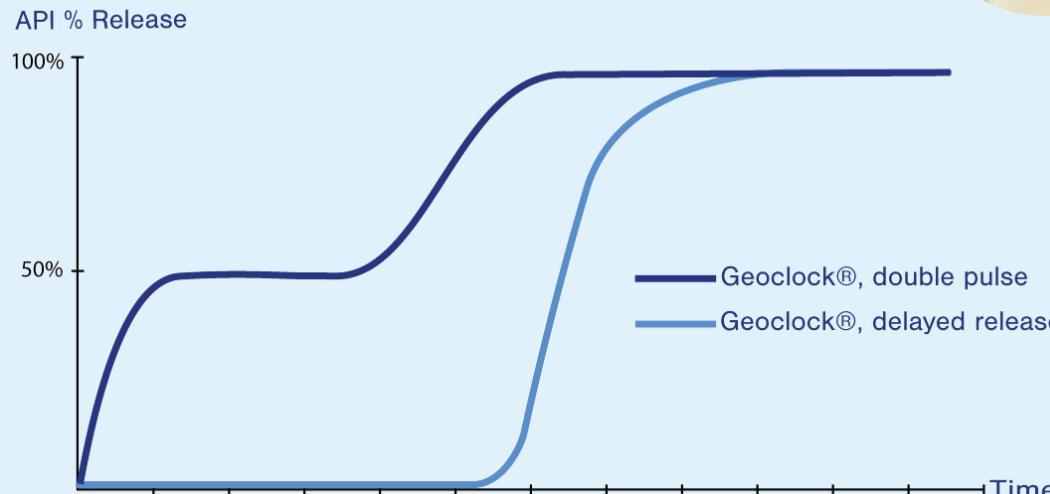
# OUR FULLY INTEGRATED OFFER



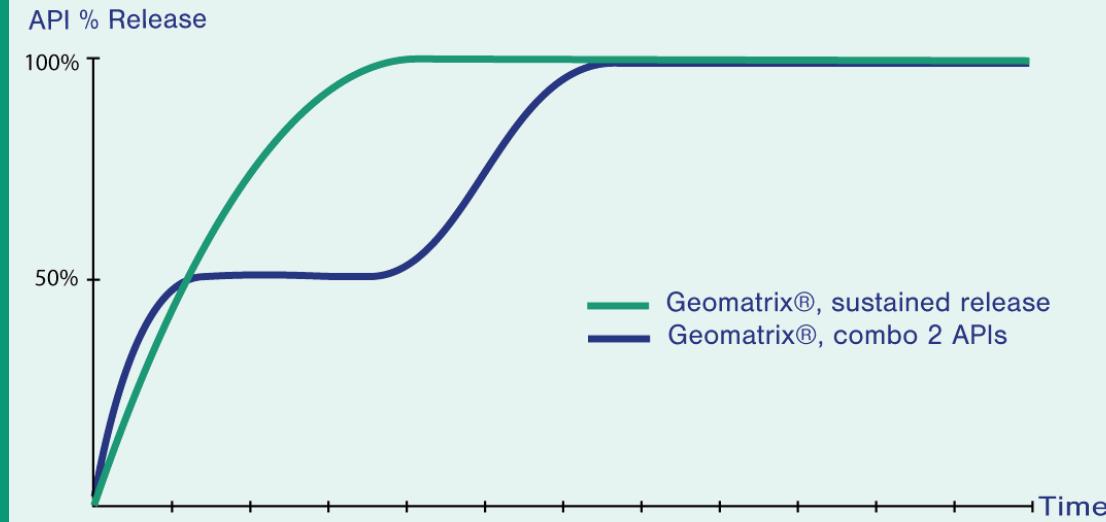


## CONTROLLED RELEASE TECHNOLOGIES – ALREADY INDUSTRIALIZED – CURRENTLY ON THE MARKET

### GEOCLOCK® Press-coated tablets



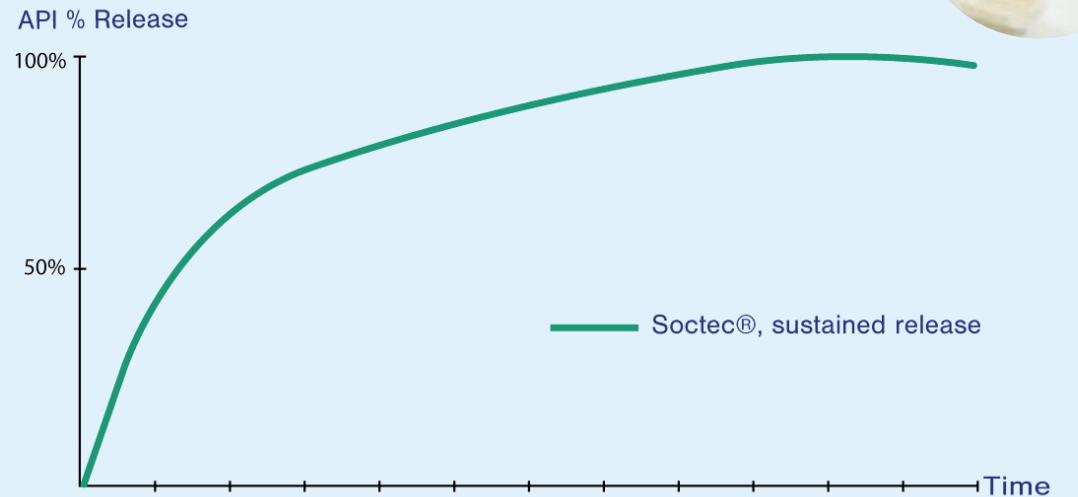
### GEOMATRIX® Multi-layer tablets





## CONTROLLED RELEASE TECHNOLOGIES – IN DEVELOPMENT PHASES – PROOF OF CONCEPT

### SOCTEC® Gastro-retentive capsule



### MEDICATED CHEWING-GUM

Local delivery for poorly soluble drug

#### How it works ?

Skyepharma's technology uses an approach similar to multilayer tabletting. A combination of layers modulates the release rate of the active ingredients and flavouring agents when the gum is chewed.

## PHARMACEUTICAL DEVELOPMENT

- 'Quality by design' approach (FMEA, FTA, DOE, etc.)
- Formulation/process design
- Expertise in controlled-release oral dosage forms
- Scale-up modelling/compression simulator

## SPECIFIC EQUIPMENT

- Wet granulation : ProCept HSM 1 & 4L
- Drying : ProCept FBD 1 & 4L
- Milling : Erweka AR 403 + FGS
- Lubrification/Blending : Erweka AR 403 + Cube
- Tableting : Styl'One Evolution (with multi-layer and press-coating modules)
- Film coating : ProCept Pan Coater
- Packaging : PMC bottle line / Rohrer blisterline

## SCIENTIFIC EXCELLENCE

- Collaboration with Bordeaux University (Pr. Tchoreloff) – PhD thesis financed by Skyepharma
- Scientific communications (Compaction Simulation Forum US / EU, OnDrugDelivery,...)
- Skyepharma supported by French Government R&D Tax Credit (CIR)





## BOTTLE

- Plastic and glass bottle
- Cylindrical or square
- Desiccant - Additional cotton
- All types of caps
- Bottle width 18 to 90 mm
- Caps's width 7 to 50 mm
- Bottle height 35 to 180 mm
- 100% visual counting & inspection



## BLISTER

- PVC, PVDC, Aclar, Triplex / Alu
- Alu/Alu
- Blister lenght 70 to 140 mm
- Blister width 30 to 86 mm
- Depth Up to 12 mm
- 100% visual counting & inspection

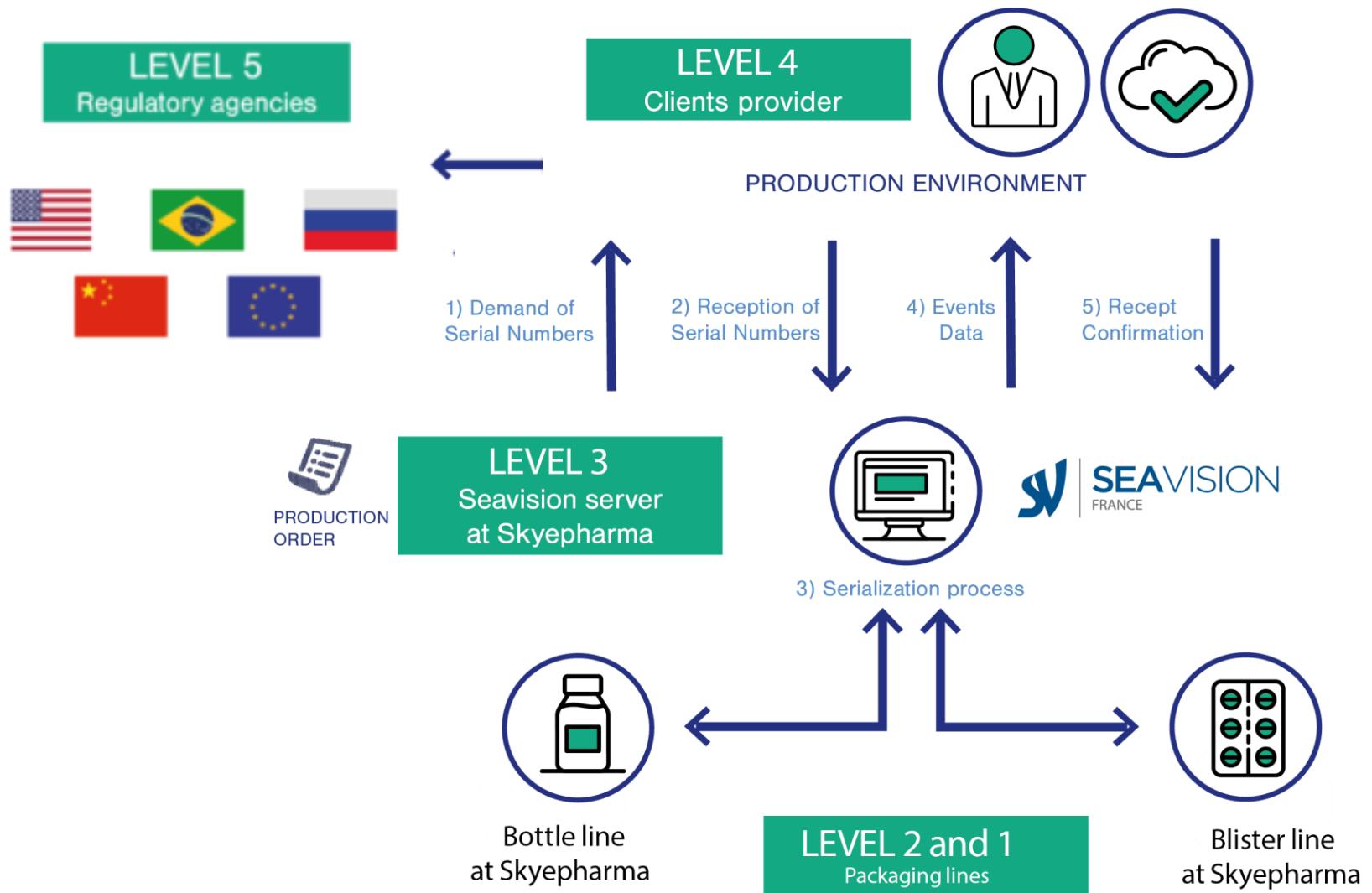


## STICK-PACK

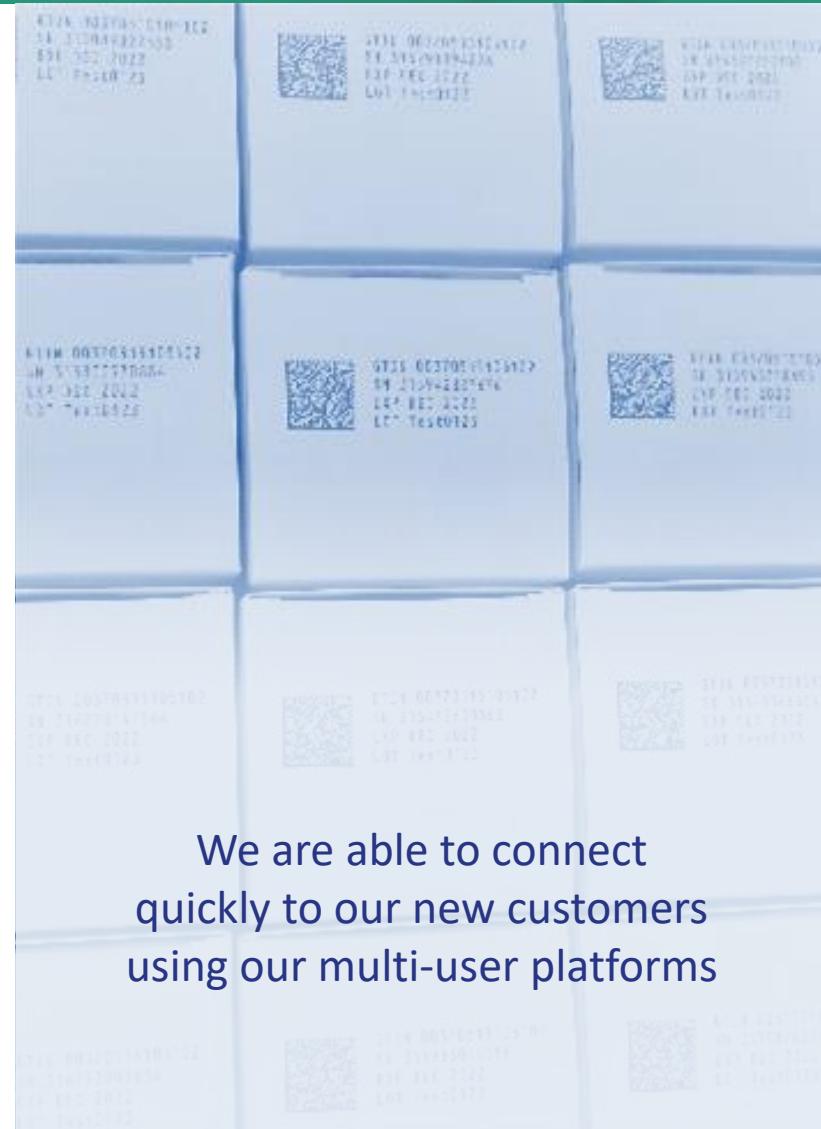
- Filled with powder, granules and pellets



# Serialization and Aggregation services



We are able to connect quickly to our new customers using our multi-user platforms





# Discover our facilities, team and services on our Youtube Channel !



Skyepharma CDMO -  
Pharmaceutical Development



Skyepharma CDMO -  
Microfluidizer Technology



Skyepharma CDMO -  
Manufacturing capabilities



Skyepharma - Packaging  
services 2020



Skyepharma - "What do we  
mean by Fully Integrated CDMO



Skyepharma - "What do we  
mean by Agile CDMO ?"



Skyepharma - "What do we  
mean by Reliable CDMO ?"



Skyepharma CDMO - "What  
do we mean by TEAM IS..."

# THANK YOU !

CPhI Worldwide 2019 - Frankfurt

