

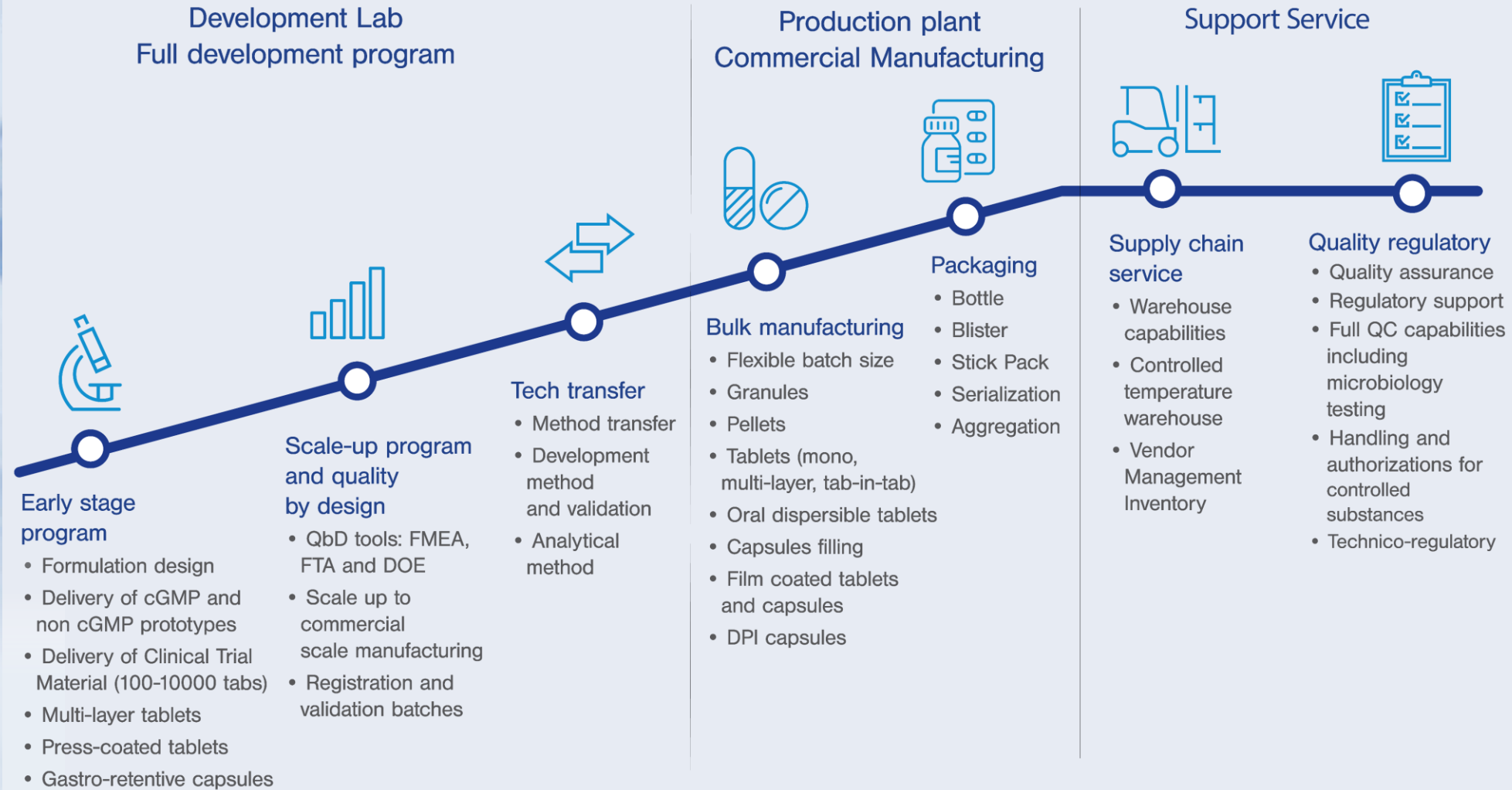
FULLY INTEGRATED EXPERT & AGILE CDMO

Complex and classic oral solid dosage forms

Fully integrated CDMO



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, 000m²

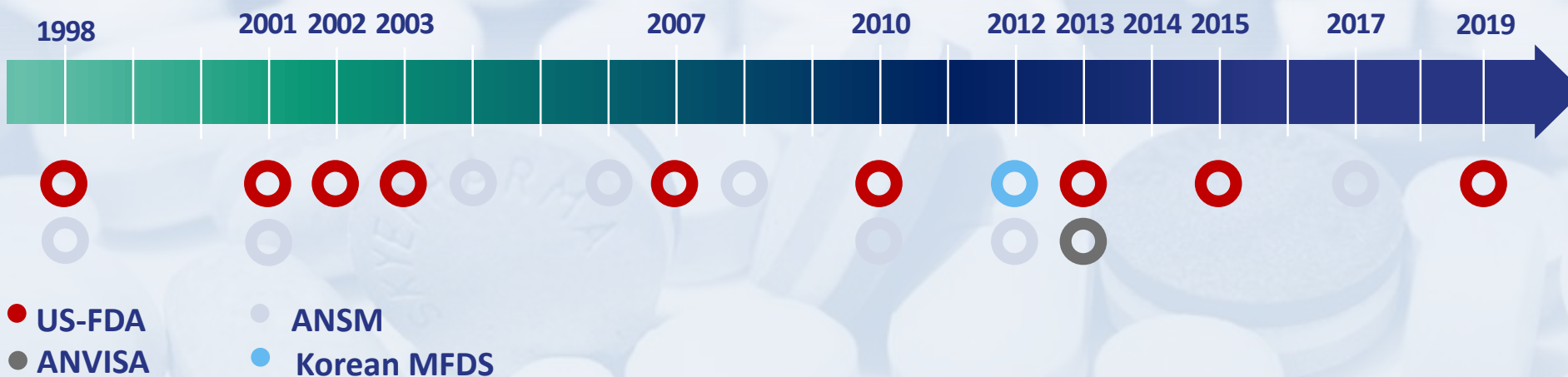
piece of land near
Lyon France

22, 000m²

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



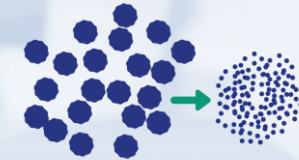
DPI CAPSULES

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

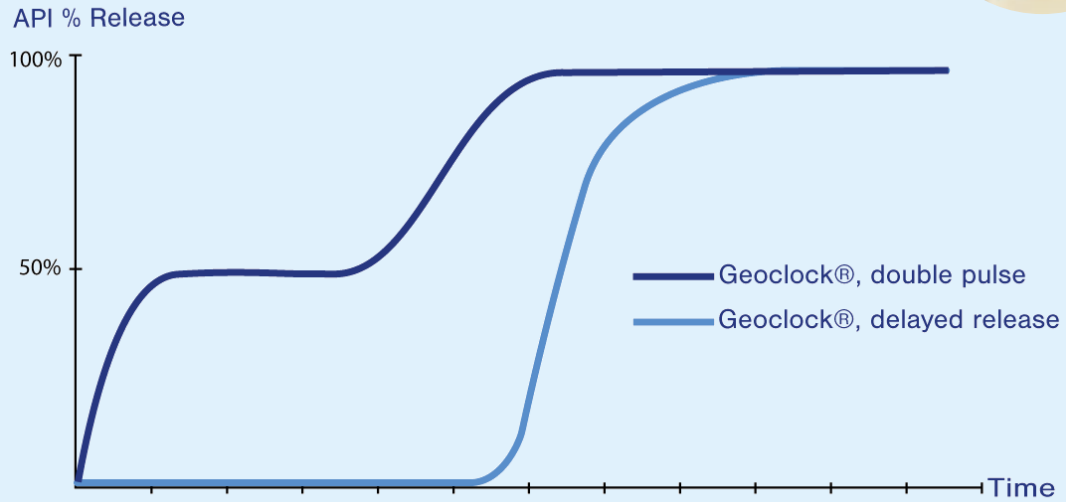
OUR FULLY INTEGRATED OFFER



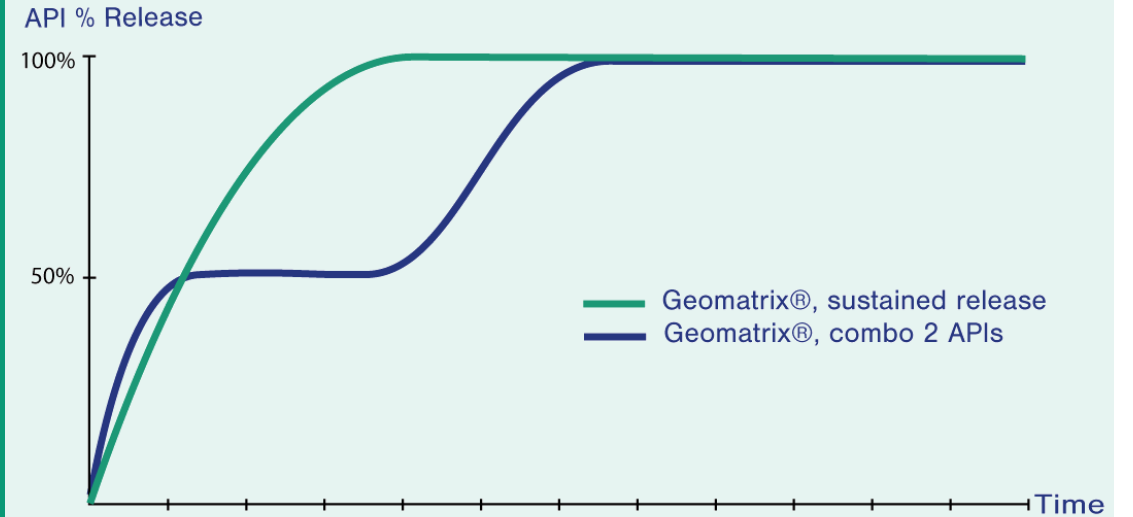


CONTROLLED RELEASE TECHNOLOGIES – ALREADY INDUSTRIALIZED – CURRENTLY ON THE MARKET

GEOCLOCK® Press-coated tablets



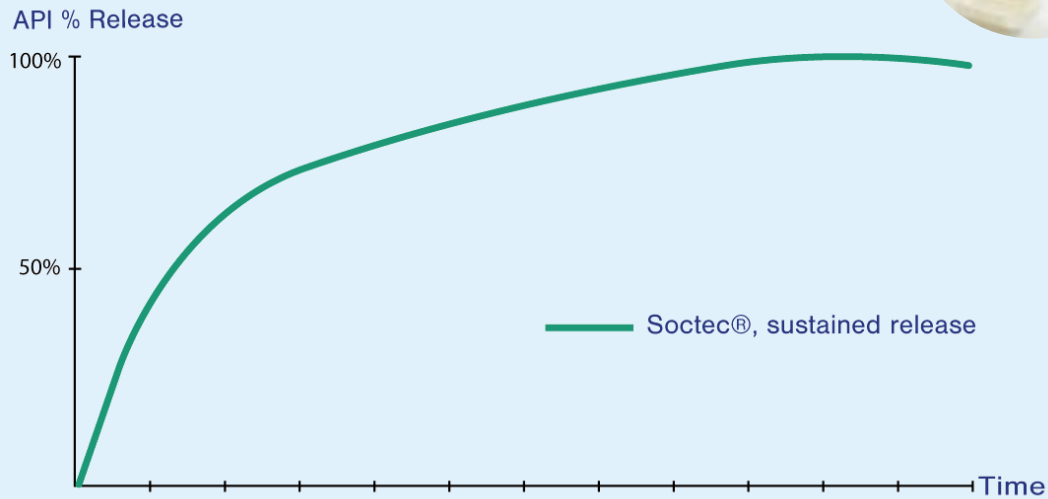
GEOMATRIX® Multi-layer tablets





CONTROLLED RELEASE TECHNOLOGIES – IN DEVELOPEMENT 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 tableting.

A combination of layers modulates the release rate of the active ingredients and flavouring agents when the gum is chewed.

Development from early stage to registration

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)



Commercial packaging capabilities



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 length 70 to 140 mm
- Blister width 30 to 86 mm
- Depth Up to 12 mm
- 100% visual counting & inspection

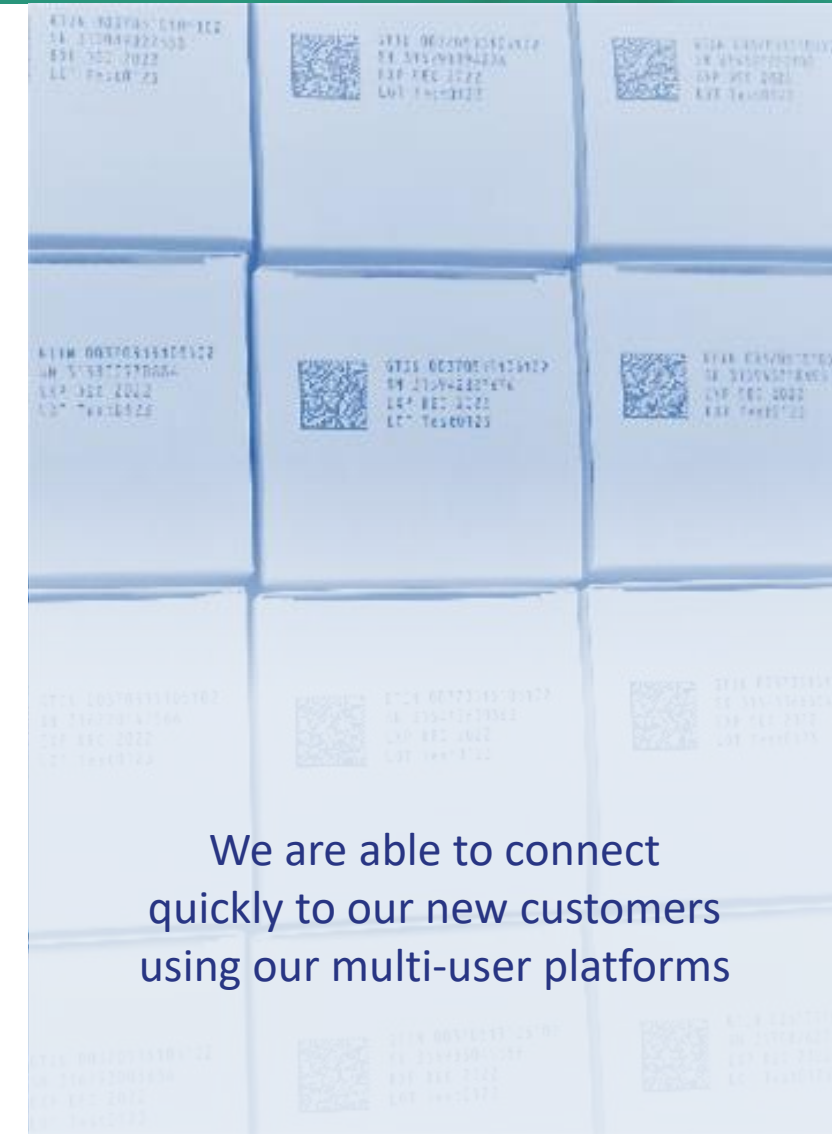
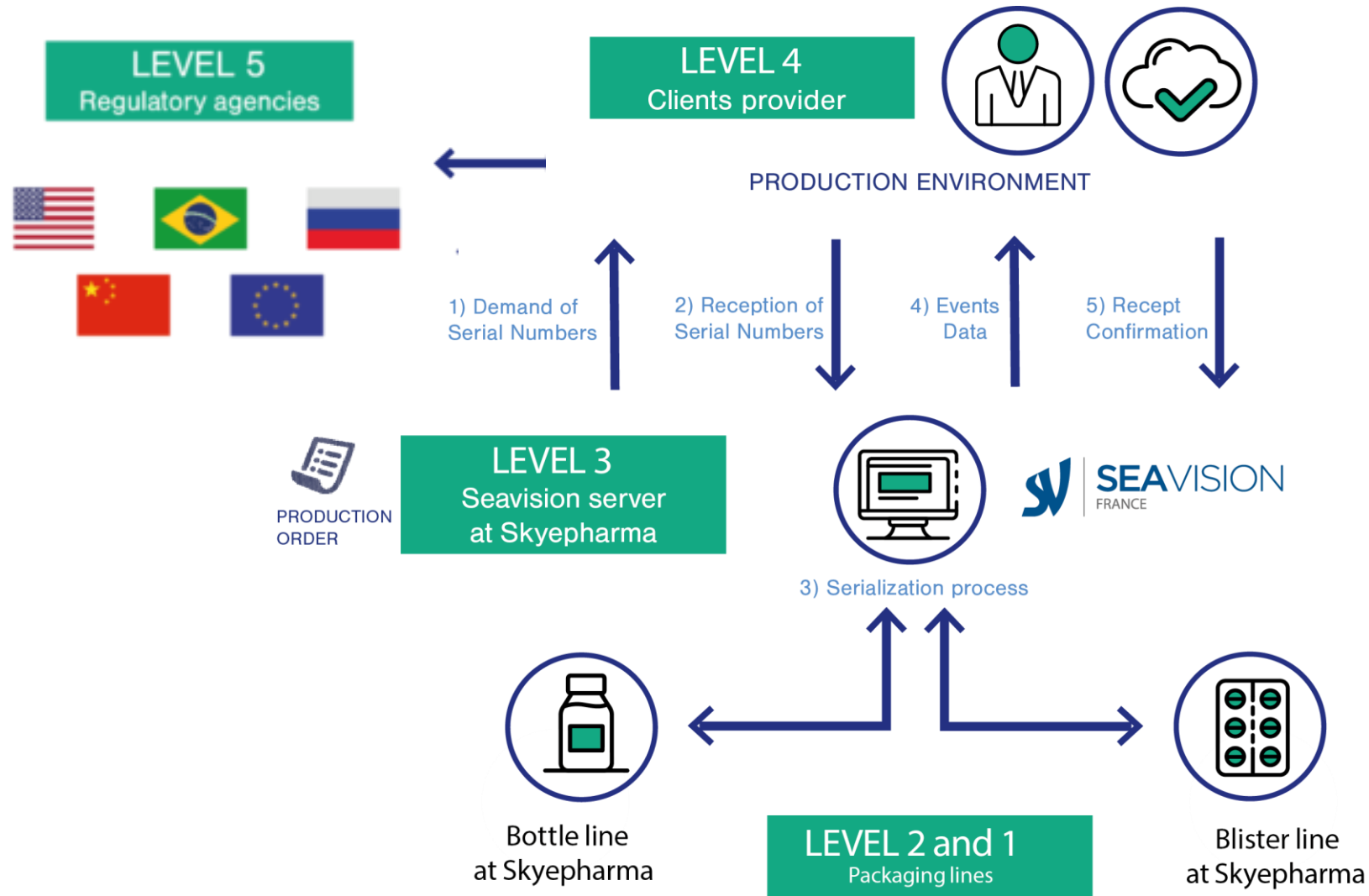


STICK-PACK

- Filled with powder, granules and pellets



Serialization and Aggregation services





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 !

CPH Worldwide 2019 - Frankfurt

