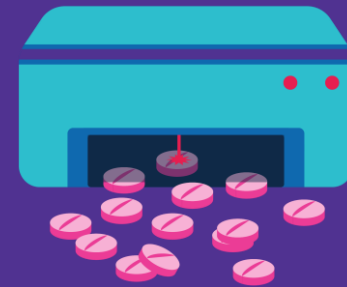


# Digitalizing the production of pills

3D medical printing conference

February 2021  
Christoph Hüls

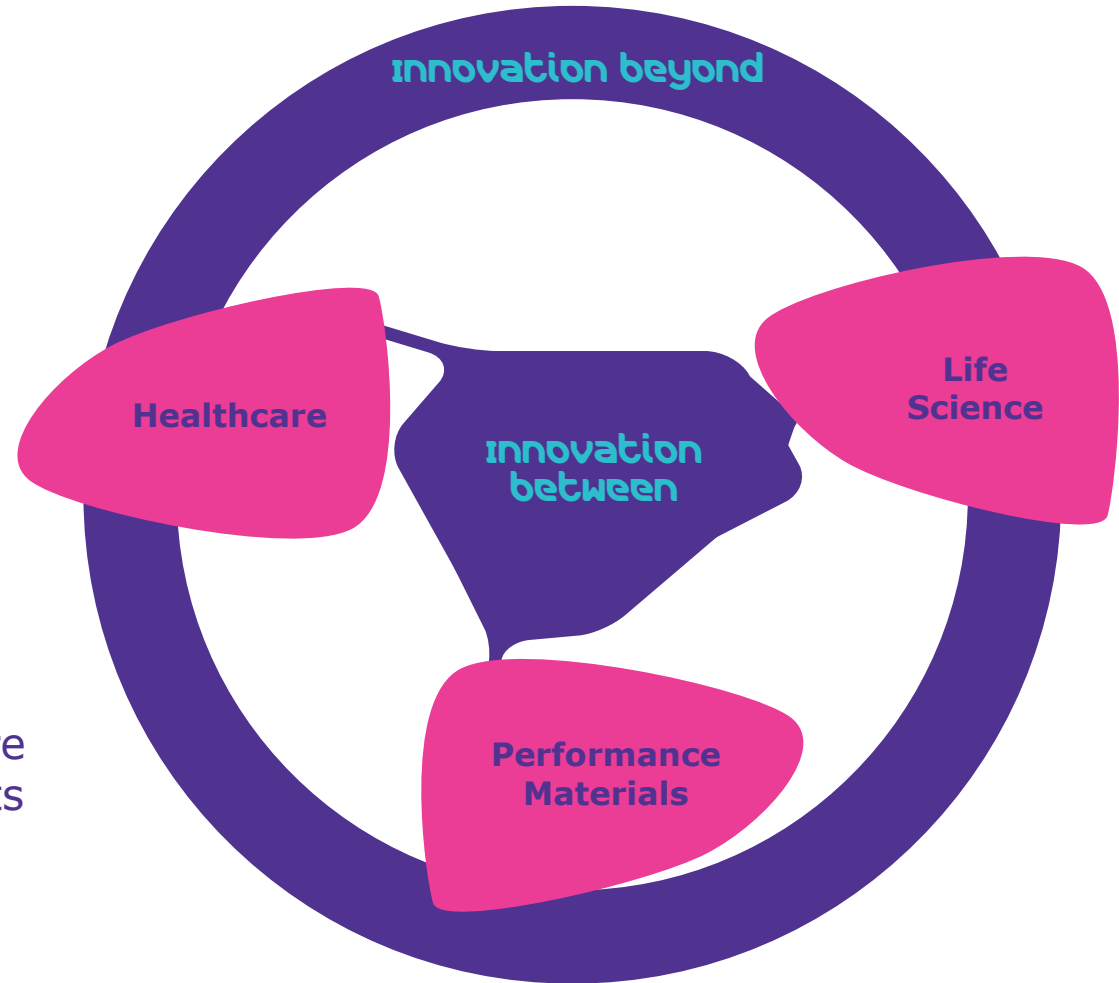


**MERCK**

# Driving CROSS & beyond sector innovation

to generate new business for Merck

In the Merck Innovation Center, we identify innovative approaches at an early stage and scale them to viable new businesses. Ideas are grown into innovation projects based on assets of Merck.



help ideas  
**grow** -  
and scale up  
to **viable**  
new business.

Beyond current boundaries.

**propel**  
strategic  
growth fields

Innovation  
Fields &  
Exploratory  
platforms



**build**  
strong internal  
innovation  
project portfolio

Boost project  
progress



**create**  
platform for  
serendipity

Be the place for  
intrapreneurs  
to realize  
their ideas



**establish**  
valuable  
partnerships

Startups, Academia,  
Cross Industry



**strengthen**  
innovator skills  
& innovation  
culture

Innovator  
Academy

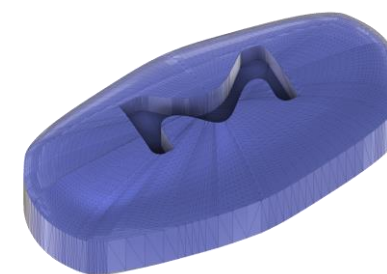
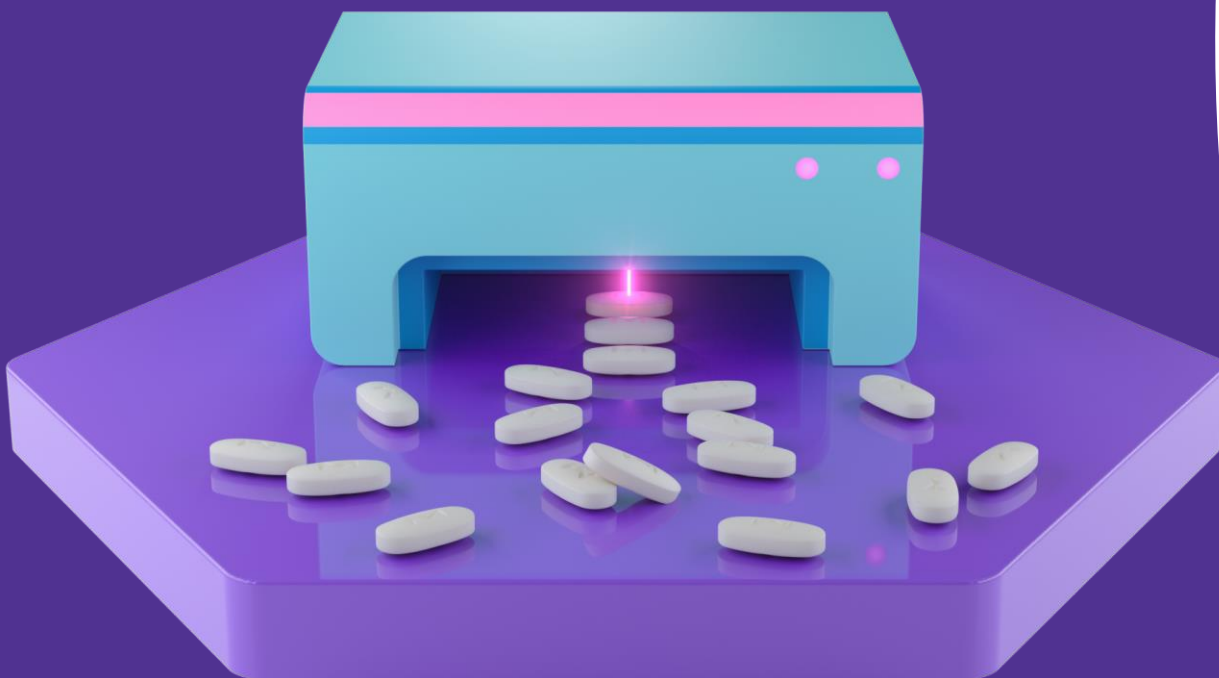


# WE 3D-print Medicine

Revolutionizing the production of tablets

Digitally designing and varying tablets

Enabling a digital, decentralized production



# 3D Printing of solid oral dosage forms

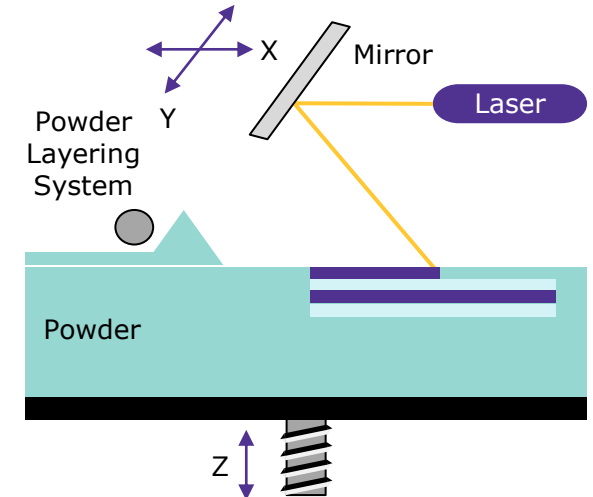
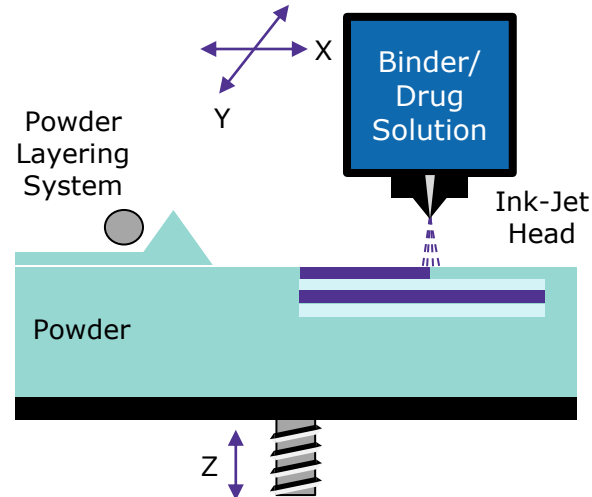
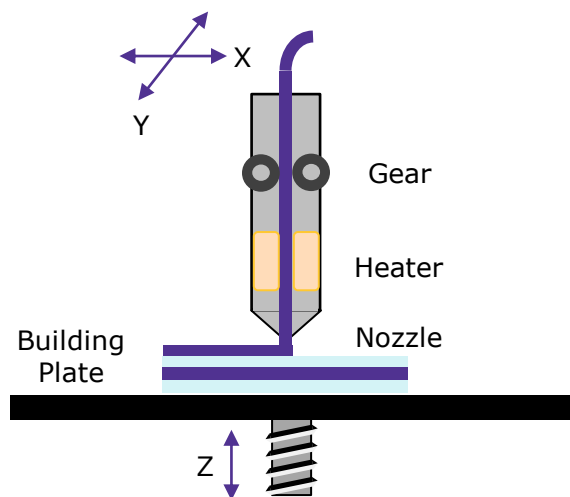
## One name, several technologies

### Additive Manufacturing

Fused  
Deposition  
Modeling

Binder Jetting

Selective  
Laser Sintering



# 3D printing for solid oral dosage forms

## Comparison to established technologies

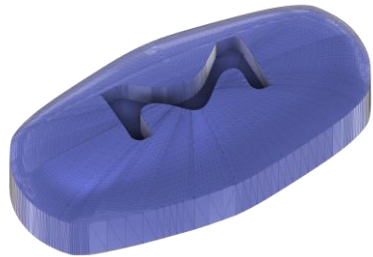
	Conventional		3D Printing		
	Capsule filling (Xcelodose)	Tablet pressing (production size)	Fused Deposition Modeling (FDM)	Inkjet/ binder jetting	Powder bed fusion
Appearance	Capsule	Very good	Irregular surface	Irregular surface	Satisfactory shape & surface
Mechanical properties	n.a.	Good variability	High variability	High variability	Acceptable variability
Cost per tablet	~10€	<0.01€	TBD	<1€	<1€
Throughput per day	1000	>1M	150	~100,000	100,000
Batch size	1,000-30,000	>100,000	50	up to 10,000	up to 25,000
Formulation dev. time	3-4 month	>12 month	6-12 month	4 month	4 month

**Powder bed fusion to build the bridge from prototyping to manufacturing scale**

- Appearance
- Throughput
- Cost
- Time

## Laser Sintering

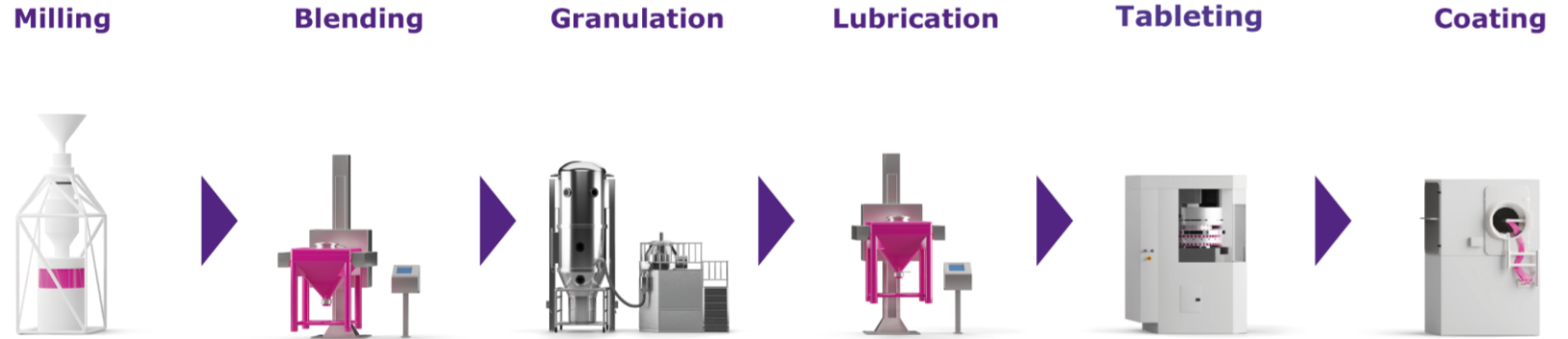
# Proof of Concept demonstrates printed tablets exhibit the desired properties of conventional tablets



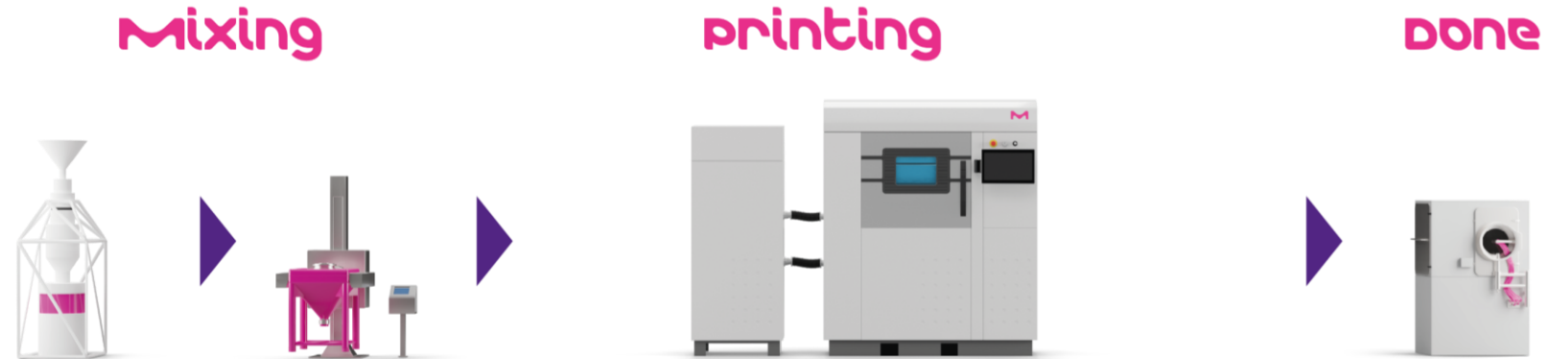
- Shape in specification
- Acceptable surface roughness
- Tablet mass in expected specification
- Tablet hardness in expected specification
- Uniform API content
- No API degradation detected
- Dissolution profile comparable to traditional manufacturing

# Additive Manufacturing of tablets is simple, inexpensive and flexible

Traditional tablet manufacturing process

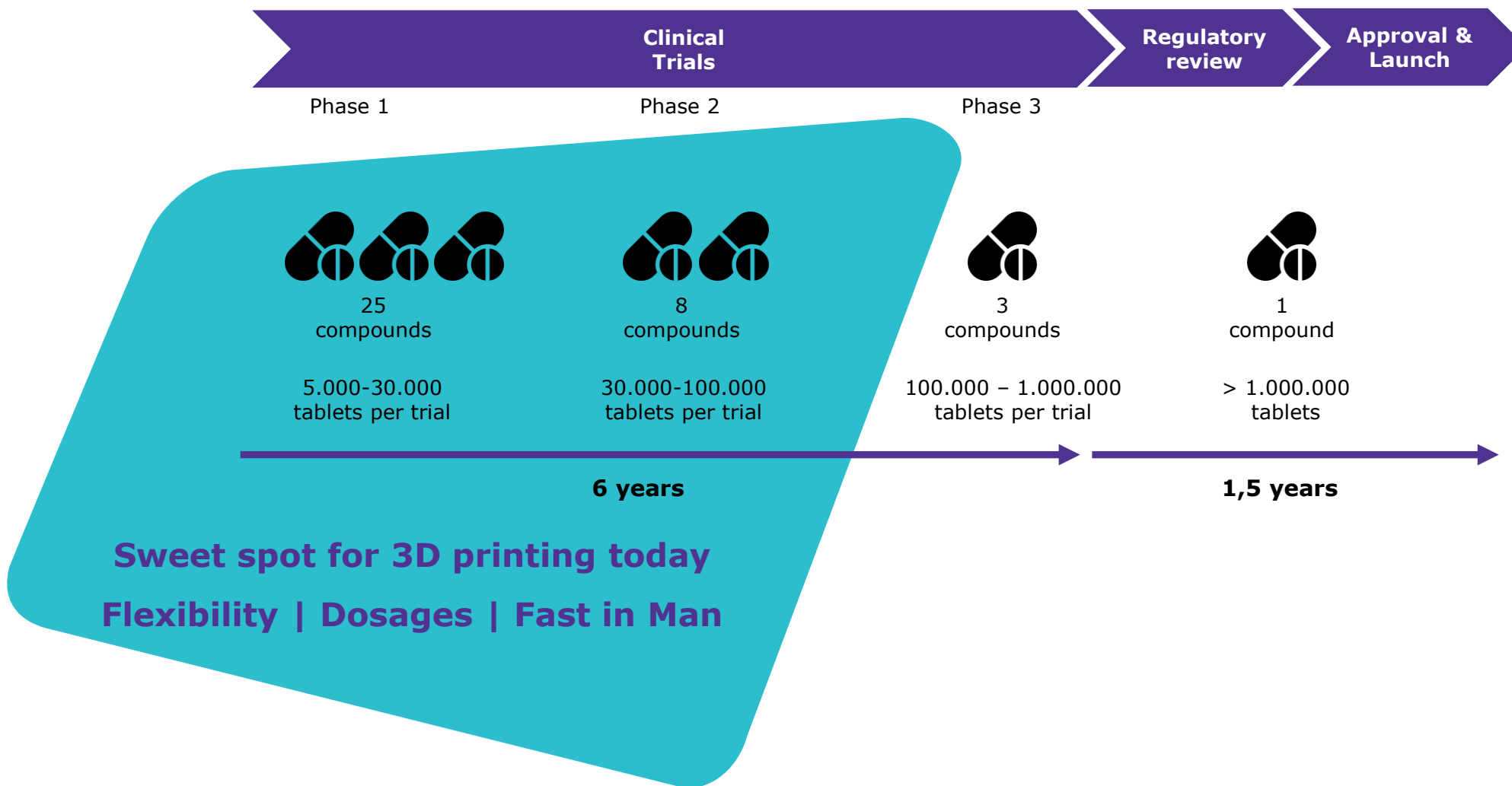


Next generation tablet manufacturing  
3D printing of tablets based on laser sintering





# 3D printing is especially beneficial for early clinical trials



# Benefits in numbers

**70% cost savings potential in early clinical trials processes for tablet production**

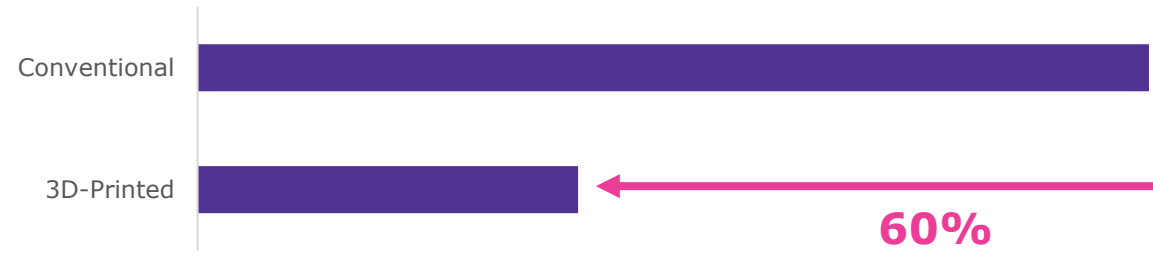
## Required API for production and formulation

Phase 1 to 3 combined



## Average formulation development time

Phase 1 to 3 combined



## API savings

- Average amount of API required for Phase 1 clinical trial supply incl. development: app. 10 kg
- Tablet printing for clinical trial supply could reduce required API by 50%

## Time savings

- Average duration required for formulation development & clinical trial supply across clinical phase I-III: 2-3 years
- Tablet printing could, in best case (when used in clinical phase I-III), reduce time by 60%

Digital flexibility

## Tablet properties are adjusted digitally and not mechanically



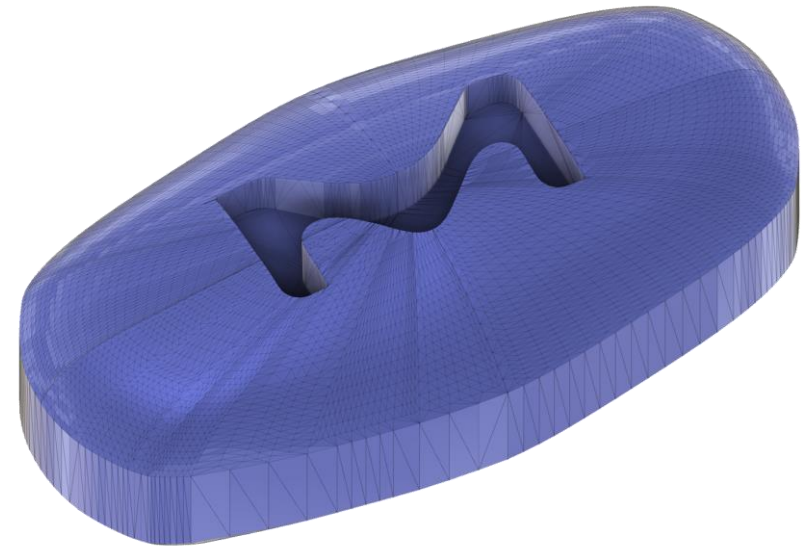
### Digitally adjustable 3D printing

- API dose/ tablet volume
- Tablet shapes
- Laser power and speed > dissolution
- Irradiation pattern
- Orientation of objects on building chamber
- Batch size

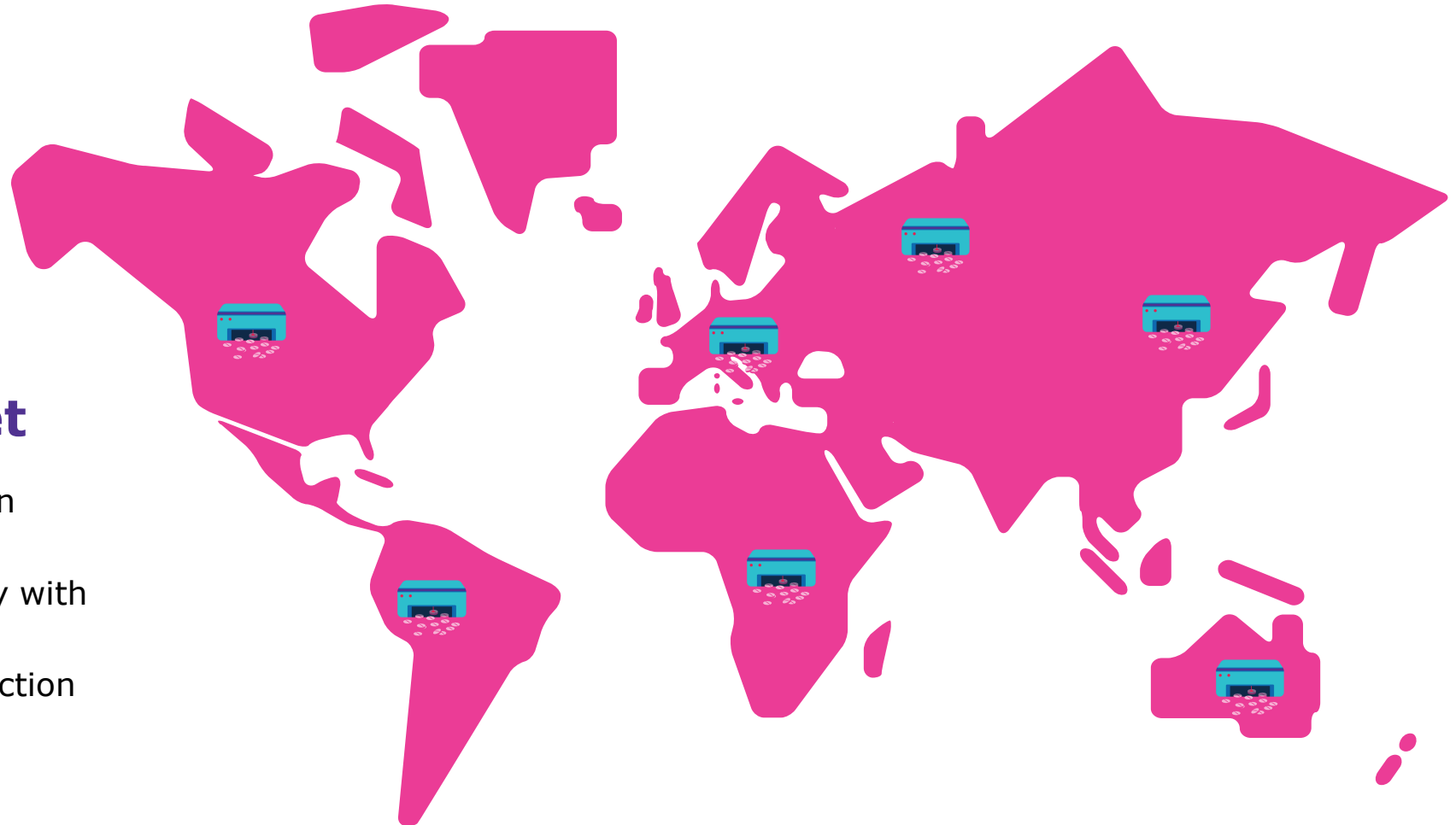


### Tablet properties

- Appearance
- Content & Purity
- Dissolution properties
- Hardness
- Dosage with volume



# Vision: decentralizing the production footprint

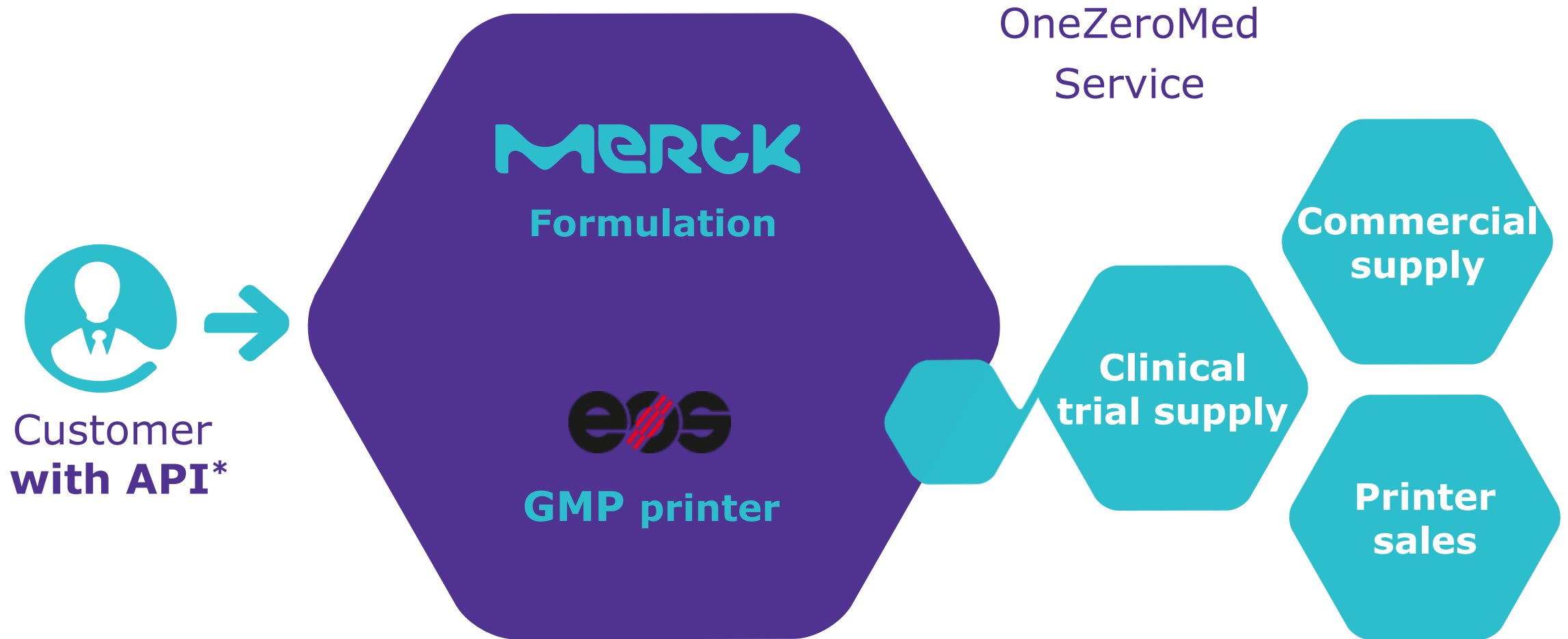


## Scale with market

- Don't invest in one facility in your head quarters
- Scale the commercial supply with local 3D printers
- Digitalize the pharma production

# Business Concept

## OneZeroMed Service: GMP certified manufacturing platform



**THANK YOU!**

