

oncomed manufacturing a.s.
where courage meets knowledge

Technical presentation

oncomed

member of medac group

about us



founded in 2010



**located in Brno,
Czech Republic**



**more than
200 employees**



**40 years of experience
with HPAPI injectables**

our technological excellence as a CDMO



organic solvents
handling



single-use
systems



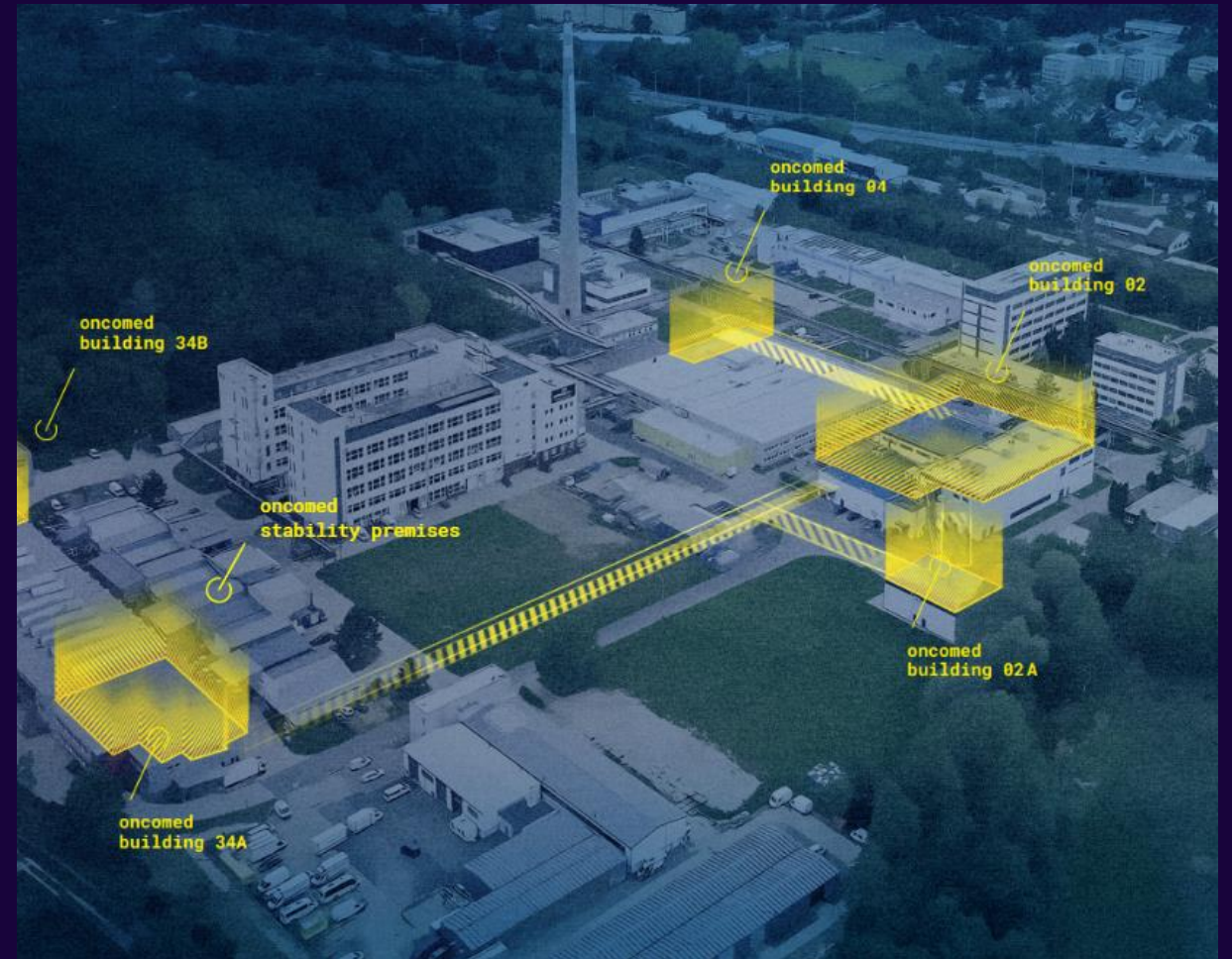
high-potent
APIs



sensitive API
handling

site layout

- ▶ **02** Production site and administration
- ▶ **02a** Power center
- ▶ **04** Administration offices (QA, BA, IT)
- ▶ **34a** Warehouse (auxiliary, technical and packaging materials), BD offices
- ▶ **34b** Product warehouse



portfolio scope



formulations



dosage forms



manufacturing
scale



molecule type

- ▶ liquid
- ▶ liquid terminally sterilized
- ▶ freeze-dried

- ▶ vials
- ▶ syringes *(in process)*
- ▶ cartridges *(in process)*

- ▶ **small scale**
(pre-clinical, clinical phase I & II)
- ▶ **large scale**
(clinical phase III, commercial)

- ▶ **small molecules**
(HPAPI non-cyto, cytotoxic, cytostatic)
- ▶ **large molecules**
(biologics, ADCs, oligonucleotides)

our offerings



small molecules offering

- ▶ development services
- ▶ clinical supply services
- ▶ commercial supply services
- ▶ analytical/microbiological
- ▶ stability
- ▶ optical inspection
- ▶ packaging & bulk product release

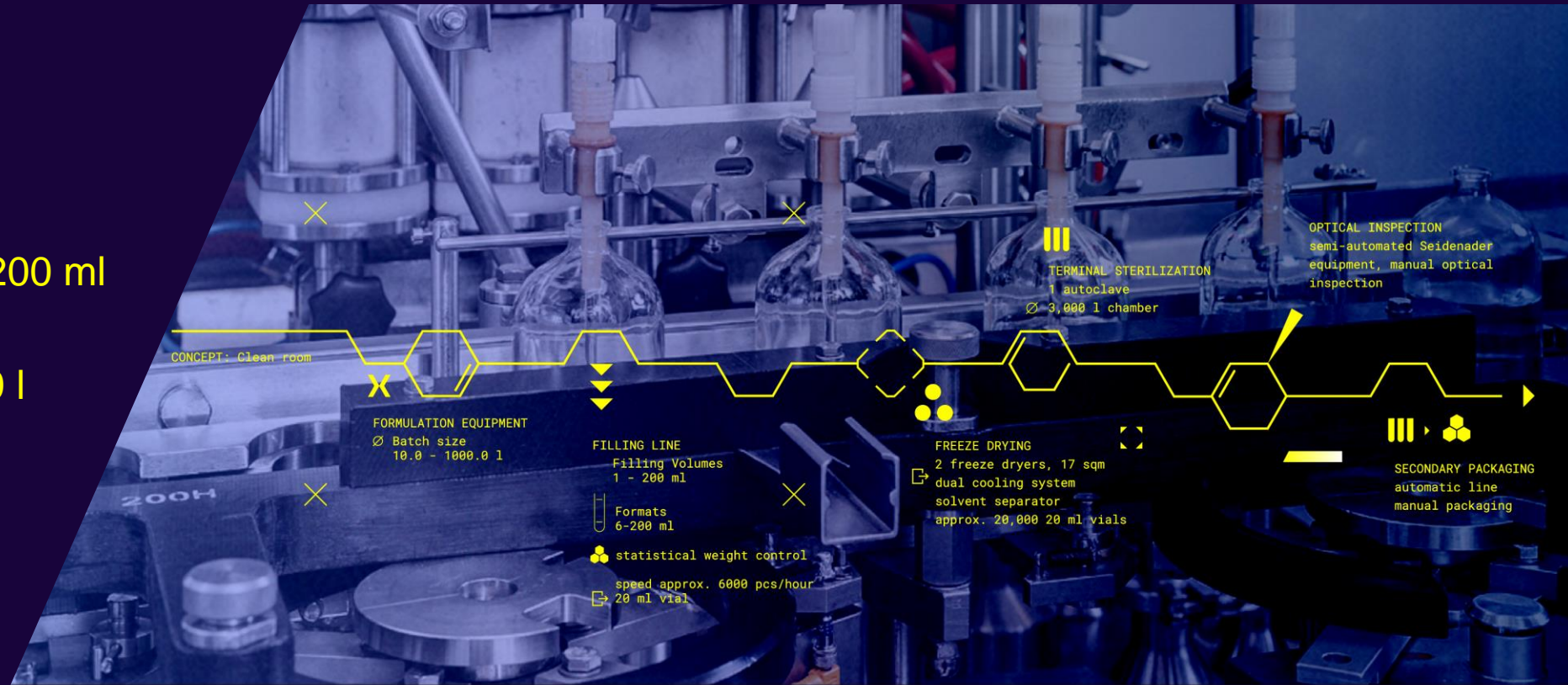


large molecules offering

- ▶ clinical supply services
- ▶ commercial supply services
- ▶ stability
- ▶ optical inspection
- ▶ packaging & bulk product release

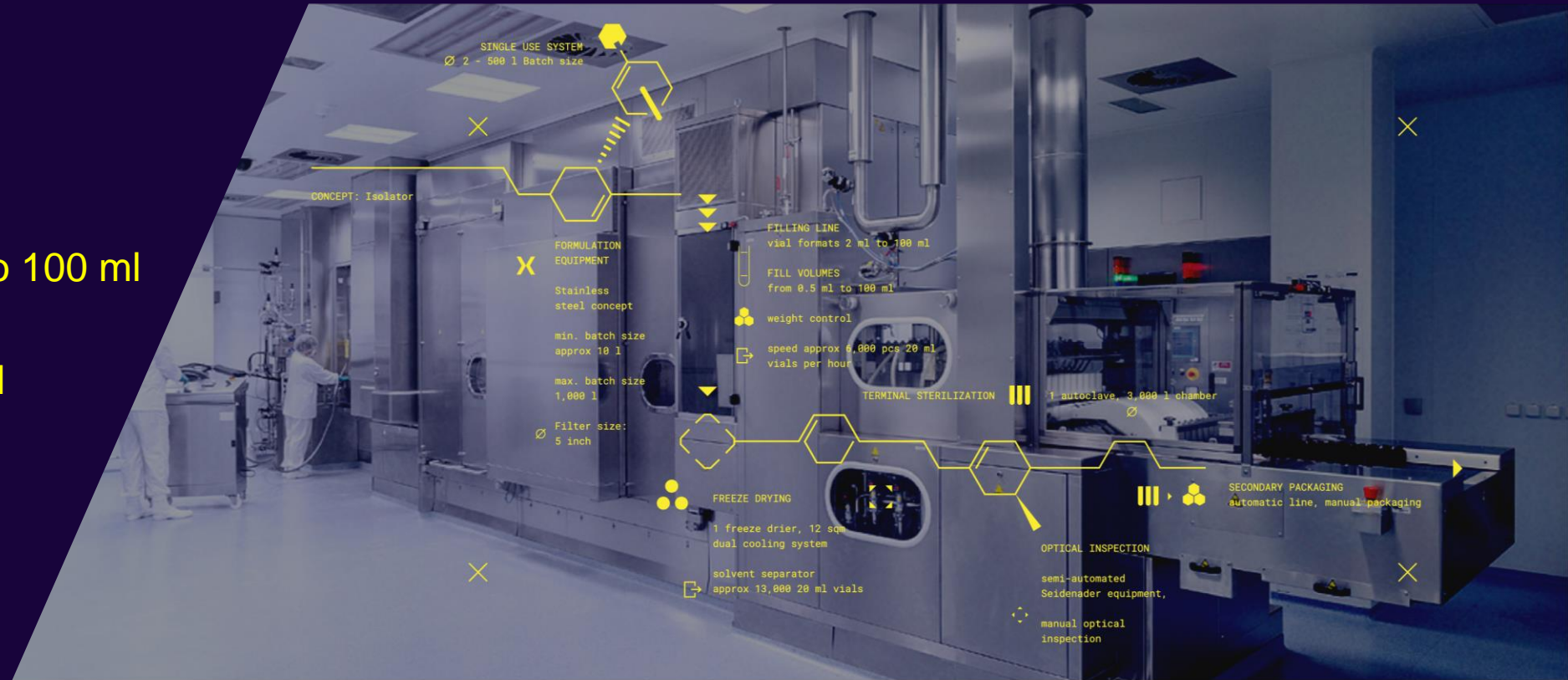
production line 1

- ▶ clean room concept
- ▶ fill volumes from 1 ml to 200 ml
- ▶ batches from 10 l to 1000 l
- ▶ 2 freeze dryers



production line 2

- ▶ isolator concept
- ▶ fill volumes from 0.5 ml to 100 ml
- ▶ batches from 2 l to 1000 l
- ▶ 1 freeze dryer

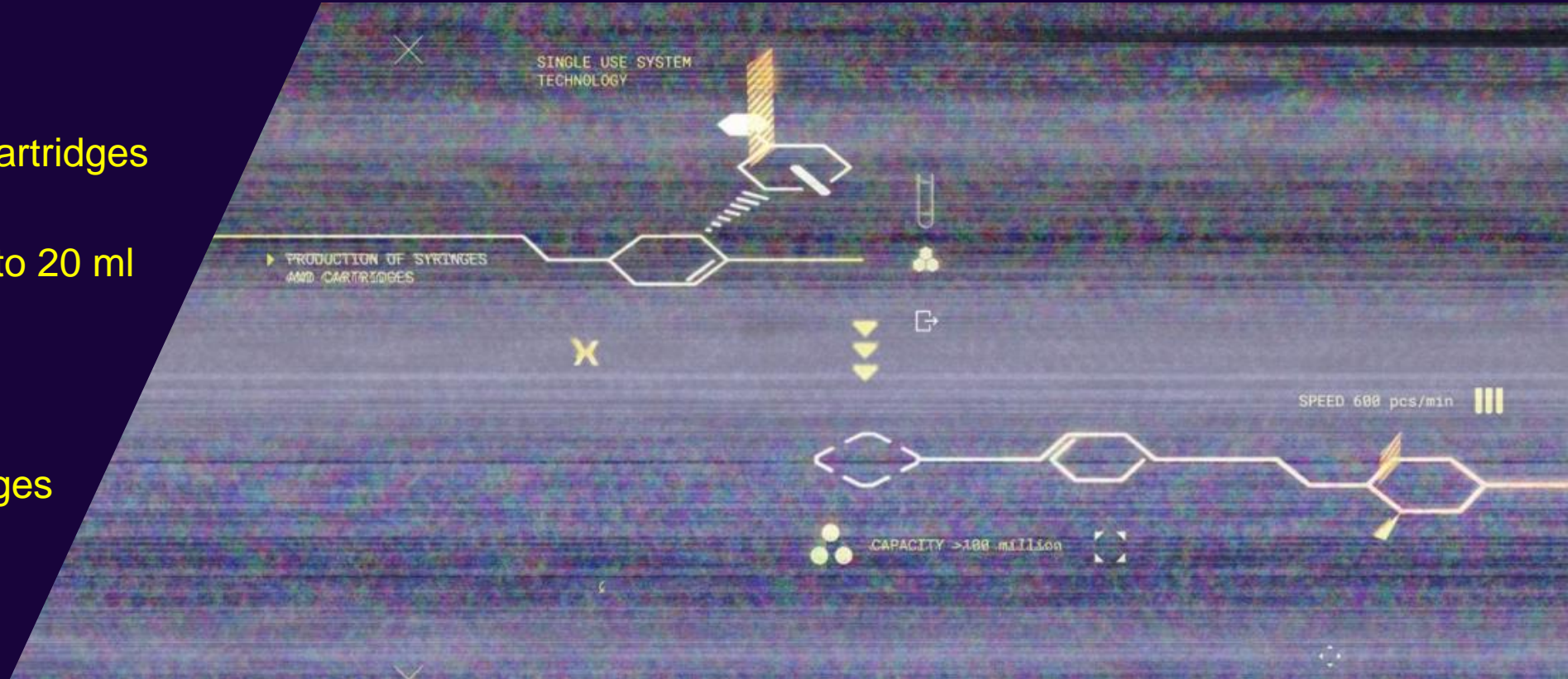


production lines comparison

		Line 1	Line 2
Construction/ installation		▶ 1997 / 1998	▶ 2007 / 2012
Concept		▶ Clear room A/B/C/D	▶ Isolator
Formulation equipment	Batch size	▶ 10 l to 1.000 l	▶ 2 l to 1.000 l
Filling line	Manufacturer	▶ Groninger	▶ IMA
	Formats/filing volumes	▶ 6R to 200H (1 ml to 200 ml)	▶ 2R to 100H (50H for lyo) (0,5 ml to 100 ml)
	Automatic weight control	▶ Statistical	▶ 100%
	Speed	▶ 6.000 vials/h nominal, i.e. 1.000 vials/h (200H) 4.000 vials/h (6R)	▶ 6.000 vials/h nominal, i.e. 2.000 vials/h (100H) 5.000 vials/h (2R)
Freeze drying	Nr. of equipment	▶ 2 x 17 sqm	▶ 1 x 12 sqm
	Manufacturer	▶ GEA	▶ GEA
	Capacity	▶ 300 kg of ice/ 24 h 38.000 vials (6R) 7.000 vials (100H)	▶ 200 kg of ice/ 24 h 24.000 vials (6R) 6.500 vials (50H)
Terminal sterilization		▶ 1 autoclave STERIS, 3.000 l chamber	
Optical inspection		▶ Semi-automatic Seidenader inspection machine	
Secondary packaging		▶ Groninger labelling machine, manual packaging	

production line 3 in progress

- ▶ production of syringes/cartridges
- ▶ fill volumes from 0.5 ml to 20 ml
- ▶ batches from 1 l to 500 l
- ▶ capacity > 100 mil syringes



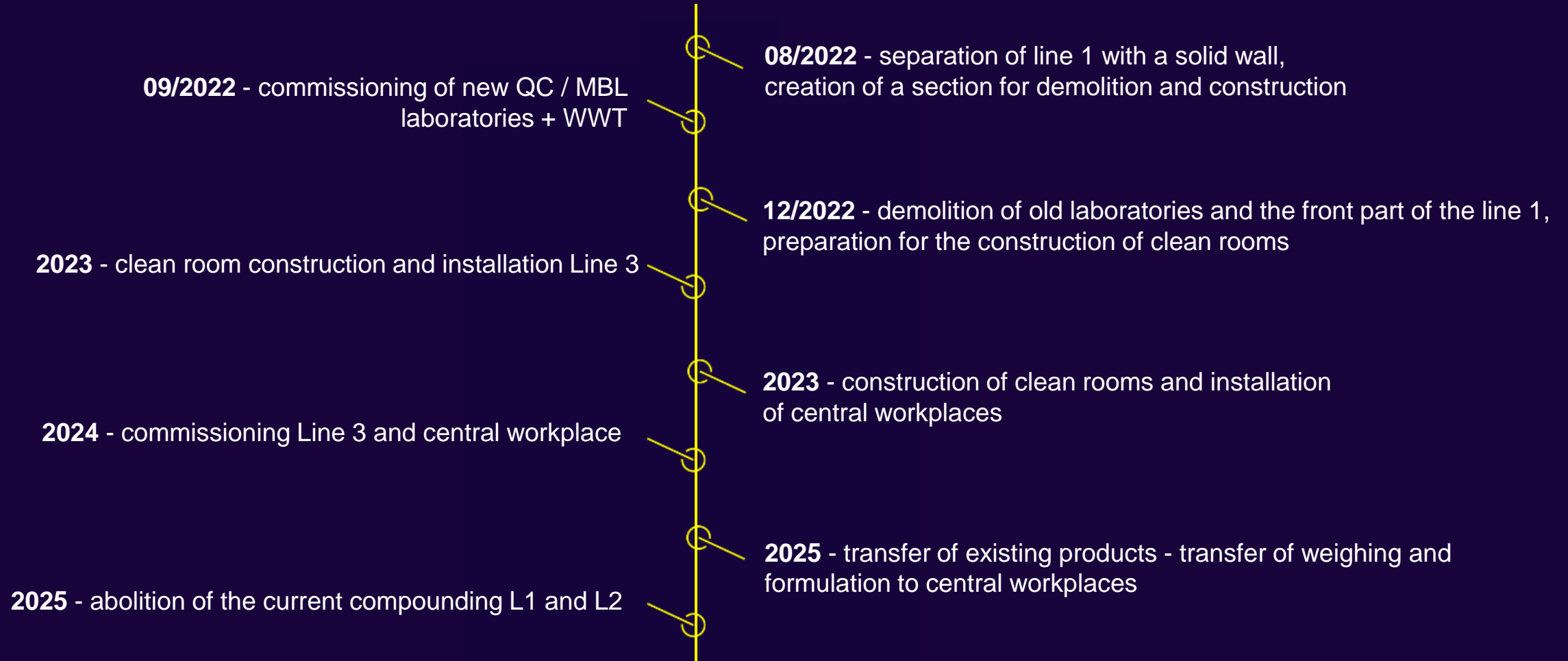
line 3 parameters

Concept	Isolator	
Filling line	Batch size	▶ up to 500L
	Manufacturer	▶ Syntegon
	Combi filling station concept	▶ Time pressure filling system
		▶ Peristaltic pumps (single use)
	Filling volume	▶ 0,1 - 30ml
	Type of containers	▶ Syringe (1 - 50ml)
		▶ Cartridge (1 - 50ml) *
	Automatic weight control	▶ Statistical
Speed	▶ 28.500 pc/hour **	

* No ball insertion

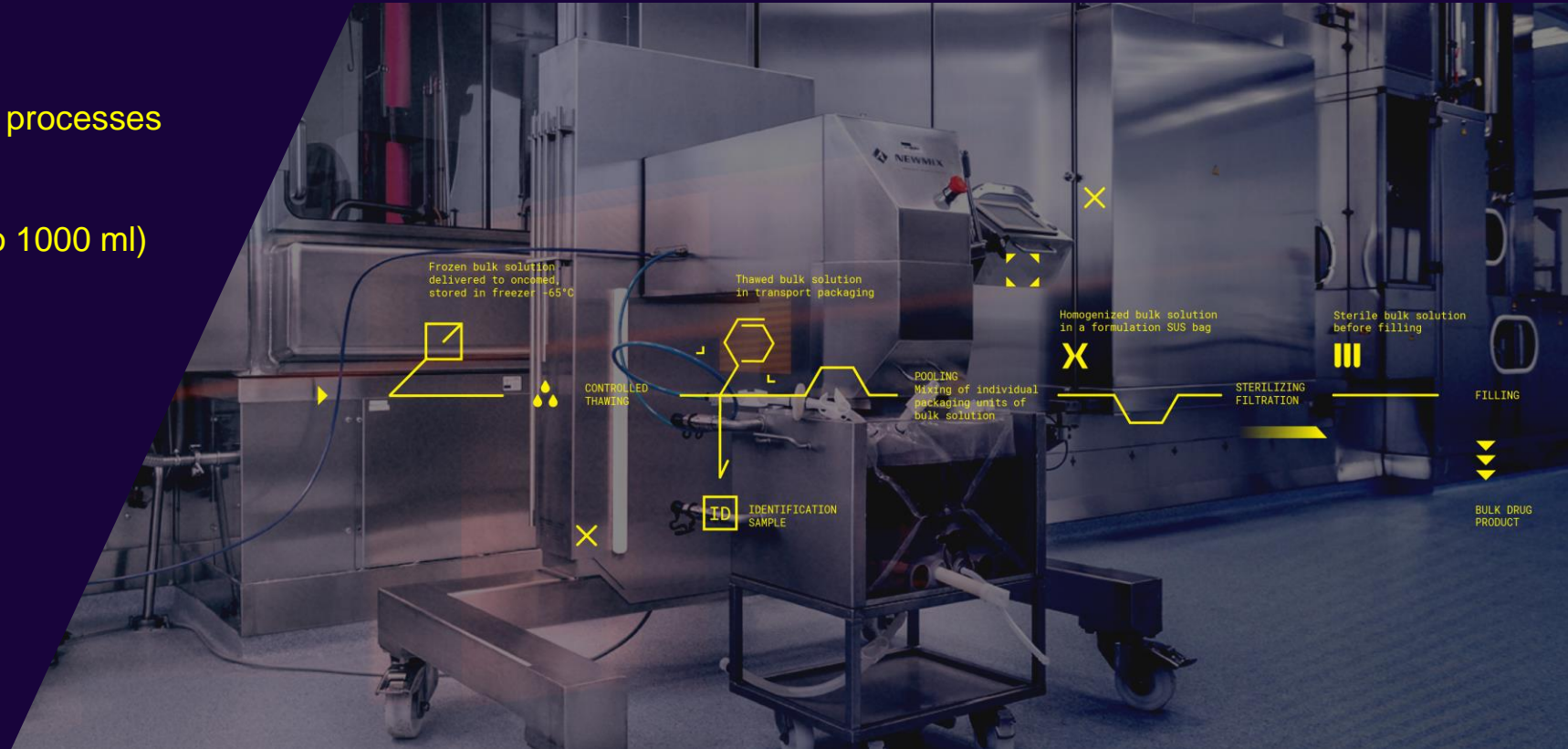
** Speed applies to 1% weight control

line 3 project scope



single use systems

- ▶ elimination clean-in-place/ steam-in-place processes
- ▶ lower losses of solution (approx. 500 ml to 1000 ml)
- ▶ reduction of cross contamination
- ▶ production of not just cytotoxic, but also non-cytotoxic products
- ▶ suitable for small volume batches



quality control



microbiological laboratory

- ▶ 2 biohazard boxes
- ▶ LAL test (gel method, turbidimetric method)
- ▶ Identification
- ▶ 9 incubators
- ▶ New clean rooms D – ready to install sterility isolator in new QC

analytical laboratory


- ▶ 10 HPLC Dionex ThermoFisher (UV/VIS + refractometric detection, MS)
- ▶ 2 GC (+1 new in 9/2022)
- ▶ 2 GUV, NIR, IR
- ▶ Glove boxes
- ▶ Stopper puncture test
- ▶ Laser sub-visible particle count
- ▶ Microscope for particle count
- ▶ KF, potentiometric titrator, other small lab equipment



stability

We are able to perform:

- ▶ registration and ongoing stability studies according to ICH Q1A(R2)
- ▶ photostability studies according to ICH Q1B
- ▶ in-use, infusion and transport studies (from -25 °C to +50 °C)



conditions	total volume of samples that can be stored
2 – 8 °C	1,500 l
25 ± 2 °C / 60 ± 5% RH	5,000 l
30 ± 2 °C / 65 ± 5% RH	5,000 l
30 ± 2 °C / 75 ± 5% RH	880 l
40 ± 2 °C / 75 ± 5% RH	450 l

support systems

- ▶ **Water** Brno city drinking water distribution
- ▶ **Purified water** Shared for both lines (pretreatment, RO, EDI, 16.000l tank)
- ▶ **WFI / PS** Line independent (2 FinnAqua + Kemitem distillers)
- ▶ **Compressed air** 2 compressors (Atlas Copco)
- ▶ **Nitrogen** Technical Nitrogen for cooling lyo + gas Nitrogen (pharma grade)

support systems

- ▶ **HVAC** 5 AHU for Line 2 (Bösch) & 8 AHU for Line 1
- ▶ **Heat** 2x 3 t Steam vessel Bosch, 1 MW Hot water boiler Bosch
- ▶ **Electricity** 2,6 MW Trafo 22kV/400V + back-up Diesel 1 MW + battery
Co-generation unit - 230kW electrical energy/370kW heat
- ▶ **Warehouses**
(in 34 and 02) Technical & Packaging materials (2-30°C)
Starting material (15-25°C, 2-8°C, -18°C, -80°C)
Semi – finished and finished products (20-25°C)
Semi-finished and finished products (20-25°C, 2-8°C)

GMP status



- ▶ SÚKL (2021)
- ▶ including IMP GMP certificates

- ▶ ANVISA Brazil (2022)
- ▶ Iraq (2017)
- ▶ MFDS South Korea (2014)
- ▶ IFDA Iran (2013)
- ▶ FDA approval expected in 2024

Thank you.



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