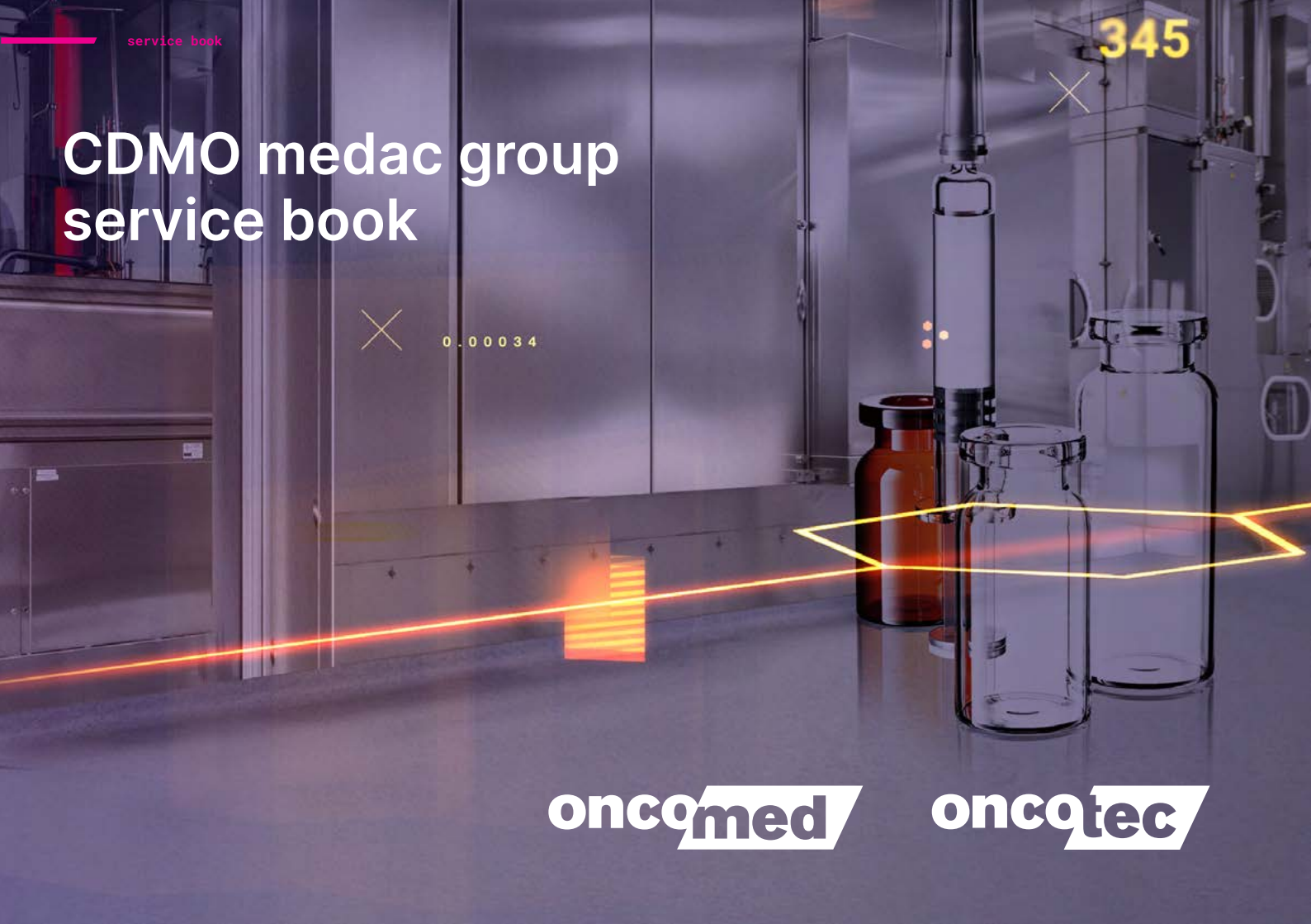
CDMO medac group service book



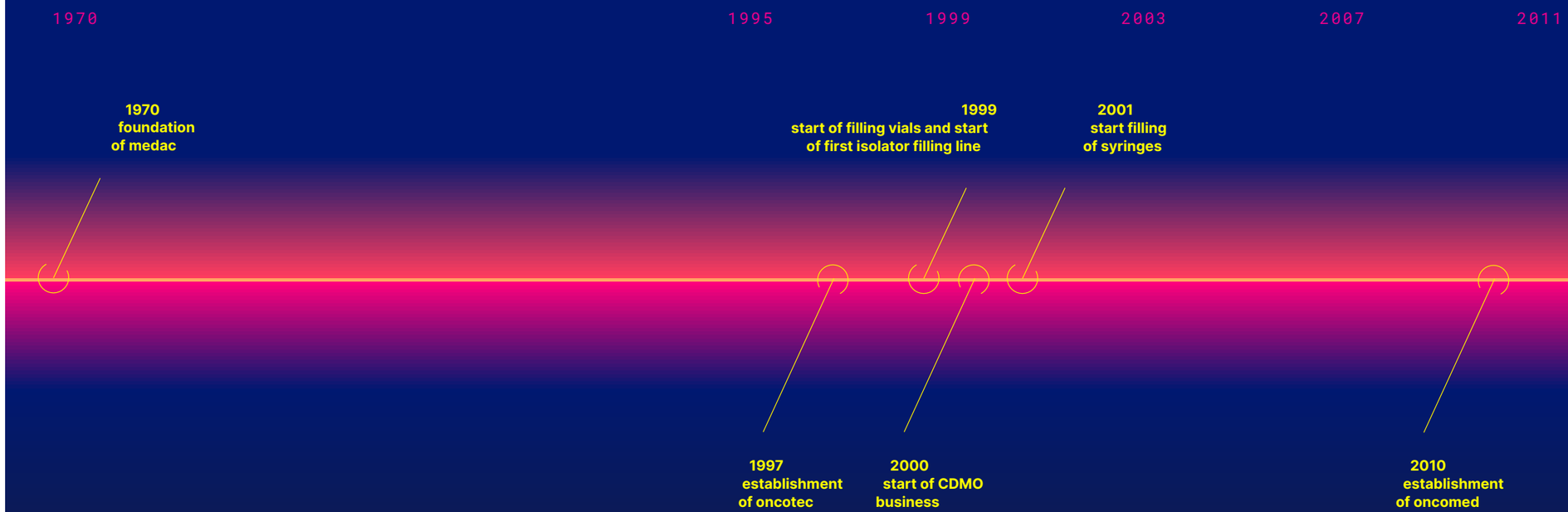
oncomed oncotec

we are medac group

We are medac group - your reliable partner and a Contract Development and Manufacturing Organization (CDMO) specialized in aseptic processing of injectables in clinical and commercial scale. We work in a strategic partnership with you to provide customized solutions for sterile manufacturing.

We focus on high potent and low potent drugs and biologicals for your worldwide markets.

service book we are medac group



we act global

medac is a global, privately held company with over 50 years of experience in developing and manufacturing of pharmaceutical products and continuously growing business. Within the CDMO medac group, we offer sterile manufacturing services at our production sites oncomed and oncotec.

We are determined to make essential treatments available.

worldwide markets

We are here to bring your products to worldwide markets. We provide more than 50 years of global regulatory experience.

portfolio scope

We offer production of high potent and low potent injectables, including both small molecule and large molecule drugs and biologics, like ADCs, HPAPI proteins and oligonucleotides.

formulations

- liquid
- liquid terminally sterilized
- freeze-dried

molecule type

small molecules
- high potent
- low potent

large molecules
- biologics
- oligonucleotides
- ADCs

dosage forms injectables

pre-filled nested syringes
- small volume 0.5 to 3 ml (filling dose from 0.1 ml)
- large volume 20 ml / 50 ml (filling dose up to 30 ml), filling volume 0.1 to 30 g (0.15 – 30 ml)

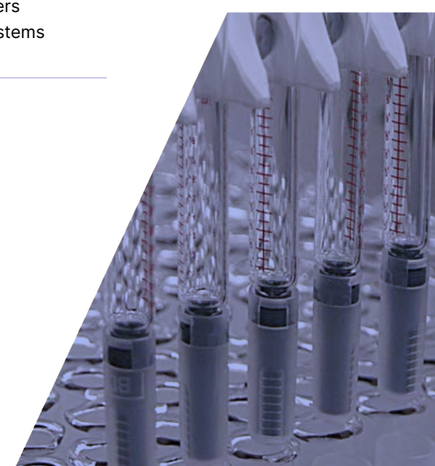
nested cartridges (single chamber)
- small volume cartridges (0.5 – 5 ml)
- large volume cartridges (up to 20 ml)
- filling volume 0.1 to 20 g (0.15 – 20 ml)

vials
- small volume vials (2R to 50 H/R, 80 ml)
- large volume vials (100 ml, 200 H)
- filling volume 0.3 to 200 g (0.15 – 200 ml)

scalable batch size

flexible compounding
- small scale 1-10 l
- large scale 60 – 1,500 l
- in campaign up to 11,000 l

different compounding systems
- stainless steel
- plastic lined stainless steel
- glass containers
- single-use systems



niche technologies

As a specialized CDMO we bring our expertise to sterile processing and aseptic Fill & Finish of complex formulations. We master high-potent and provide access to our niche in-house technologies.

HPAPI handling & processing

Highly potent and toxic substances from OEB 3 (OEL < 1.000 µg/m³) till OEB 6 (OEL < 10 µg/m³) are handled using high-tech containment technology and processes.

organic solvents handling & processing

Organic solvents are handled using unique developed processes and upgraded equipment accessories which allows us to process organic solvents also in freeze-drying.

freeze-drying

Freeze-dryers are equipped with Automatic Loading and Unloading System placed in Class A. Loading directly on pre-cooled shelves assures the protection of temperature sensitive products.

single use system

No cross-contamination of small molecules and biomolecules thanks to custom systems of specific drug production. Single use systems technology minimizes losses when using high price APIs.

sensitive products

Formulation vessels, product pipeline and filter housings are temperature controlled. Red light is used for processing light sensitive products. Nitrogen is applied in every production step.

production lines comparison

manufacturing line	technology	products	filling volume	batch sizes	lyophilizer	single use systems
line 1	RABS	liquid vials lyophilized vials	1 – 200 ml	10 – 1,500 l	2 × 17 m²	no
line 2	isolator	liquid vials lyophilized vials	0.5 – 100 ml	2 – 1,000 l	12 m²	yes
line 3	isolator	syringes (in 2025) cartridges (end 2025)	0.1 – 30 ml 0.1 – 20 ml	2 – 500 l	-	yes
oncomed						
oncotec						
line 1	isolator	for replacement and for your project	–	–	possible	no
line 2 (development line)	isolator	liquid vials syringes	flexible	flexible	0.6 m²	no
line 3	isolator	liquid vials lyophilized vials	6 – 100 ml	80 – 500 l	2 × 14 m²	no
line 4	isolator	syringes cartridges	0.2 – 5 ml	50 – 200 l	-	no
line 5	isolator	liquid vials lyophilized vials	2 – 200 ml 2 – 100 ml	50 – 500 l	30 m²	yes

service book line overview line comparison

our services

We offer competent solutions covering the whole lifecycle of products with focus on “speed to market” internally or with external partners. We are flexible and able to adapt processes and project set-up to fulfill customer needs.

We transform our long history and expertise in sterile processing and aseptic Fill & Finish into large molecules space by using state-of-the-art isolator lines combined with single-use system technology.

development

Literature search scoping, pre-formulation, formulation studies and lyophilization cycle development are assured by our qualified external partners. Our in-house capabilities further support process development, optimization and scale-up. Stability studies, analytical and microbiological method development & validation are assured in-house and/or in cooperation with qualified external partners.

clinical supply

Clinical batches are manufactured on commercial lines which assures cost savings related to eventual tech transfer and commercial supplies of the products. We offer various vial formats in wide range of batch sizes in order to cover all clinical phases. By using the single-use system technology, we offer clinical Fill & Finish services also for biomolecules and high-price APIs.

commercial supply

We offer various vial formats in wide range of batch sizes in order to fulfil the commercial needs of our partners and adapt to unexpected market changes. The commercial supplies are assured via agile and seamless technology transfer covered by our Project Management Office with all necessary support services included. By using the single-use system technology, we offer commercial Fill & Finish services also for biomolecules and high-price APIs.

analytical laboratory

- LC-MS system (Triple Quadrupole Mass Spectrometer)
- HPLC/UHPLC (DAD and Refractometric detection)
- GC (Liquid or Head-space injection, FID detection)
- UV-Vis spectrophotometry
- FT-IR spectroscopy
- Karl Fischer titration (Volumetric and Coulometric)
- Potentiometric titration
- Sub-visible particle count (Laser and Microscope)
- Plus other compendial methods (pH, tests for visible inspection...)

analytical / microbiological

Service is offered to support development and clinical & commercial supply activities of small molecules. Our team of experts provides support in analytical/microbiological method transfer/validation covered by Project Management, product release testing, cleaning methods development and validation, raw materials testing in compliance with cGMP, environmental monitoring, bioburden, bacterial endotoxins and sterility. Our state-of-the-art analytical equipment covers all necessary methods and we have extensive network of qualified laboratories to cover all needed methods which are not available in-house.

microbiology laboratory

- Microbiological examination of raw materials by Milliflex
- Microbiological examination of IPC by Milliflex
- Microbiological examination of water samples by Milliflex and Pall
- Bacterial endotoxins in water by gel cloth method
- Bacterial endotoxins by kinetic turbidimetric method (raw materials, product)

stability

We are able to perform registration and ongoing stability studies according to ICH Q1A(R2) in stability conditions mentioned in the table, photostability studies according to ICH Q1B, in-use, infusion and transport studies (from -25 °C to +50 °C).

Our services are a complete package that includes:

- Proposition of a stability protocol
- Packaging of samples
- Storage
- Sampling
- Analysis
- Release of a report with results

ICH storage conditions

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

- the capacity for samples stored in 2 – 8 ° C conditions can be increased up to 6,000 l
- capacity of storage conditions 30 °C / 75% RH can be increased up to 5,000 l.
- all samples are protected from light in paper boxes

optical inspection

We offer semi-automated inspection for vials and fully automated inspection for syringes or manual inspection by highly qualified operators for both.

packaging & storage

In-house capabilities include manual transport packaging (labelling, box, carton). Automated packaging including serialization and track & trace are assured via a qualified external partner. Storage covers all basic conditions in qualified warehouses including cold chain storage conditions.

regulatory & batch release

We offer technical bulk release for further processing by our team of qualified persons. Batch certification to market is assured via qualified external partner.

we live quality

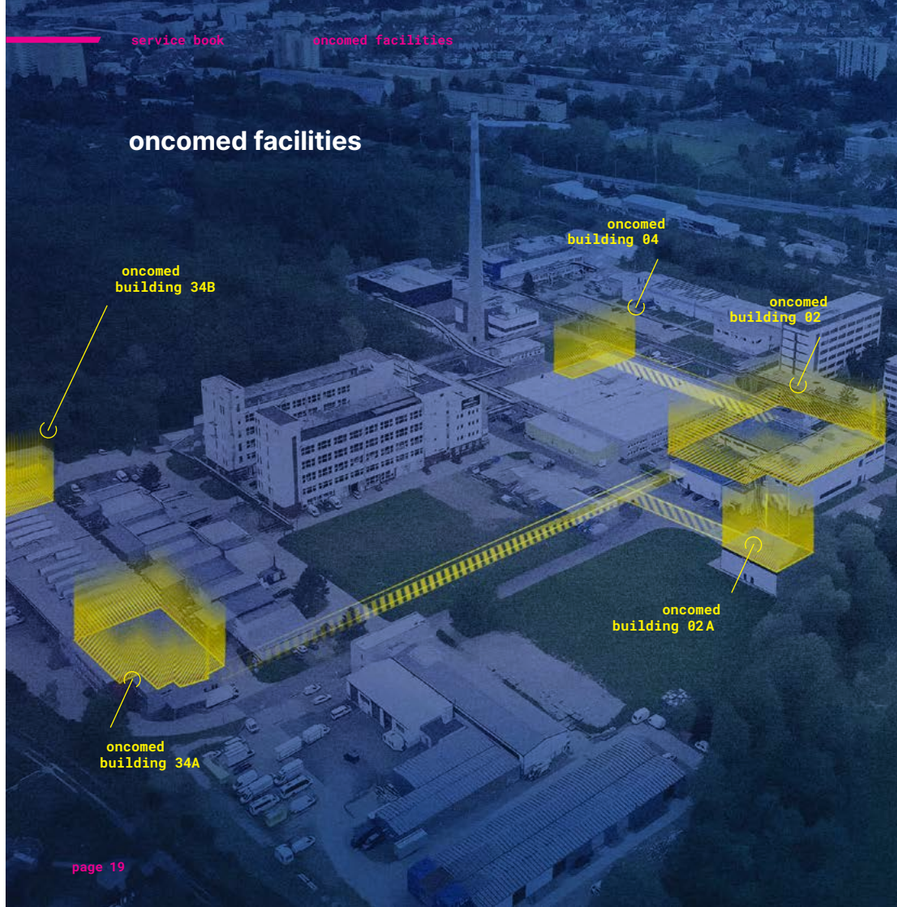
Our corporate quality system is the basis for our high-quality standard. The highest quality of products and processes creates the heart of our everyday business. Quality is built into our everyday processes and living quality has become natural to all our employees.

certification

Our quality system is being continuously improved in order to meet the latest developments of the regulatory environment. It is in line with all EU GMP, ICH, WHO, PIC/S regulations. We are inspected by:

- European Authorities
- US FDA
- ANVISA Brazil
- PMDA Japan
- Health Canada
- Iraq Authority
- MFDS South Korea
- IFDA Iran
- Russian Authorities
- Saudi Arabia Authority

oncomed facilities



oncomed

Despite being established in 2010, we build on the decades-long chemical and pharmaceutical industry heritage. We are continuously growing, both in our competences and technology.

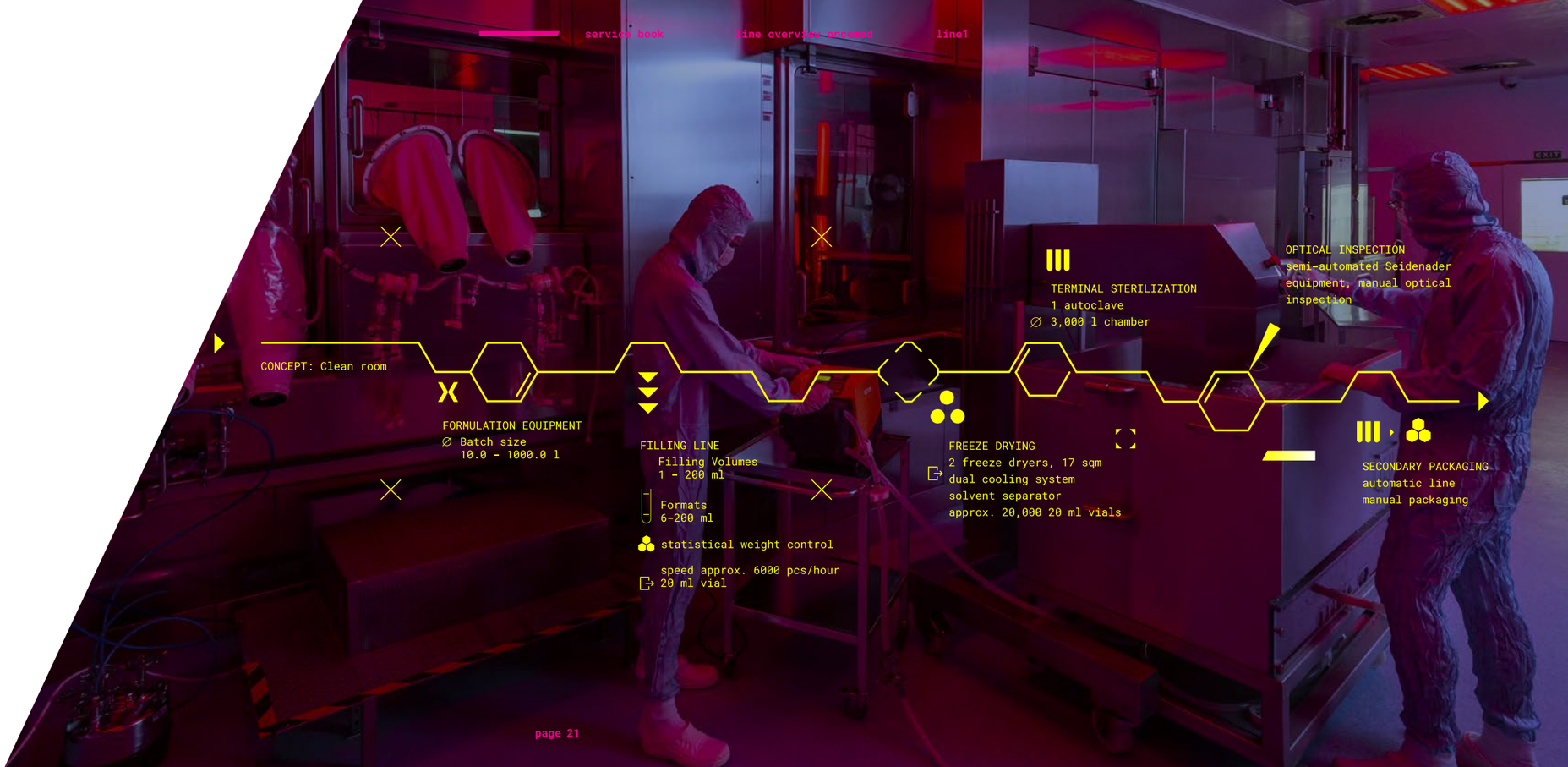
We are not just a contract development and manufacturing organization, we are your flexible, reliable, and dedicated partner in bringing your innovative ideas to life. With a team of dedicated experts and state-of-the-art facilities focusing on vials, syringes and cartridges, we are ready to go the extra mile, ensuring that we meet and exceed our customers´ unique requirements. Continuous improvements are an intrinsic part of our culture and are reflected in our practice.

Our mission is clear: we help to cure.

production line 1

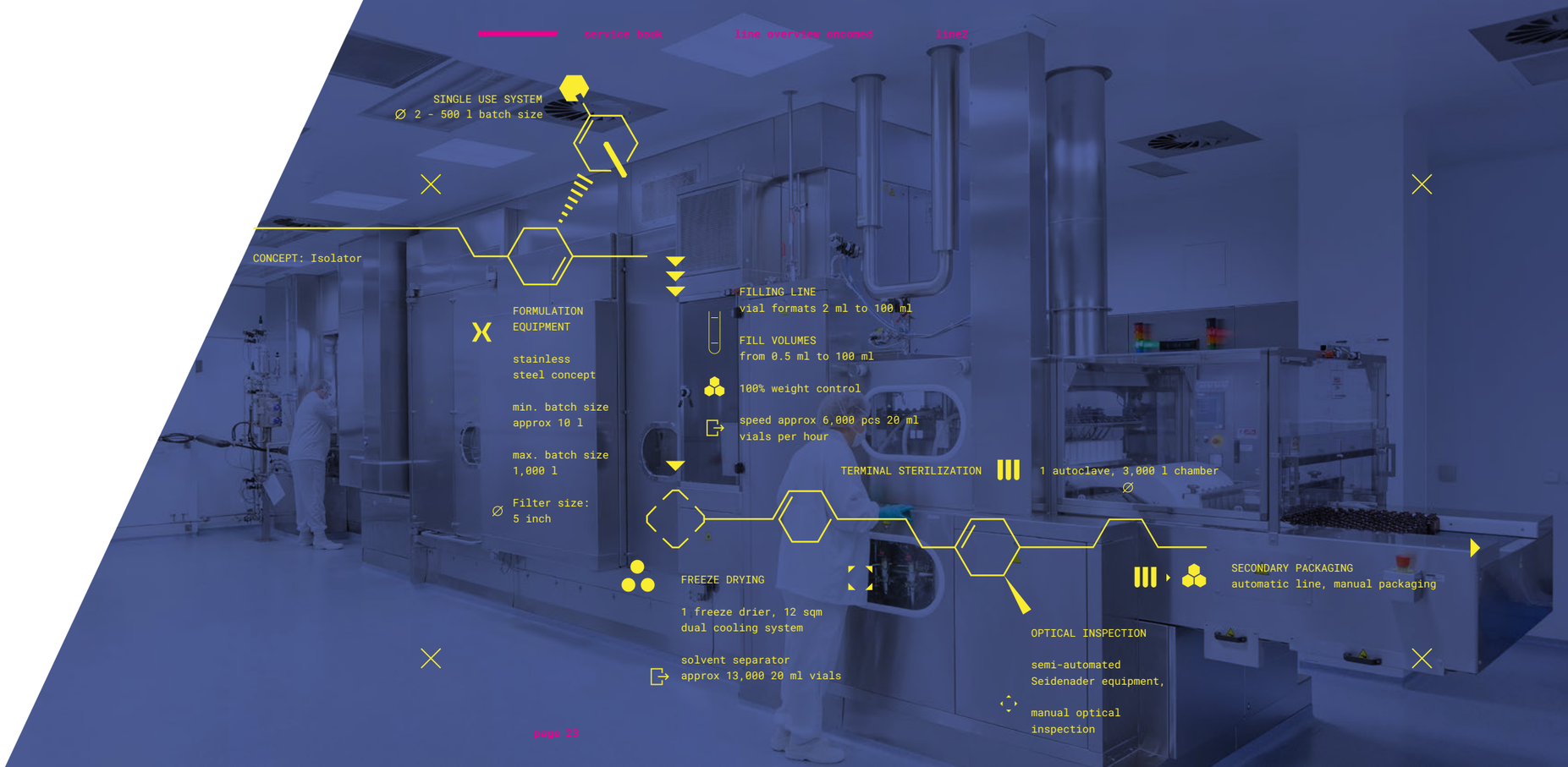
Production line 1 uses a conventional RABS filling line concept that allows us toproduce batches from 10 to 1,000 liters using a stainless steel technology. Our line 1 features two freeze dryers with shelf area of 17 sqm each. The vial fill volumes range between 1 ml and 200 ml.

service book line overview oncomed line1



production line 2

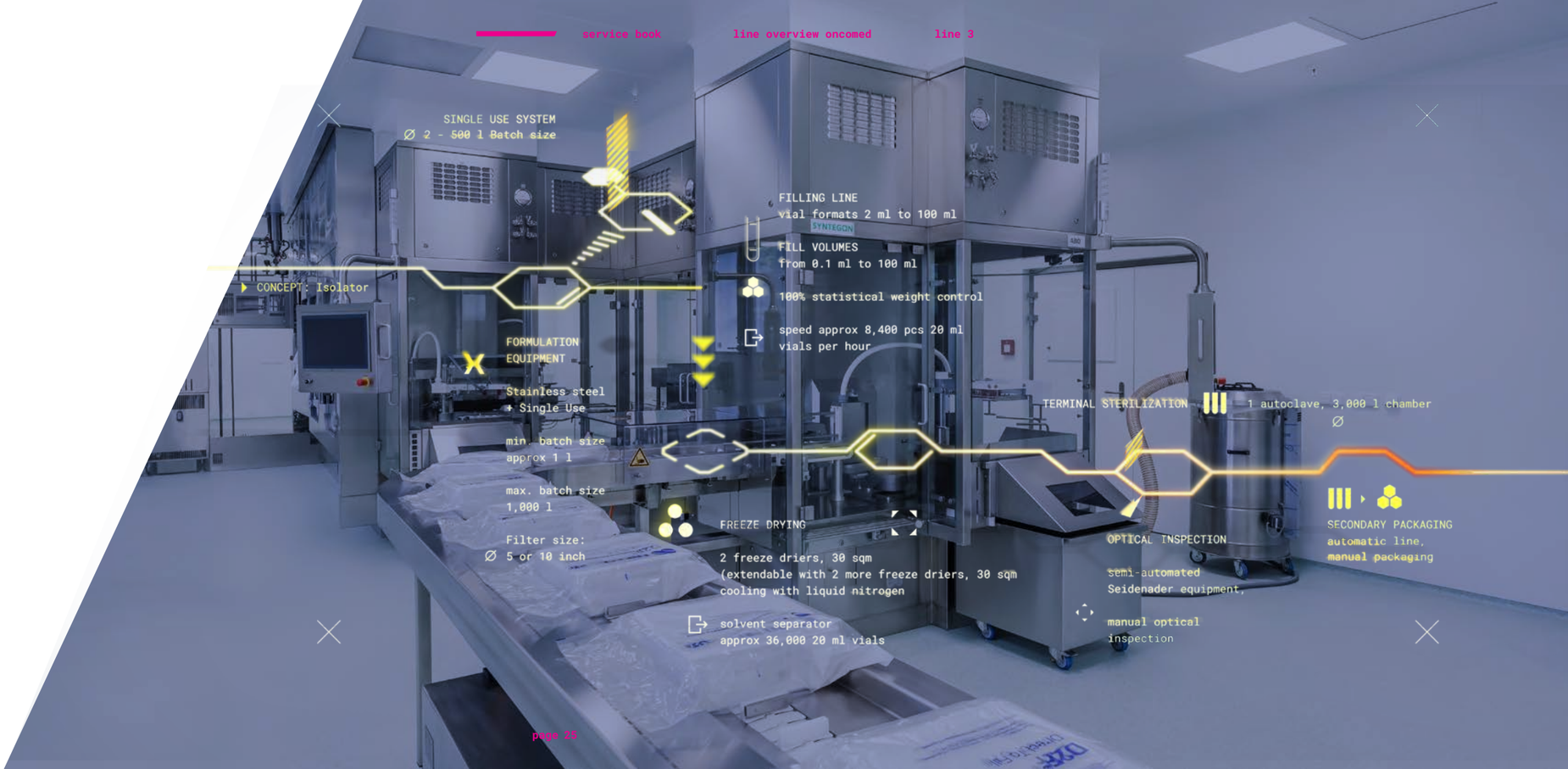
Production line 2 uses an isolator concept and allows us to produce batches from 2 to 1,000 liters using a stainless steel or a single-use system technology. Our line 2 features one freeze dryer with shelf area of 12 sqm and is equipped with a dual cooling system and a solvent separator to process non-aqueous formulations. The vial fill volumes range between 0.5 ml and 100 ml.



production line 3 in commissioning

Production line 3 is focused on the production of pre-filled syringes and cartridges. The line will use a stainless steel or a single-use system technology and its capacity will be more than 100 million syringes/cartridges per year in volumes from 1 l up to 500 l. A dual filling system will feature a time-pressure system and a peristaltic pump with a speed of 600 pcs/min. The syringe/cartridges filling volumes will range between 0.5 ml and 20 ml.

service book line overview oncomed line 3



single-use systems

Single use systems have many benefits such as:

- Elimination of 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, biologics, etc.
- Suitable for small volume batches

equipment overview

formulation – ATMI Newmix PadDrive 1000 Premium

- in use from 2008 on
- suitable for batches 10- 50 l
- PQ – Media Fill, mixing trials, placebo batch production

formulation – WandMixer

- in use from 2008 on
- suitable for batches 1-20 l (development batches, clinical trials)

Formulation – PALL LevMixer® single use mixer

- bought in 2021, Qualified in 2023
- suitable for batches 50L – 1000L
- cubical jacketed cells for mixing tanks (loading cell for 1000 l)
- jacket operating range max. 6.2 bar, temparutere range – 5/90 °C
- levitation mixing technology (no mechanical shear) for sensitive molecules
- product contact layer Allegro™ (ULDPE)

production line comparison oncomed

line 1

concept
clean room

formulation & Aseptic filtration
stainless steel concept,
min. batch size approx. 10 l,
max. batch size 1,000 l,
1,500 l, in campaign up to 11,000 per week

filling line
vial formats 6 ml to 200 ml,
fill volumes from 1 ml to 200 ml,
automatic statistical weight control,
speed – approx. 6000 pcs/hour, 20 ml vial,
manufacturer: Groninger

freeze drying
2 freeze dryers, 17 sqm each,
approx. 20,000 20 ml vials,
lowest shelf temperature: -55 °C,
lowest ice-condenser temperature:
-85 °C – compressor,
ice capacity: 300 kg,
manufacturer: GEA

terminal sterilization
1 autoclave, 3,000 l chamber,
manufacturer: STERIS

optical inspection
semi-automated Seidenader equipment,
manual optical inspection

secondary packaging
automatic line, manual packaging

line 2

concept
isolator

formulation & aseptic filtration
stainless steel concept,
min. batch size approx. 10 l,
max. batch size: 1,000 l

single use system
min. batch size approx. 2 l,
max. batch size: 1,000 l,
custom design option

filling Line
vial formats 2 ml to 100 ml,
fill volumes from 0.5 ml to 100 ml,
100% weight control,
speed – approx. 6000 pcs/hour, 20 ml vial,
manufacturer: IMA

freeze Drying
1 freeze dryer, 12 sqm,
approx. 13,000 20 ml vials,
dual cooling system,
lowest shelf temperature: -60 °C,
lowest ice-condenser
temperature: -75 °C – compressor
-90 °C – liquid nitrogen,
ice capacity: 200 kg,
solvent separator,
manufacturer: GEA

terminal sterilization
1 autoclave, 3,000 l chamber

optical inspection
Semi-automated Seidenader equipment,
manual optical inspection

secondary packaging
Automatic line, manual packaging

line 3

concept
isolator

formulation & aseptic filtration
stainless steel concept,
min. batch size approx. 10 l,
max. batch size 1,000 l,
1,500 l, in campaign up to 11,000 per week,

single use system
min. batch size approx. 2 l,
max. batch size 500 l,
custom design option

filling line
syringe/cartridge formats 2 ml to 30/20 ml,
fill volumes from 0.15 – 30 ml,
automatic statistical weight control,
speed – approx. 30,000 pcs/hour, 1 ml syringe,
manufacturer: Bosch

optical inspection
fully automated equipment,
manual optical inspection

service book line comparison line comparison oncomed

technical infrastructure oncomed

media

• **water** - Brno city drinking water distribution • **purified water** - shared for both lines (pre-treatment, RO, EDI, 16,000 l tank) • **WFI / pure steam** - line independent (2 FinnAqua + Kemiterm distillers) • **compressed air** - 2 compressors (Atlas Copco) • **nitrogen** - technical nitrogen for cooling lyo + gas nitrogen (pharma grade • **HVAC** - 5 air handling units for line 2 (Bosch) & 8 AHU for line 1 • **heat** – 2 × 3 t steam vessel Bosch, 1 MW hot water boiler Bosch

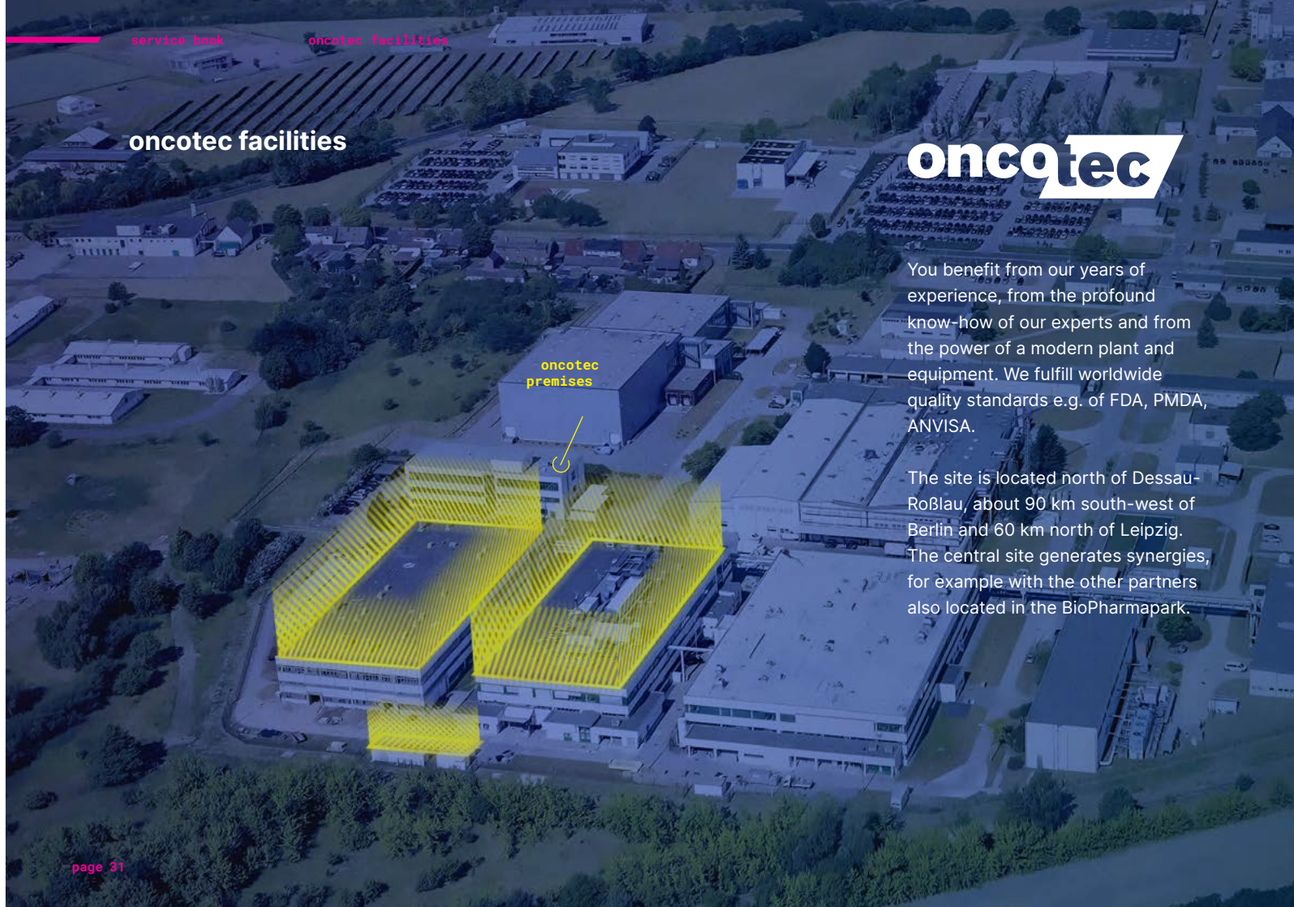
electricity

- **2.6 MW Trafo** 22kV/400V + back-up Diesel 1 MW + battery
- **co-generation unit** - 230kW electrical energy/370kW heat
- all critical processes connected in case of power black-out – no impact on operations

warehouses

- technical & packaging materials (2-30°C) (in 34 and 02)
- 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)

oncotec facilities



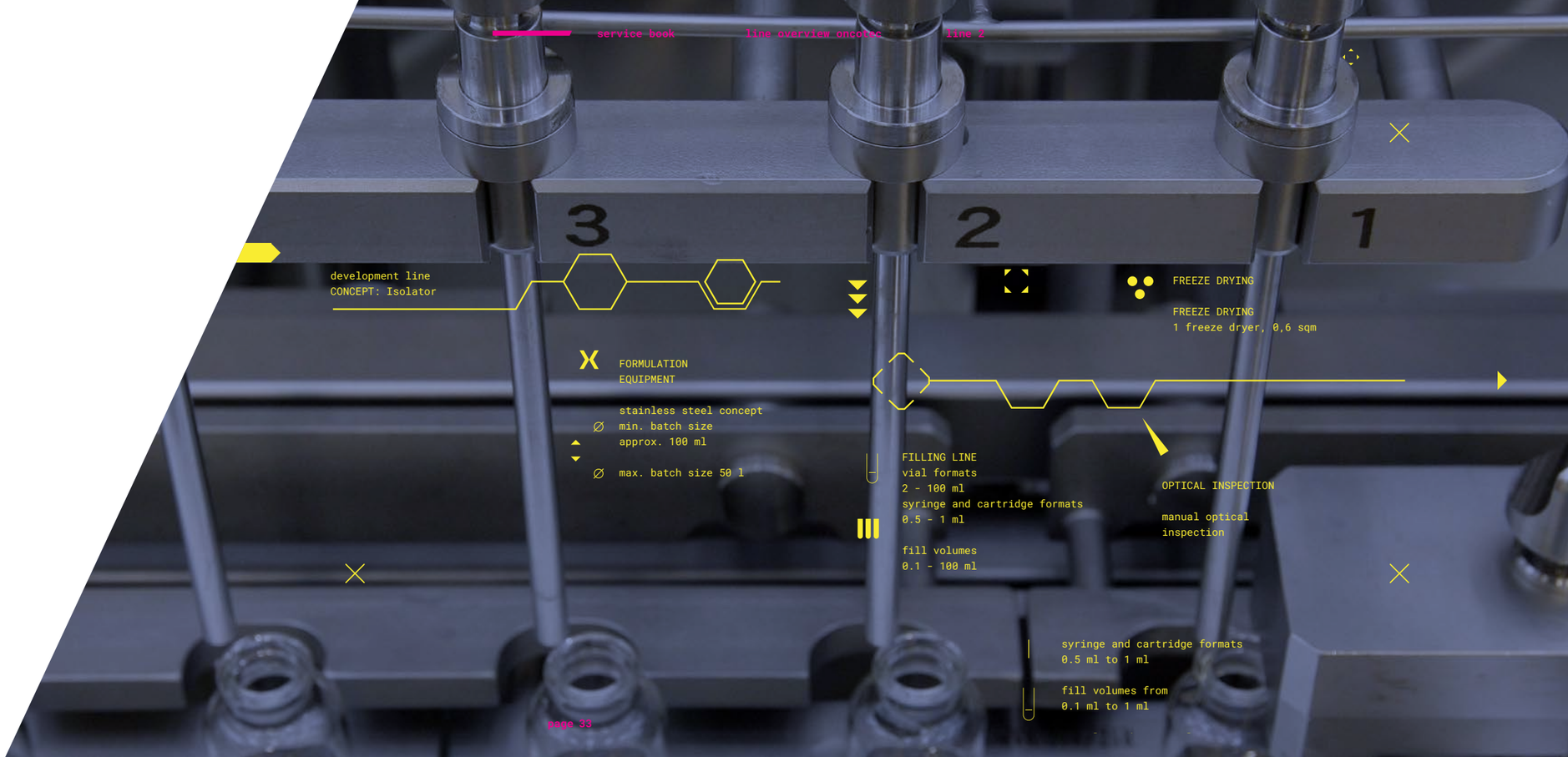
You benefit from our years of experience, from the profound know-how of our experts and from the power of a modern plant and equipment. We fulfill worldwide quality standards e.g. of FDA, PMDA, ANVISA.

The site is located north of Dessau-Roßlau, about 90 km south-west of Berlin and 60 km north of Leipzig. The central site generates synergies, for example with the other partners also located in the BioPharmapark.

production line 2

Development line 2 is a highly flexible isolator filling line that allows us to produce small scale clinical trial material in vials or syringes and to perform optimization of freeze-drying cycles. The pilot freeze dryer has a capacity of 0.6 sqm. External surface of the vials is decontaminated using a robotic washing machine.

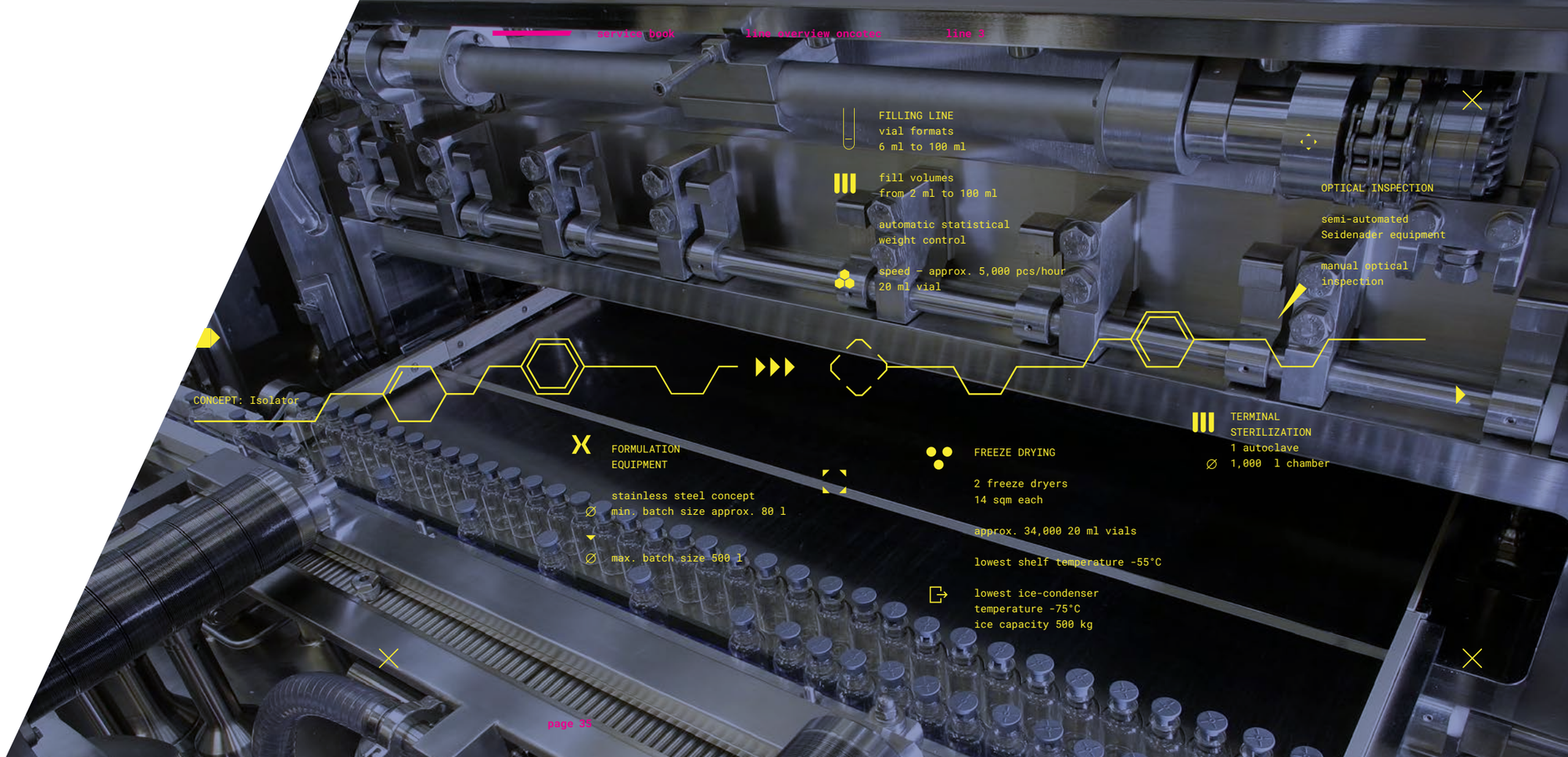
service book line overview oncotec line 2



production line 3

Production line 3 is an isolator filling line which allows us to produce batch sizes between 80 and 500 liters. It is equipped with two freeze dryers with shelf area of 14 sqm each. The vial fill volumes range between 6 ml and 100 ml using a time-pressure-filling system.

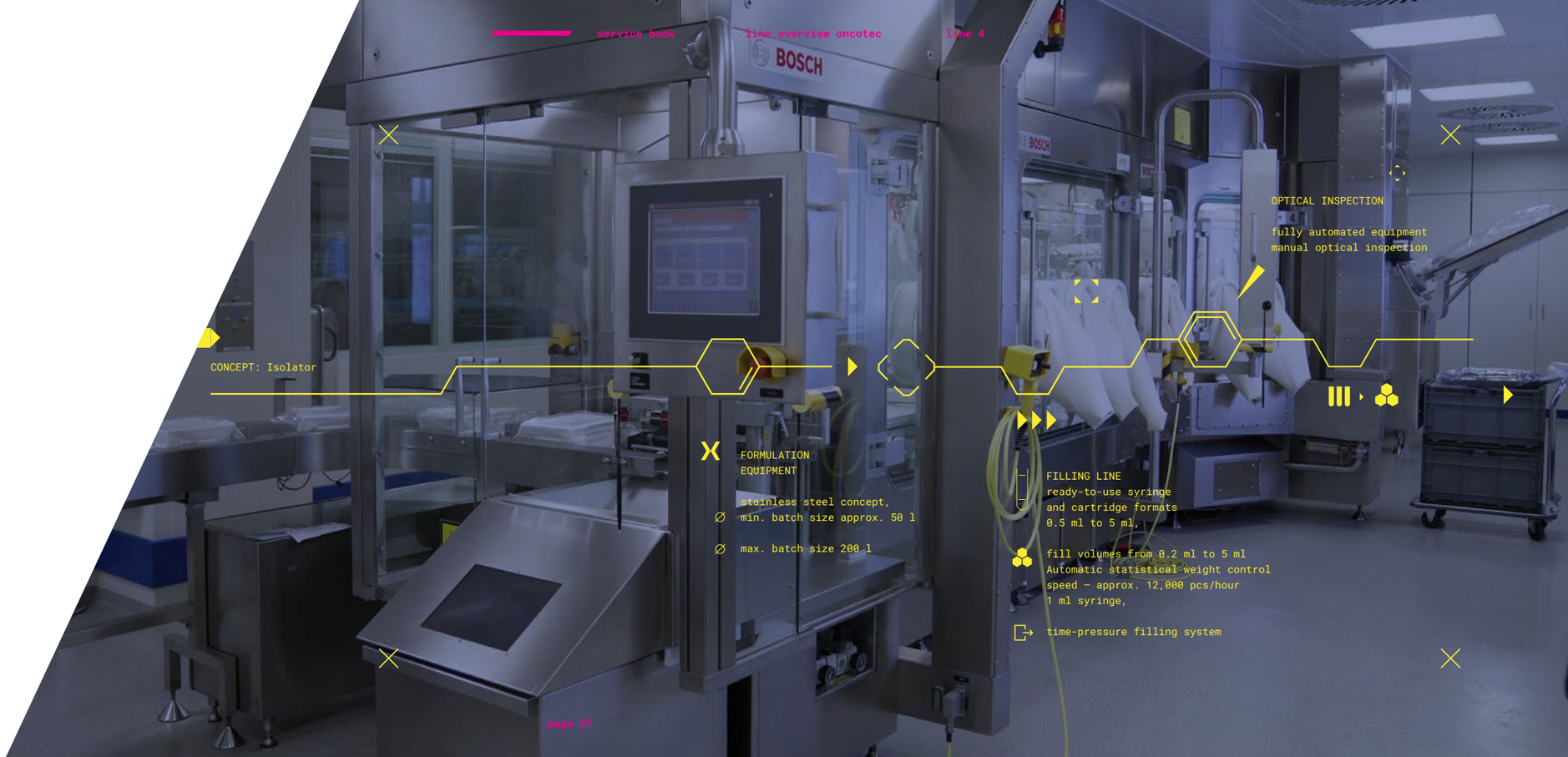
service book line overview oncotec line 3



production line 4

Production line 4 is an isolator line for filling of nested pre-filled syringes and cartridges. Its capacity is 50 million syringes/cartridges per year with batch sizes from 50 till 200 l, using a time-pressure filling system. The filling volumes range between 0.2 ml and 5 ml.

service book line overview oncotec line 4



production line 5

Production line 5 is a very flexible robotic isolator filling line which allows us to produce batch sizes between 50 and 500 liters of aqueous and non-aqueous solutions using stainless steel or single-use technology. It offers a freeze dryer with shelf area of 30 sqm. The vial fill volumes range between 2 ml and 100 ml (freeze dried product) or 200 ml (liquid), using a peristaltic filling system.

service book line overview oncotec line 5

antibody-drug conjugates

Oncotec established a fully integrated end-to-end solution for the production and manufacturing of antibody drug conjugates (ADCs) together with experienced partners. It is designed to simplify the supply chain and shorten time to market: from DNA to commercial production of the finished ADC drug product – all according to the highest quality standards of national and international markets.

service book antibody-drug conjugates

example of ADC fill & finish process

production line comparison oncotec

Note: line 1, space for replacement and for your project.

service book line comparison line comparison oncotec

line 2

development line
concept:
isolator

formulation & aseptic filtration
stainless steel concept,
min. batch size approx. 100 ml,
max. batch size 50 l

filling line
vial formats 2 ml to 100 ml,
fill volumes from 0.1 ml to 100 ml,
syringe and cartridge formats 0.5 ml to 1 ml,
fill volumes from 0.1 ml to 1 ml,
manual weight control,
speed – approx. 120 pcs/hour,
manufacturer: Optima

optical inspection
manual optical inspection

line 3

concept:
isolator

formulation & aseptic filtration
stainless steel concept,
min. batch size approx. 80 l,
max. batch size 500 l

filling line
vial formats 6 ml to 100 ml,
fill volumes from 2 ml to 100 ml,
automatic statistical weight control,
speed – approx. 5,000 pcs/hour, 20 ml vial,
manufacturer: Groninger

freeze drying
2 freeze dryers, 14 sqm each,
approx. 34,000 20 ml vials,
lowest shelf temperature -55°C,
lowest ice-condenser temperature -75°C,
ice capacity 500 kg,
manufacturer: Klee

terminal sterilization
1 autoclave, 1,000 l chamber,
manufacturer: Belimed

optical inspection
semi-automated Seidenader equipment,
manual optical inspection

line 4

concept:
isolator

formulation & aseptic filtration
stainless steel concept,
min. batch size approx. 50 l,
max. batch size 200 l

filling line
ready-to-use syringe and cartridge formats
0.5 ml to 5 ml, fill volumes from 0.2 ml to 5 ml,
automatic statistical weight control,
speed – approx. 12,000 pcs/hour, 1 ml
syringe, time-pressure filling system,
manufacturer: Bosch

optical inspection
fully automated equipment,
manual optical inspection

line 5

concept:
isolator

formulation & aseptic filtration
stainless steel concept,
min. batch size approx. 50 l,
max. batch size 500 l

single use system
min. batch size approx. 2 l,
max. batch size 500 l,
custom design option

filling line
vial formats 2 ml to 200 ml,
fill volumes from 0,3 ml to 200 ml,
100% weight control,
speed – approx. 5,000 pcs/hour, 20 ml vial,
manufacturer: Steriline

freeze drying
1 freeze dryer, 30 sqm,
approx. 37,000 20 ml vials,
lowest shelf temperature -60°C,
lowest ice-condenser temperature -80°C,
ice capacity 500 kg,
manufacturer: Christ

terminal sterilization
1 autoclave, 1,000 l chamber,
manufacturer: Belimed

optical inspection
semi-automated Seidenader equipment,
manual optical inspection

technical infrastructure oncotec

media

• **water** – from central site services • **purified water** – 3,5/1.8 sqm/h, storage capacity 5.6/13 sqm • **WFI** - 3.5/0.8 m³/h, storage capacity 2.5/1.5 m³ • **pure steam** – 700/800 kg/h • **compressed air** - from central site services • **nitrogen** - from central site services • **plant steam/ heating steam** - from central site services • **cooling water** - from central site services • **chilled water** - from central site services • **HVAC** - Dedicated AHUs per filling suite / area (100% fresh air operation)

electricity

• **Trafo** – 2× 1000 kVA/2×800 kVA
• **NEA** – 1× 450 kVA/1× 1000 kVA
• **USV** – 1000 kVA* / 500 kVA (1000 kVA*)
• all critical processes connected in case of power black-out – no impact on operations

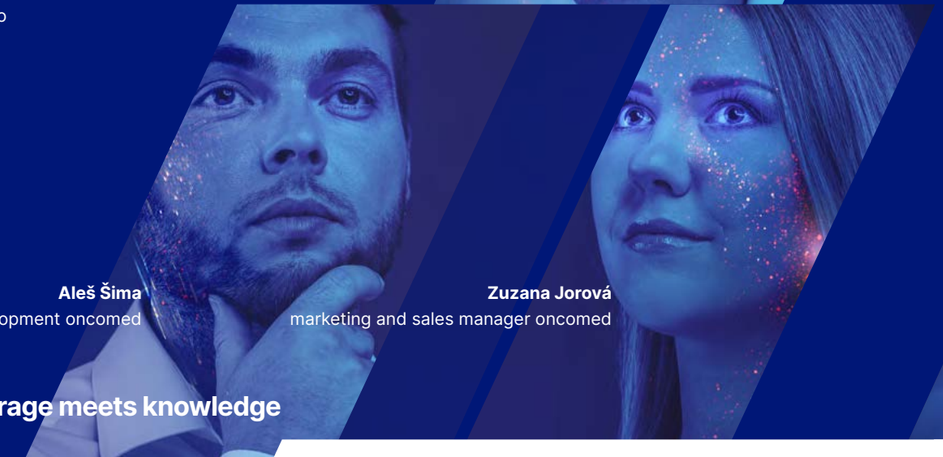
warehouses

• 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, 2-8°C)

*) currently under establishment

we want to hear from you!

Radek Fialka
chief business officer oncomed



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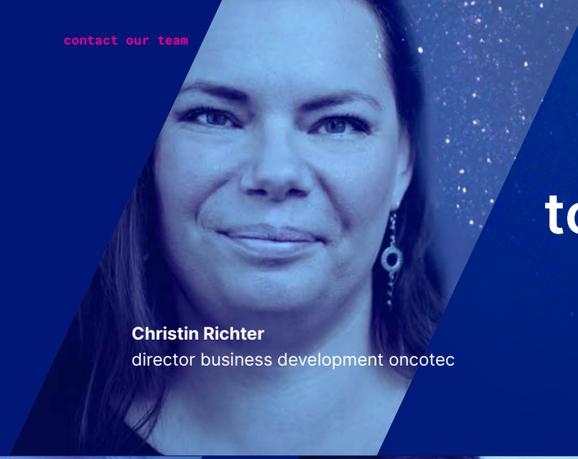
contact us today and meet us tomorrow



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oncotec improvement needs expert knowledge

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