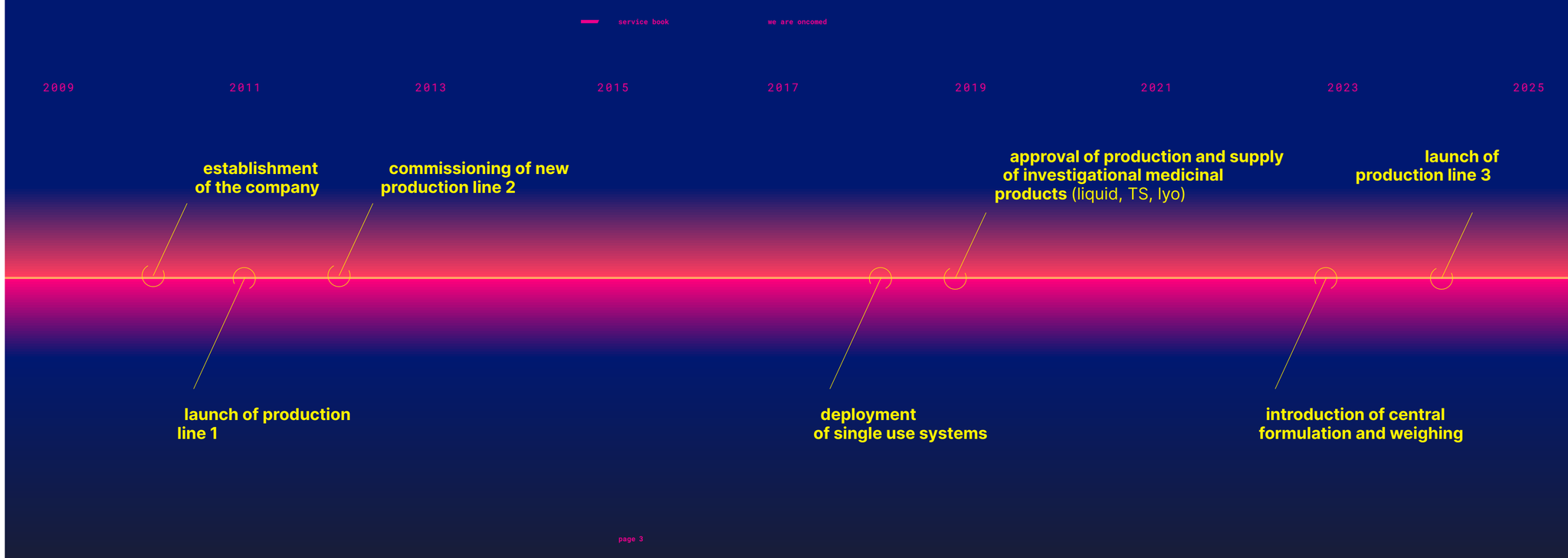
service book

oncomed

member of medac group

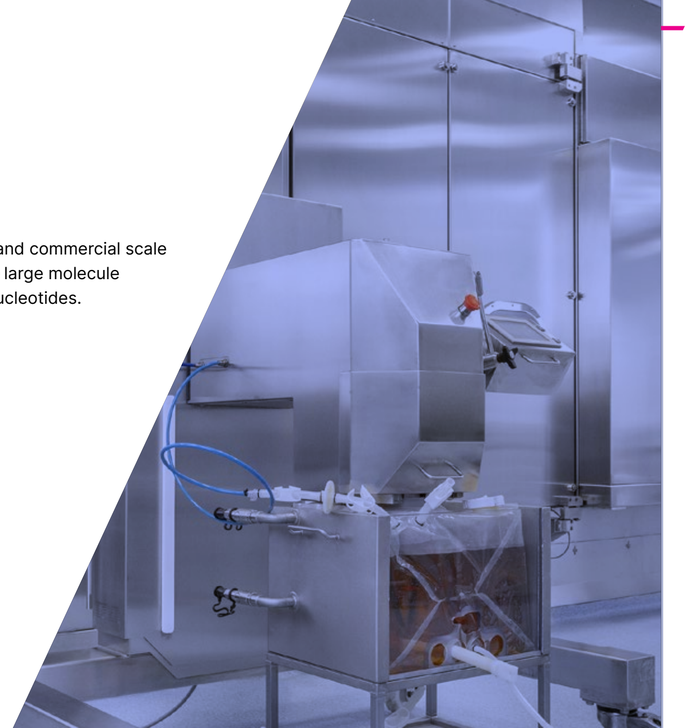
we are oncomed

We are oncomed – a Contract Development and Manufacturing Organization (CDMO) specialized in aseptic processing of oncology injectables in clinical and commercial scales. We deliver drugs with high potent and cytotoxic characteristics to fight cancer, worldwide.



portfolio scope

We offer production of high potent and anticancer injectables in clinical and commercial scale including small molecule APIs (end-to-end solution) and more innovative large molecule drugs (Fill & Finish service), like ADCs, HPAPI proteins & mAb and oligonucleotides.



formulations

- Liquid
- Liquid Terminally Sterilized
- Freeze-Dried

dosage forms

injectables – vials
(2 ml – 200 ml)

manufacturing scale

small scale production
(pre-clinical, clinical phase I & II)

large scale production
(clinical phase III, commercial)

molecule type

small molecules
(HPAPI non-cyto, cytotoxic, cytostatic)

large molecules
(biologic, oligonucleotides)

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 cyto and provide access to our niche in-house technology.

HPAPI handling & processing

Highly potent and toxic substances (OEB 3 – OEB 6) are handled using HIGH-TECH containment technology and processes which are OHSAS 18001 certified.

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.

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.

freeze-drying

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

single use system

No cross-contamination of small molecules and biomolecules thanks to custom systems of specific drug production. SUS technology to minimize losses when High Price APIs are handled.

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

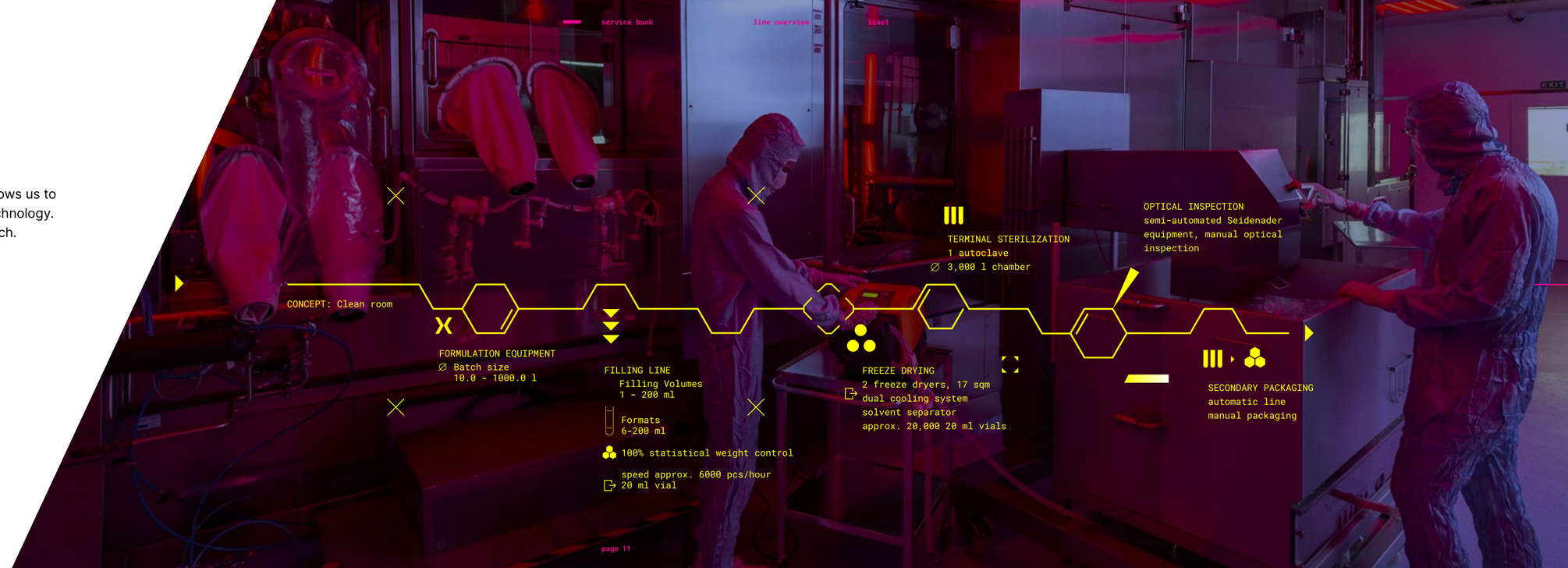
- Bought in 2008
- Suitable for batches 10- 50L
- PQ – Media Fill, mixing trials, placebo batch production

Formulation –
WandMixer

- Bought in 2019
- Suitable for batches 1- 20L (development batches, clinical trials)

production line 1

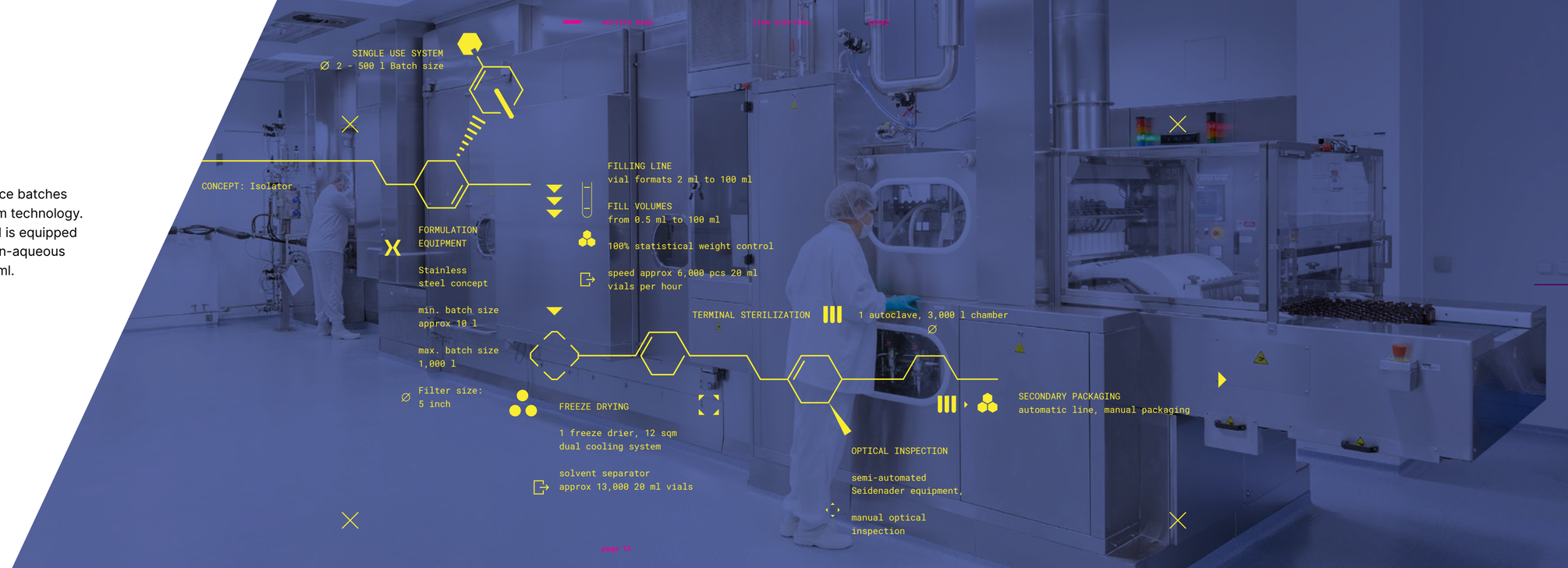
Production line 1 uses a conventional clean room concept that allows us to produce batches from 10 to 1,000 liters using a stainless steel technology. Our line 1 features two freeze dryers with shelf area of 17 sqm each. The vial fill volumes range between 1 ml and 200 ml.



production line 2

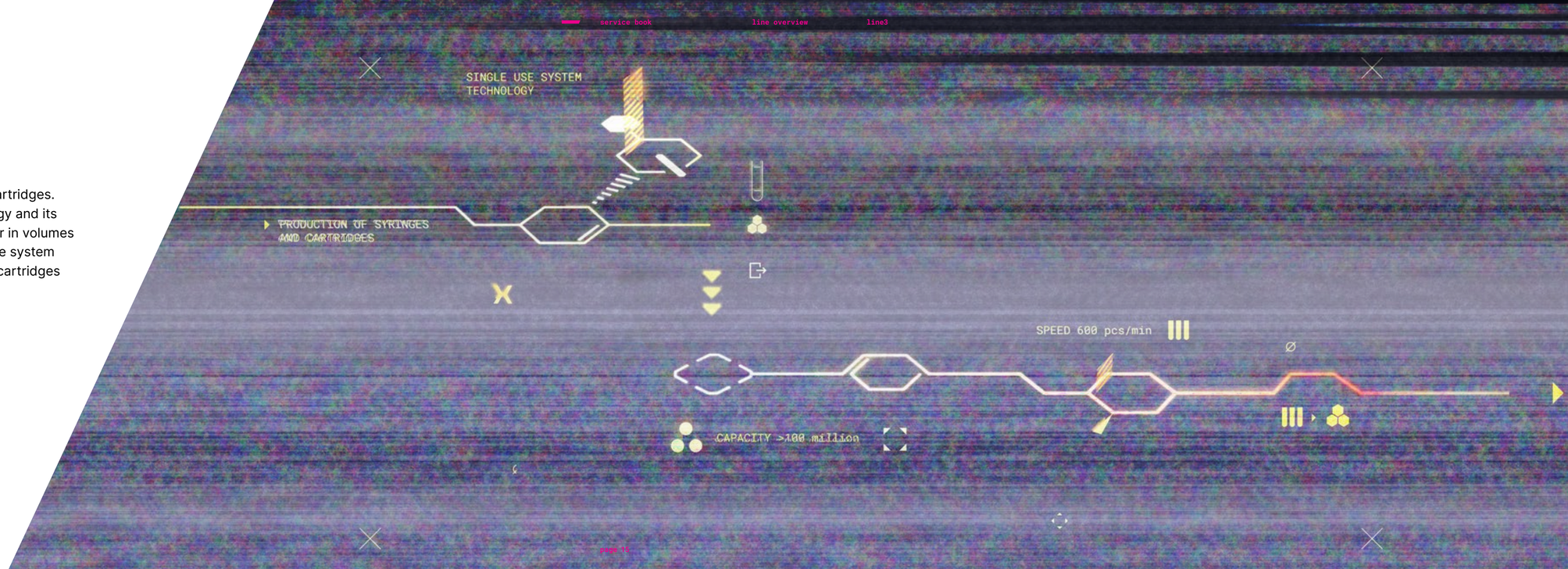
Production line 2 uses an isolator concept and allows us to produce batches from 2 to 1,000 liters using a stainless steel or a single-use system technology. Our line 2 features one freeze dryer with shelf area of 12 sqm and is equipped with a dual cooling system and a solvent separator to process non-aqueous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

service book line overview line2



production
line 3 in progress

Production line 3 will be focused on production of 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 1l up to 500l. 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.



production vial lines comparison

Line 1

Concept
Clean room

Formulation & Aseptic filtration
Stainless steel concept
min. batch size approx. 10 l
max. batch size 1,000 l
Filter size: 5 and 10 inch

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

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
Filter size: 5 inch

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 0.5ml to 100 ml
100% weight control
Speed – approx. 6000 pcs/hour, 20 ml vial

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

our services

small molecules end-to-end solution

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

large molecules fill & finish

We transform our long history and expertise in sterile processing and aseptic Fill & Finish into large molecules space by using a state-of-the-art isolator line combined with a 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 a 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 a single-use system technology, we offer commercial Fill & Finish services also for biomolecules and high-price APIs.

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.

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...)

microbiology laboratory

- Microbiological examination of raw materials by Milliflex
- Microbiological examination of IPC by Milliflex
- Microbiological examination of water samples by Milliflex
- 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).

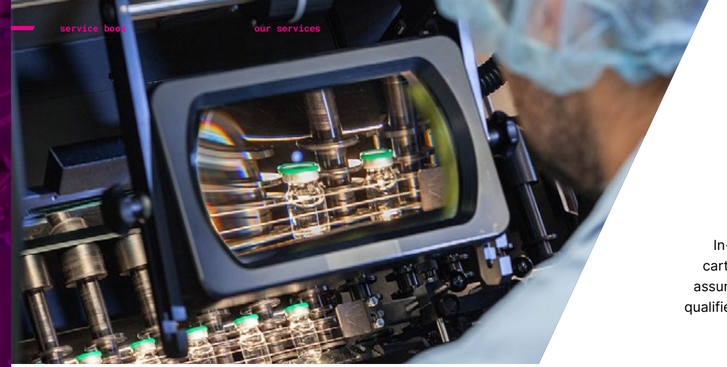
Our services include a complete offer which include:
- Proposition of a stability protocol
- Packaging of samples
- Storage
- Sampling
- Analysis
- Release of a report with results

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

service book our services



optical inspection

We offer semi-automated inspection using Seidenader device and manual inspection assured by highly qualified operators.

packaging & storage

In-house capabilities include manual transport packaging (labelling, box, carton). Automated packaging including serialization and track & trace are assured via qualified e xternal 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.

quality policy

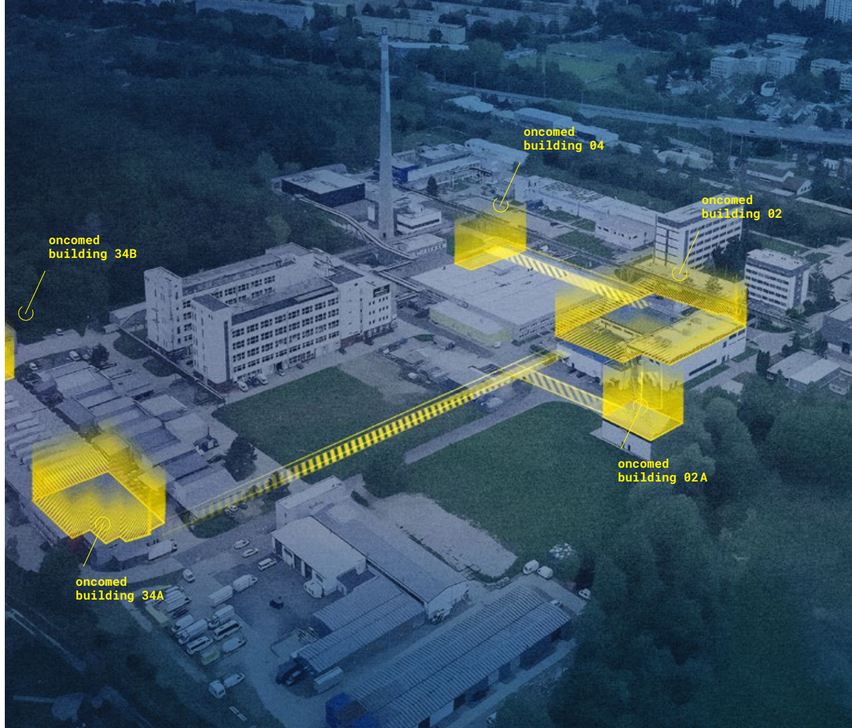
we live quality

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 in line with all EU GMP, ICH, WHO, PIC/S regulations and soon FDA inspected. The quality system is being continuously improved in order to meet the latest developments of the regulatory environment.

oncomed facilities



we want to hear from you!

contact us today and meet us tomorrow

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“We here at oncomed are passionate about our work and so we are moving forward every day a few steps to improve.

— Gerhard Wurzer, CEO oncomed

“Be always ahead in final dosage form development and formulation.

— Adam Häring, chief scientific office

oncomed where courage meets knowledge