pharmoduct

AUTOMATIC COMPOUNDING SYSTEM

A BATCH APPROACH FOR PATIENT SPECIFIC ONCOLOGY DRUGS

PHARMA

COMECER
an ATS company

ONCOLOGY DRUGS COMPOUNDING

Compounding is the creation of a personalized drug to *meet the unique needs of a patient.*
It is performed by a licensed pharmacist, a licensed physician or a person under the supervision of a licensed pharmacist.
In Hospitals and Compounding Labs worldwide, an enormous number of oncology treatments are prepared every day.

There are several key persons involved in the antiblastics preparation process: oncologists, pharmacists, nurses and health technicians. It's important to have full collaboration between these parties in order to avoid mistakes and allow the patient to receive a *tailor made drug that is precise in dosage and fully sterile, in a reasonable timeframe.*

Limits of manual compounding

Despite the importance of compounding, there are many risks associated to this activity.
Compounded preparations are not FDA-approved; this means that the safety standards are often lower compared to the requirements of the pharmaceutical industry.

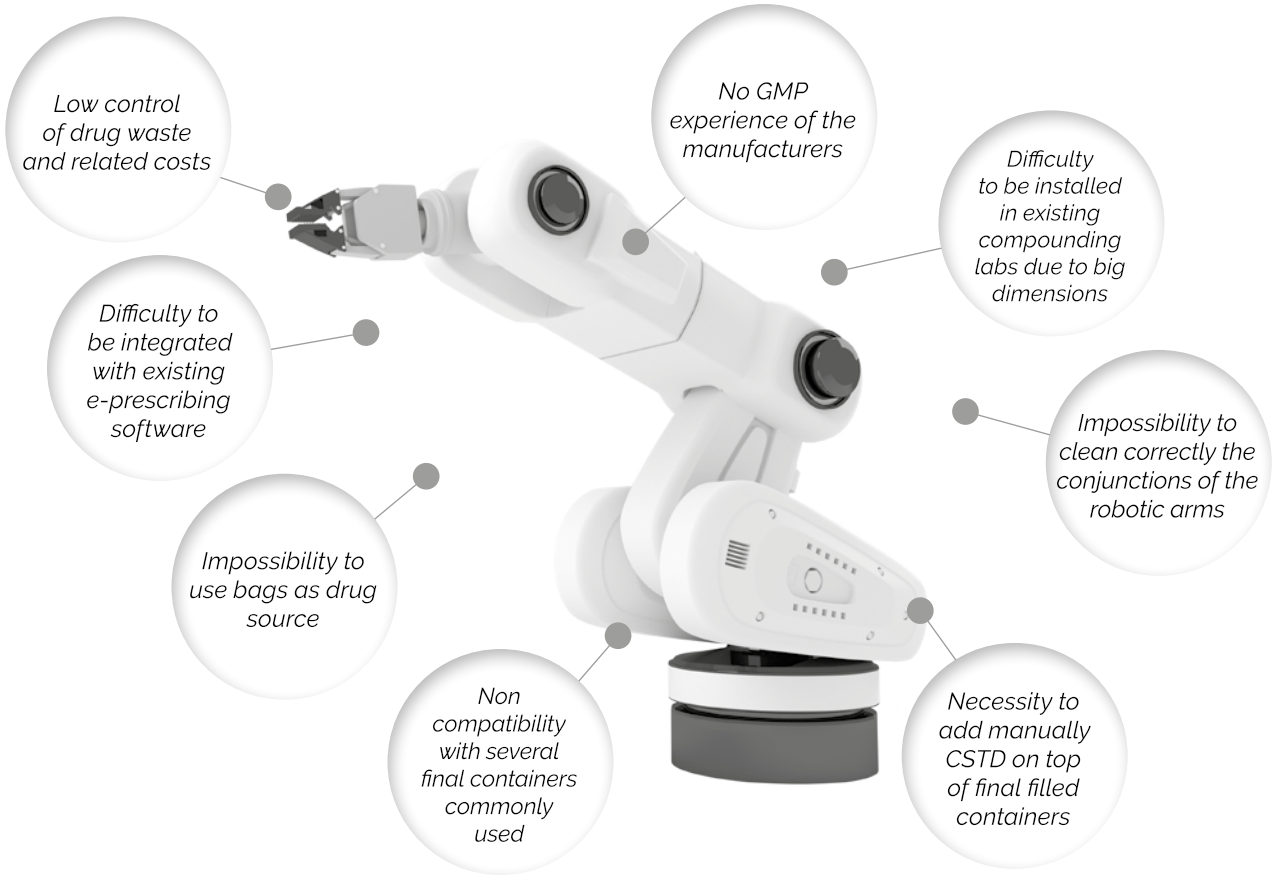
In the majority of cases, antiblastic drugs are nowadays compounded manually under a laminar flow hood.

There are several limits to this approach:

Limits of existing robotic compounding systems

Existing robotic compounding systems only replicate manual operations without any real optimization of the whole compounding process: therapies are prepared one after the other in the order of prescription. The main consequence of this is the fact that pharmacies still have a very low control of drug waste and related costs.

More in general, existing robotic compounding systems have the following limits:



Pharmoduct is an automated and patented device for the sterile preparation of personalised oncology drugs, including chemotherapy and biologicals.

Pharmoduct is able to reconstitute, transfer and dilute oncology drugs in order to prepare final doses (patient specific) and multi-dose bags (pharmacy bulk package). The system can manage more than 300 different drugs.

The introduction of Pharmoduct in the Compounding Lab will improve the whole oncology drugs preparation workflow.

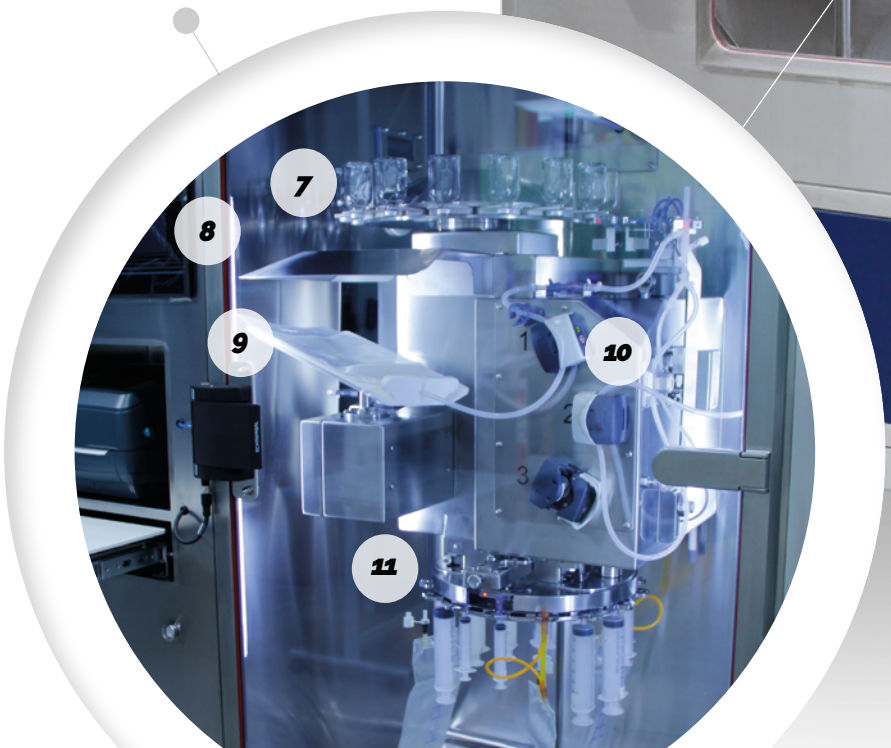
Multi-dose bags preparation

- Pharmoduct reads the electronic prescriptions and collects the ones that are based on the same API in a comprehensive macro-dose
- The operator loads Pharmoduct with the right drug vials and consumable kits, as suggested by software
- All drugs are identified by automatic label reading, all kits by RFID or barcode
- The system empties all vials (including over-fill) in the multi-dose bag
- In case of powders, drugs are automatically reconstituted before emptying into the multi-dose bag
- The dosage is checked in real time by a gravimetric scale
- Emptied vials are automatically wasted in a segregated area
- A personalised barcode label is printed for the multi-dose bag, with all the necessary preparation information
- Accordingly with the drug stability, multi-dose bags can be kept in the storage area and used in a later session as drug source

Final containers preparation

- The operator decides the drug source between multi-dose bags filled by Pharmoduct in a previous session, commercial multi-dose bags and commercial vials
- The operator loads drug source, diluent and up to 15 final containers (different typologies of final containers can be managed in the same session)
- All items are identified by RFID or barcode
- The system fills final containers one by one with the required quantity of drug and diluent (pre-filled bags can also be managed)
- The dosage is checked in real-time by gravimetric scales
- An additional final check of the dosage is performed through a dedicated external scale with integrated RFID reader
- A personalised barcode label for each container is printed, with all necessary information on the patient and dose

1. *Automatic ozone cleaning system*
2. *Negative pressure LAF with ULPA-U15 filters*
3. *15" touch screen monitor*
4. *Thermal transfer printer for personalized labels*
5. *Barcode identification system for diluent kit*
6. *RFID identification system with integrated scale for consumable kits*
7. *Upper rotating assembly for drug vials*
8. *Label identification system for vials*
9. *Gravimetric scale for multidose bag*
10. *Peristaltic pumps for liquid transfer*
11. *Lower rotating assembly for final containers*
12. *Segregated waste area with bag heat sealing*



Highlights

Patient safety
- Maximum sterility
- Top class decontamination with ozone

Operator protection
- High containment technology
- No direct operator manipulations

Full traceability
- Optical label identification of the drug vials
- Barcode & RFID identification of the final containers and kits

High performance
- Up to 35 preparations/h
- Liquid and powder drugs managed

Top accuracy
- Accurate gravimetric dosage system
- Less than 5% global error

Total flexibility
- More than 300 drugs managed
- Ready doses in all possible final containers

Significant savings
- Zero drug residuals
- Cost reduction

Easy installation
- Plug & play
- No structural intervention in the Compounding Lab

Main features
- Patented Class I Medical Device
- Liquid and powder drugs management
- Final containers and multi - dose bags preparation

Final containers (all brands)
- Syringes - up to 60 ml
- IV bags - up to 1000 ml
- Elastomeric pumps/infusors - up to 300 ml
- Bottles - up to 500 ml
- Other containers (with LL connection)

Multi-dose bags
- Multi-dose bags - up to 2000 ml

Drug source
- Vials (ISO 13/ISO 20)– up to 100 ml
- Multidose bags (filled by Pharmoduct or available on the market) - up to 2000 ml

Performance
- Syringes - 35/h
- IV bags - 25/h
- Elastomeric pumps - 20/h

Accuracy
- Dose accuracy - ± 5%

HL7 integration with e-prescribing software

Pharmoduct is conceived to be easily integrated with existing e-prescribing software, in order to maximize the efficiency of the whole chemotherapy workflow.

Once therapies are prescribed by oncologist and validated by pharmacist, become visible directly in the screen of the system – ready to be compounded.

Drug-based approach

Unlike other robotic compounding systems – that prepare doses one after the other, following the order of prescription – Pharmoduct groups them by drug (API) and operate through a batch approach.

This method allows to acquire, quantify and use the whole quantity of drug present within the vials.

All Luer Lock final containers compatibility

Pharmoduct is able to compound doses in all existing final containers with Luer Lock connection. Thanks to dedicated adaptors and support, even containers of new generation can be easily used.

The system can manage up to 15 final preparations in one batch, even of different typologies in the same session.

Safety first

Compliance

- DIRECTIVE 93/42/EC (Medical device)
- DIRECTIVE 2014/35/EU (Low voltage)
- DIRECTIVE 93/465/CEE in CE mark labelling
- EN12469 Performance criteria for microbiological safety cabinets (applicable selections)
- UNI EN ISO 14644 Cleanroom (ISO 5 air quality)
- CEI IEC 62304:2006 (Medical device software)
- CEI EN 60601-1-1:2007
- CEI EN 61326-1:2007
- CEI EN 61010-1: 2nd edition
- UNI EN ISO 14698-1:2004
- UNI EN ISO 11737-1:2006
- UNI CEI EN ISO 14971:2012

PHARMODUCT IS A MEDICAL DEVICE

CE 0476

Technical data

CONSTRUCTION MATERIALS	Support frame material	Stainless steel AISI 304
	External casing material	AISI 304 - Scotch-Brite™
	Working chamber material	AISI 316L - Scotch-Brite™
	Moving parts material	Aluminium
	Front door material	Lexan
VENTILATION SYSTEM	Box air-tightness	Class III (EN 12469)/negative pres.
	Main chamber classification	Grade A
	Air flow - LAF	450 m^3/h (0.45 m/s under the filter)
	Air flow - INLET/OUTLET	30% - 135 m^3/h
	Air flow AIR RECIRCULATION	70% - 315 m^3/h
	Air flow OZONE RECIRCULATION	200 m^3/h (0.2 m/s under the filter)
AIR FILTERS	Air inlet	F9 pre-filter
	LAF	ULPA U15
	Ozone catalysis	H14
	Air outlet	H14
DIMENSIONS	Overall dimensions (w x d x h)	1740 x 780 x 2265 mm
	Largest component dimensions (w x d x h)	1740 x 780 x 1795 mm
	Weight	670 kg

Utility requirements

Reference market	CE
General power supply	230V (1Ph+N+PE) 50/60Hz 16A TN-S
Minimum pneumatic supply (if not equipped with integrated compressor)	105 nl/min I 6 bar I ½"g female
Compressed air quality	Class 1.4.1 or higher (ISO 8573-1)
Maximum current absorption	16A
Degree of protection of the electrical panel	IP54
Electrical Plug	Shuko | 250V | 16A

BIODUCT s.r.l is the Legal Manufacturer of Pharmoduct

Distributed by:

COMECER an ATS company

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