







# LOCCIONI humancare

## **Loccioni humancare**

Our mission and principles in action.

A new synthesis of wellness, nutrition, and preventive care is emerging alongside the traditional clinical approach to healthcare - testing, diagnosing, and treating illness. The race is to anticipate, encourage, and design healthier, sustainable living. You might say the role of healthcare is evolving from lifeboat to lighthouse. More than rescuing people from illness, the future of health is in wellness and prevention, in early warning systems that predict vulnerabilities and change behavior before the roots of disease take hold.

A strategic alliance among the human being, clinical knowledge, and the creative intervention of technologies must be built on measured, interconnected systems.

**Loccioni humancare** accelerates these principles - developing a unified framework of methods, measures and innovation. **Loccioni** is transplanting decades of experience in global industries to a systematic approach to address some central issues of our time - health, nutrition and wellness.

Each scientific, technological, organizational solution is the synthesis of multi-disciplinary inputs with man, the unifying factor.

The health system truly becomes an ecosystem: the integration among research, diagnosis, technology, risk reduction, management of resources, energy costs and the environment becomes essential. The integrated approach can reduce treatment costs, validate and humanize the healthcare experience.

Measuring interventions; each treatment, each episode, mediated by the attention to the human aspect of systems, help us provide tools to improve the entire healthcare organization. Systems design, aimed at the sustainability of life is at all levels of our mission at **Loccioni humancare**.



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## APOTECA

In the oncology pharmacy, each admixture is tailored for the individual patient based on the physician's orders, real-time lab results and input from the pharmacy team.

The challenge is to prepare sterile, accurate chemotherapy doses for a specific patient, based on real-time information while the patient is waiting at the facility. Complicating the effort are the pressures of modern healthcare, including the high cost of the medications, the importance of timely, accurate information and the hazardous nature of compounds. This makes the difficulty level for manual preparations very high.

Comprehensive technology must be part of the solution. Borrowing and building on proven technology from other industries, applying worldwide best practices for safe compounding and combining a system – based emphasis on the importance of measures is the winning formula.



**Loccioni humancare** research introduces **APOTECA**chemo, the automation and information System for chemotherapy compounding.

The automated compounding process is an integral part of a patient-centered system where coordinating materials, data and activities works in synergy with the objective of maximum efficiency and risk reduction.

The technology becomes a tool to serve a higher purpose: to benefit the people involved, whether patients, family members or health care workers.

**APOTECA**chemo delivers measurable, meaningful value across many dimensions including patient safety, operator safety, pharmacist efficiency, peace of mind, physician satisfaction, nursing confidence, inventory management, cost reduction, automated record-keeping, and risk management.

## Preparation of chemotherapy drugs with automation

In oncology, the integration of materials, information and activities requires the utmost care: the oncologist and pharmacy professionals become a team around the patient to ensure the highest quality, safety and efficiency in a continuously growing area of medicine. The rising incidence of cancer and the continuous introduction of new drugs escalates the complexity.

In hospitals around the world, the development of new therapies with cancer-fighting drugs, customized to the individual patient occurs on a frequent basis. Once the treatment regimen is defined, orders are transmitted and lab parameters are satisfied, the preparation begins.



### **The manual preparation of chemotherapy carries its own set of risks.**

Consider:

- \* patient specific dosing and variability increases the possibility of error
- \* wrong patient label placed on the final container
- \* chemotherapy drugs are hazardous and exposure threatens operator health
- \* manual tasks can lead to operator repetitive stress and workplace injuries
- \* staff recruiting and retention can be challenging for chemotherapy

Many of our customers have highlighted the importance of managing the flow of information, capturing a reliable audit trail to monitor the history of each preparation. Data omissions and transcription errors can have serious consequences for the patient and possibly the provider healthcare organization.

In this scenario, automation and measurement are valuable tools for increasing efficiency and safety.

**Loccioni humancare** developed the first automatic system for hazardous drug compounding and currently has devices installed and operating in Italy, in the largest and busiest treatment centers.

## APOTECACHemo

The rapid process of continuous development deployed by **Loccioni humancare** has enabled further significant progress with **APOTECACHemo**: automation becomes faster, more interconnected and simplistic. Reliability is the center piece of **APOTECACHemo**.

**APOTECACHemo** *fully automates* the complex and critical tasks associated with preparations of intravenous chemotherapeutic compounds.

**APOTECACHemo** is a *robotic system* capable of weighing the active ingredients and solutions, reconstituting powdered drugs (thanks to the use of a dedicated, six way anthropomorphic mechanical arm and actuators) preparing syringes, bags and other final containers while safely loading and unloading the materials and preparations.



**APOTECACHemo** provides for *patient safety*. Patients are protected by a unified, redundant safety system of technological advances such as automatic recognition of products, an automated weighing system and a barcode labelling process for total accuracy.

**APOTECACHemo** ensures *sterility* by utilizing five HEPA filters with total air exchanges every 2.3 seconds. This results in a self contained chamber for ISO 5 compliance (in accordance with ISO 14644).

**APOTECACHemo** also ensures *safety for the pharmacy staff*. The staff is protected from vapors and accidental exposure by restricting interaction with high risk medications. The compounding process takes place in a negative pressure, closed chamber, designed to prevent and contain any form of contamination.

**APOTECACHemo** further enhances the *accountability of the provider institution* with a fully automated audit trail with the ability to define process surveillance alerts, intelligent workflow queing and robust reporting for operational analytics. This is potentially helpful with risk management and clinical trials data reporting.

## Workflow

- \* The pharmacist schedules preparation cycles of therapy sent by the clinicians.
- \* **APOTECA**chemo optimizes the task list based on your operating parameters.
- \* The operator loads **APOTECA**chemo with appropriate drugs and necessary supplies.
- \* All drugs, supplies and fluids are identified via picture and barcode recognition, ensuring that you have the correct drug for the upcoming order.
- \* The accuracy of compounding is controlled by independent systems



that weigh the materials and mechanically control all manipulations

- \* If necessary the robot will remove any excess solution from the diluent bag in preparation for the production of the final dose.
- \* Powder drugs are reconstituted and diluted drugs are dosed by disposable syringes to avoid cross contamination.
- \* A final weighing of the finished dose will then take place to ensure that the product falls within the pre-established, expected weight range for a given preparation. If the dose falls out of the desired range, the device will quarantine the finished product and ask the pharmacist to visually inspect the dose and review the preparation data to determine if it should be dispensed.
- \* Completed syringes, bags or elastomeric pumps containing the drug are presented back to the operator for final scanning, labelling and administration to the patient.
- \* Partial drug vials are in **APOTECA**chemo's parking lot for later use in accordance with your inventory guidelines.
- \* Refuse is automatically disposed of without human intervention.

## Design

**APOTECA**chemo is the result of numerous interactions with healthcare professionals, many years of evolving product development, and ergonomic study such as that of **Isao Hosoe**, a noted aerospace engineer and designer, winner of four *Compassi d'Oro* (Italian industrial design award) awards.



## Performance evolution

Once accuracy and sterility concerns were mastered, our attention turned to optimizing throughput without sacrificing core measures in accuracy and sterility. After years of prototyping and experimentation, we applied a series of hardware and software changes to advance the performance in every measurement area.

**APOTECA**chemo is the only chemotherapy robot in the world with these proprietary design advances. The results have been profound.

New management of the loading worklists, new carousel placements, new software platform, structural changes and carefully defined robotic arm routes, greatly improve the speed and performance of **APOTECA**chemo. This is the safest, fastest chemotherapy automation system we have ever produced.

Preparation	Time (seconds)
Single sample preparation syringe	100
Single sample preparation bag	145

10 complete preparations - 7 bags/3 syringes in approximately 25 minutes

### Best practices

Each hospital has its own needs and work patterns and the integration of technology in hospitals requires attention and care.

The choice of **APOTEC**Achemo is the first step in an ongoing partnership with **Loccioni humancare** to continuously improve efficiency, accuracy and safety.

Our application specialists interact with medical oncologists, pharmacists,



technicians and nursing to process a system startup plan.

Skilled technicians perform a pre-installation visit to ensure a perfect match with the technical requirements of the site installation, method of installation and test activities necessary for the integration of information.

During the installation, all the parameters necessary for the proper functioning of the System are analyzed and configured in the machine. They are specific to the client (database of drugs, printing management, IT integration, etc).

## Quality

In every system the dialogue among the parties helps ensure efficiency and safety. With **APOTECAchemo**, pieces of information guide the patient's cancer therapy: the oncologist prescribes, the pharmacist monitors, the technician performs the instructions of **APOTECAchemo** and the drug is returned to the nurses to be administered to the patient. Security and integrity of information and auditability ensures maximum control.

The module for managing the process of drug preparation can be interfaced with the oncology/ pharmacy computer systems.

**APOTECAchemo** automatically receives orders and begins to process them once they have been validated by the pharmacist.

Drug utilization can be optimized automatically as **APOTECAchemo** scrutinizes the order list and parking lot.

The patient receives a chemotherapy preparation for which quality is assured.

## Maximum security and safety

The clinical validation of **APOTECAchemo** was made through rigorous protocols including the monitoring and measuring of:

- \* Lack of operator exposure
- \* Dosing Precision
- \* Correct identification of drugs
- \* Execution times and productivity
- \* Validation of performance, reliability of technical devices and the computer system governing the flow of data
- \* Integrity of HEPA filtration
- \* Lack of contamination of the preparation area, materials used and the final preparations
- \* Cleaning Procedures
- \* Using bar codes to identify all the intermediate and final products used by the machine.
- \* Automated waste management avoiding any contamination

The numerous validation tests carried out using controlled protocols in hospital pharmacies showed a total integration of **APOTECAchemo** into the operational processes.

Loading



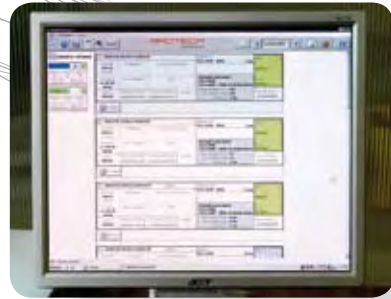
Drugs identification



Drug



Preparation of materials

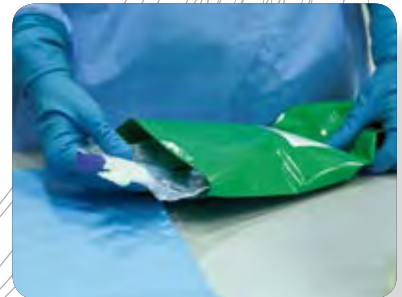


Prescription validation

Process Setup



Supply and administration



Quality Management

Identification



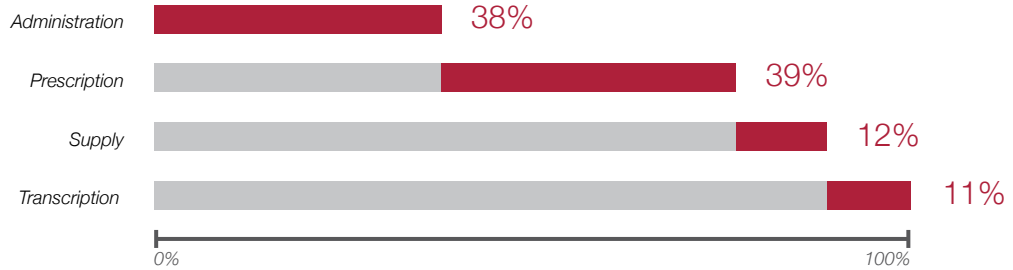
Admixture

Automatic preparation



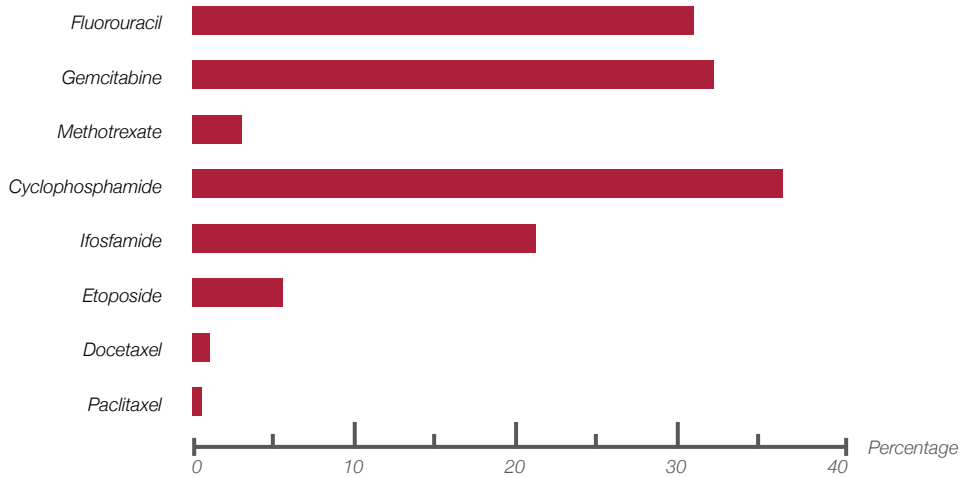
### Manual compounding challenges

#### Therapy errors



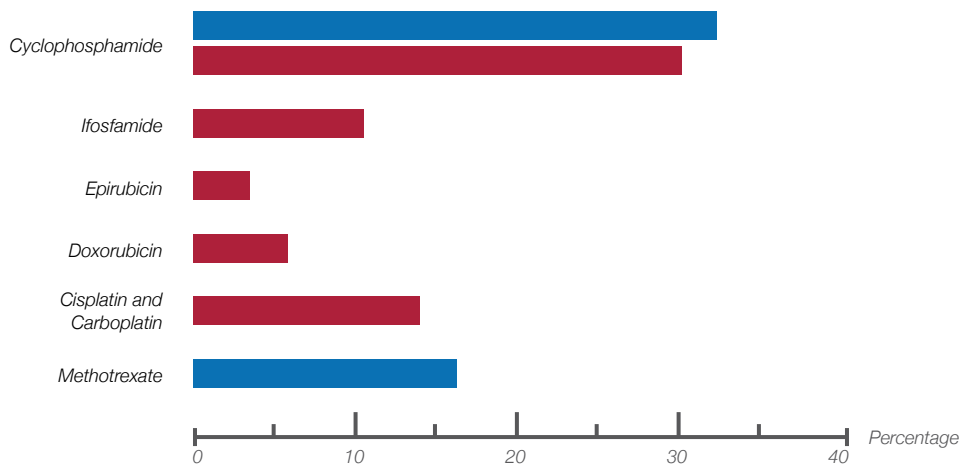
Percentage frequency of medication errors for the various operational steps [L. L. Leape et al. *Jama* 1995, 274, 35.]

#### Surface contamination



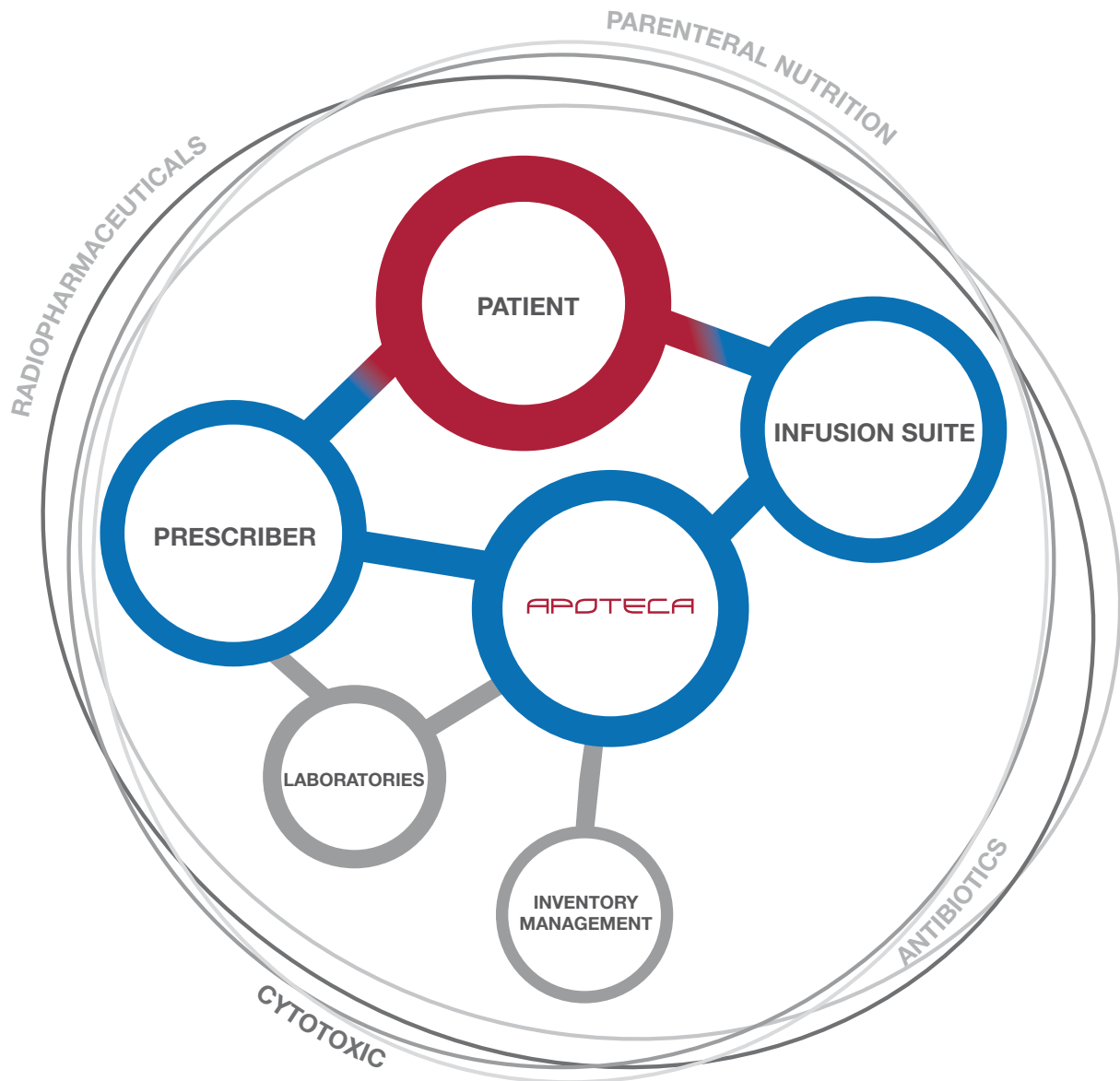
Percentage of samples contaminated surface samples divided by the active ingredients [T. Kiffmeyer et al. *J Oncol Pharm Practice* 2008, 14, 92.]

#### Biological contamination



Percentage of contaminated biological samples (urine) divided by the active ingredients [A. Barbieri et al. *Epidemiol Prev* 2005, 29, 87 (blue bar), C. Schreiber et al. *Int Arch Environ Health* 2003, 76, 11 (red bar)]

## Patient centered workflow



Consider of few of these areas in greater depth.

### PATIENT EXPERIENCE

Timely Availability | Accurate, Sterile Doses

### MATERIALS

Logistics | Just In Time Production | Waste Reduction | Waste Tracking | Durability

### INFORMATION

Integration | Alerts | Security | Audit and Traceability | Reporting

### PHARMACY OPERATIONS

Operator exposure | Confidence | Productivity | Ergonomics | Performance

### Customer experience

The value of **APOTECA**chemo is enriched by the daily experience of operators and by the continuous interaction with **Loccioni humancare** network.

Courses are provided on site or at Loccioni facilities for the new staff in order to give continuity to the use of the System. Software updates are installed and training courses are held on the proposed new function.

The operation of the System, according to the standards of performance, safety and efficiency is guaranteed by continuous preventive maintenance.

The help desk is always available to reply to each question and continuously checks the status of **APOTECA**chemo through the VPN connection. Technicians are ready to assist 24 hours per day throughout the world.

The support personnel are in direct contact with Research and Development to listen to the needs of each user (doctor, pharmacist, technicians, patient): the proposals are analyzed, developed and utilized to generate new functionalities within **APOTECA**chemo.

With **APOTECA**chemo entering the pharmacy it is possible to join the **APOTECACommunity**, a team composed by users of the System worldwide and **Loccioni humancare** network. The team meets regularly to discuss and design new functionality developments and set future targets. The ultimate goal is total quality, the combination of maximum efficiency, process improvement, productivity gains, while reducing risks and improving the patient experience.



## System features

### APOTECACHemo manages

- \* *Drugs in bottles up to 100 ml, elastomeric pumps, bags up to 1000 ml, syringes 5, 20, 50 ml*

### Warehouse Area

- \* *Carousel, vision system for drugs recognition, barcode reader*

### Preparation Area

- \* *6-axis robot, high precision scale, powder drugs mixer*

### Air treatment system

- \* *5 input HEPA filters and 1 output HEPA filter*

### Special waste collection unit

- \* *Interchangeable rigid trash automatically sealed*

### User interface

- \* *Touch screen*

### Size and weight

- \* *Height 7'10", width 6'10", depth 5'3"  
(Including ventilation)*
- \* *Weight 3580 lbs*

### Electrical requirements

- \* *Supply type: 3P+PE*
- \* *Connection Type grounding TT, TN, EN*
- \* *Input voltage (configurable at installation):  
400 VAC  $\pm 10\%$   
440 VAC  $\pm 10\%$   
480 VAC -10%, +0%*
- \* *Frequency: 50/60 Hz*
- \* *Electrical power consumption: 5kW*

### Compliance

- \* *EMC Class A (according to IEC 61326-1)*
- \* *ISO 5 (according to ISO 14644)*

Environment requires the same GMP standards as a laminar flow cabinet.

APOTECACHemo







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