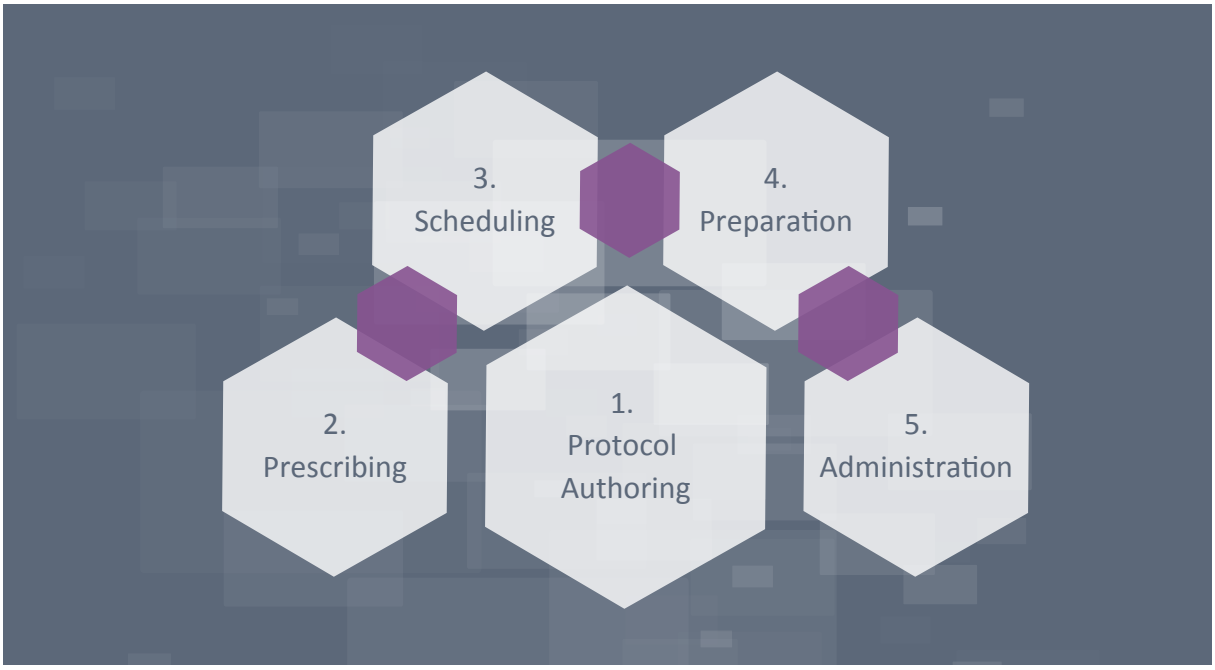
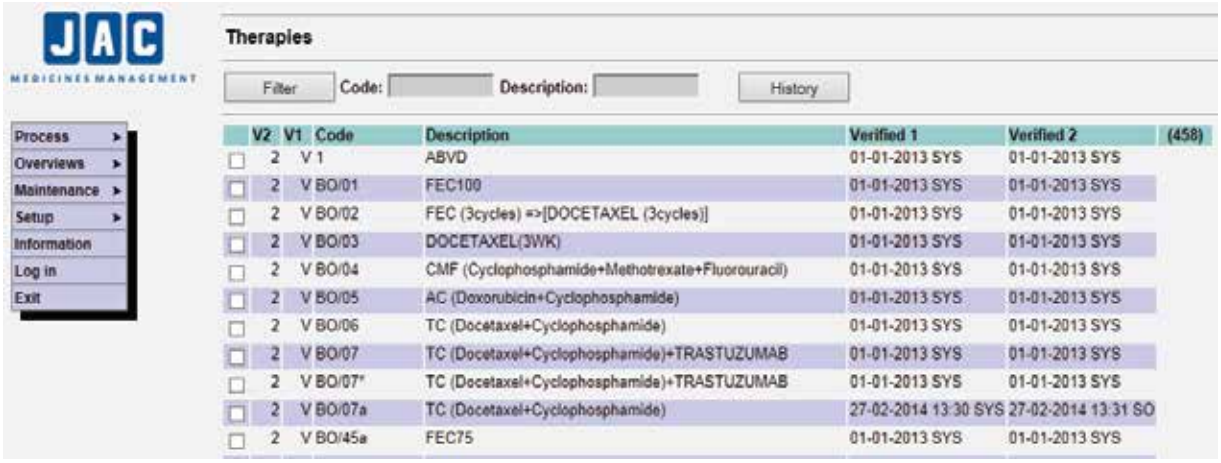
CMS Functional Walkthrough

JAC's CMS (Chemotherapy Management System) is a web-based solution for the prescribing, scheduling, preparation and administration of Systemic Anti-Cancer Therapy (SACT). The system's extensive functionality focuses on reducing errors, improving patient safety, streamlining chemotherapy processes and optimising efficiency.

CMS Components

CMS consists of five 'main' components which form a "Closed-Loop" system. The components interact with each other to dynamically manage the overall data and optimise the therapy processes.

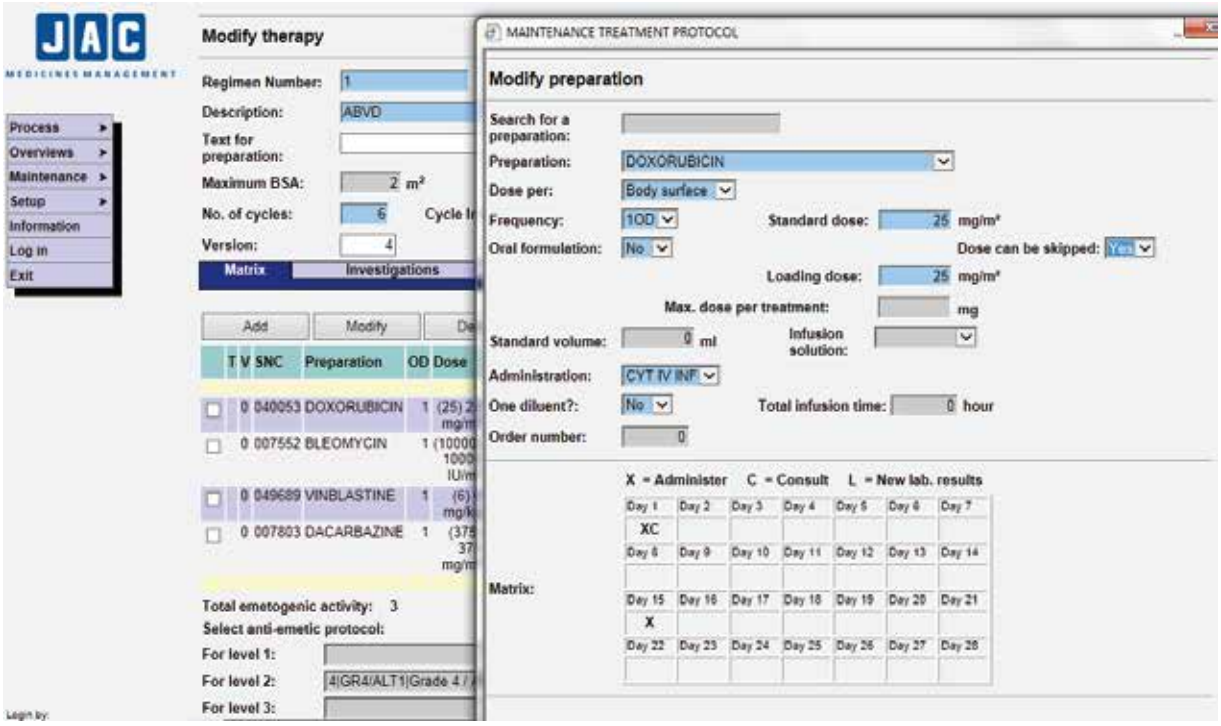




1. Protocol Authoring

CMS has the ability to build a library of protocols with version control, multiple sign-offs and full referencing. Building protocols is easy, intuitive and consistent throughout the system. The protocols supported include:

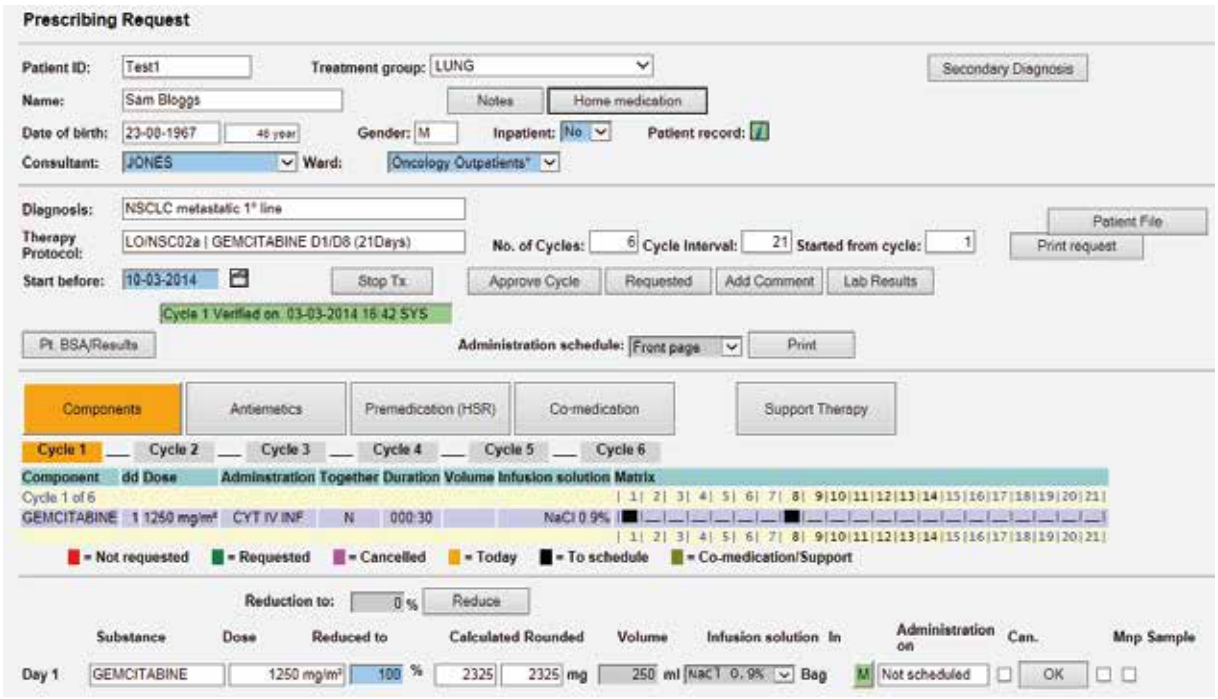
- Standard and off-label therapy protocols for SACT with matrix visibility for current and future cycles, BSA capping and a link to specific investigations including blood results.
- Individual treatment plans linking various standard therapy protocols.
- Individual protocol libraries allowing Consultants to pick relevant protocols within their scope of practice, with the ability to add decision support such as “proceed” rules and dose modifications per drug component.



- Antiemetic protocols for acute and delayed emesis, which are classified according to the therapy's level of emetogencity. These can be assigned automatically to each standard therapy protocol or applied separately at the point of prescribing.
- Supportive therapy protocols for specific toxicity groups.
- High-level preparation protocols for the aseptic manufacturing of cytotoxics, monoclonals and antibody-drug conjugates.
- Complete administration protocols with detailed instructions and guidance for nurses.

2. Prescribing

The prescribing functionality is safe and intuitive. Once a new patient is selected, a request navigator will appear to the prescriber which will route the request to either a therapy protocol, a treatment plan, or a support protocol. The patient file can also be accessed at this point for a detailed clinical picture including previous diagnoses, a history of chemotherapy administration or a summary of previous assessments.

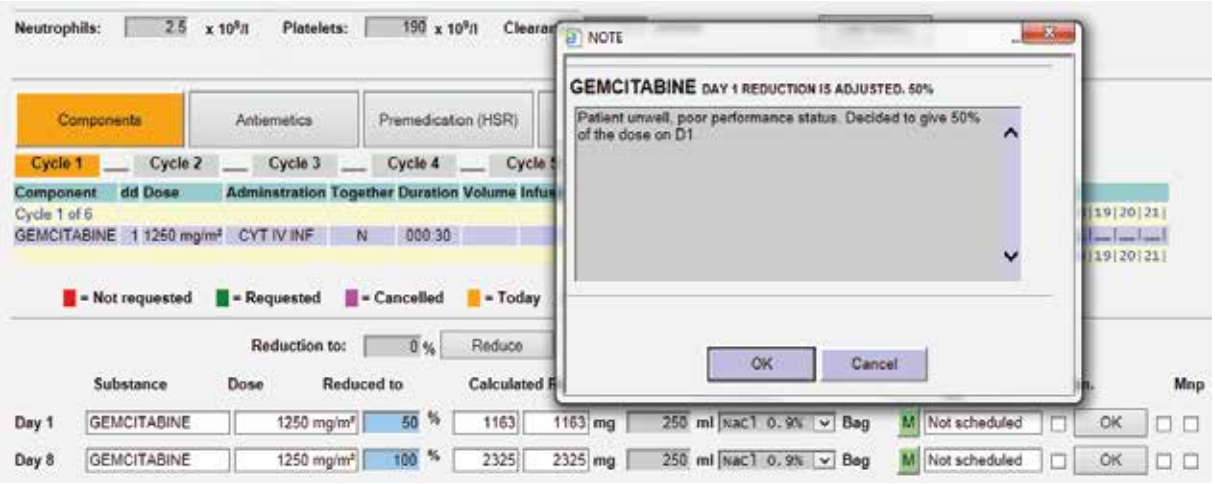


CMS will propose a list of therapy protocols or treatment plans based on the patient's diagnosis, intent to treat and the prescriber's scope of practice. Once a protocol is selected, the complete therapy is displayed immediately on a comprehensive screen.

Based on the patient's demographics and blood values, and using validated formulas (such as Dubois and Dubois, Mosteller, Cockroft-Gault, MDRD, Calvert for carboplatin dosing), either a

loading or maintenance dosage will be automatically calculated by the system. Dose capping, rounding and banding as well as cumulative dose recording, are all supported in CMS.

The system also gives dose reduction proposals for the prescriber to review. Dose reductions can be applied to the entire protocol or individually per drug component, with a mandatory field detailing the reason for this reduction.



Once satisfied with the therapy protocol, the prescriber may propose a date for the therapy to start. The therapy is then provisionally approved and will be subject to final approval based on lab results prior to commencing treatment.

CMS can propose a default antiemetic protocol based on the level of emetogenicity of the therapy. The prescriber can either approve it or choose an alternative protocol based on the patient's clinical picture. At this stage, the prescriber can also add any pre-medication and support medication, if necessary.

Pharmacist clinical verification is available within the system and offers robust tools for checking current and future cycles. Notes can be added and easily retrieved at any point during this process.

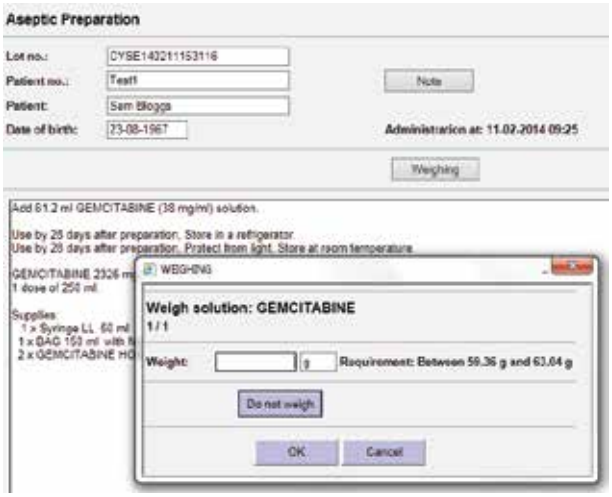
3. Scheduling

CMS offers intelligent functionality for scheduling cancer patients on the ward to receive treatments, and preparations in the aseptic pharmacy production unit.

Ward scheduling pulls out information from the administration protocols and links it to the available time slots on the treatment chair or bed, offering an accurate and realistic capacity planning tool. This functionality can also produce appointment letters/cards to patients.

Once doses have been approved, scheduled on the ward, and clinically verified by the pharmacist, they will appear in the pharmacy schedule. The system will automatically prioritise the manufacturing, taking into account stability of the product, time and date of the administration, capacity inside the cabinet and campaign manufacturing. Any changes in the patient therapy schedules will be directly reflected in the pharmacy production schedule.

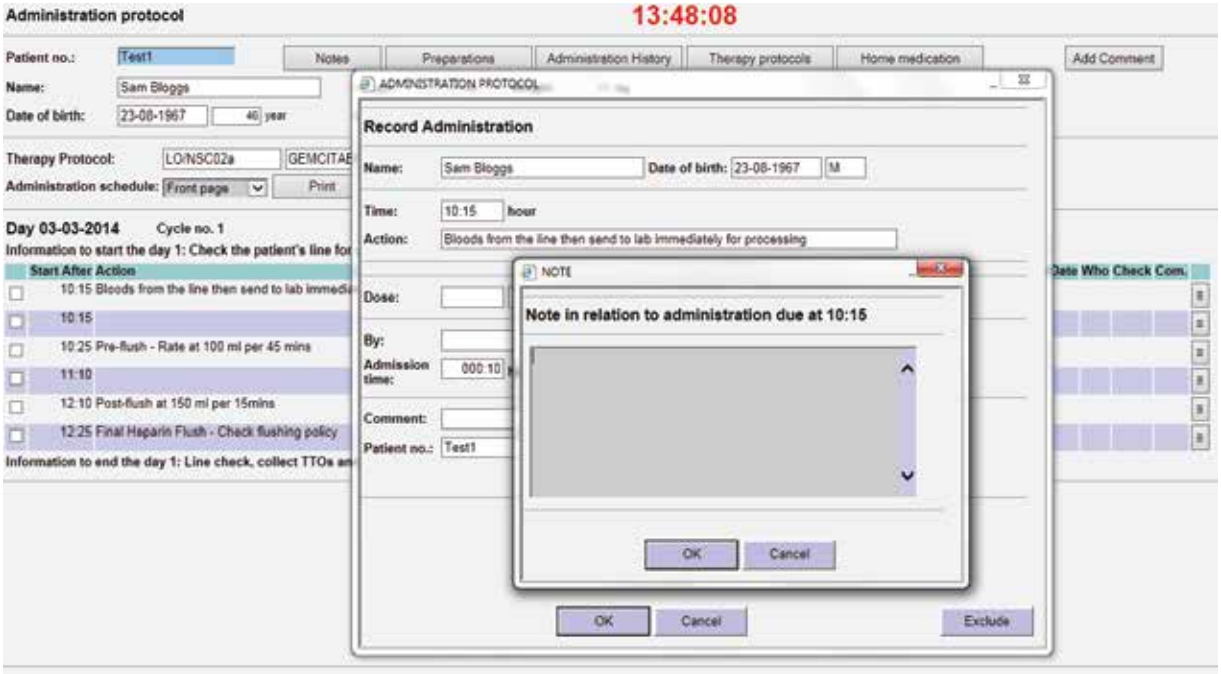
4. Preparation



CMS supports paperless manufacturing, barcode scanning for pre-process raw material checks, and electronic weighing of the active ingredient offering improved quality assurance of the final product. The single component protocol files are very complete with detailed fields relating to stability and preparation steps.

The label on each final product carries a patient-specific barcode with a batch number, expiry date and time, dose and diluent. By scanning the barcode on the label, details of the product are displayed on the screen including the pre-process and preparation check reports. This, alongside the physical checks made on the final product and raw materials constitute the final accuracy check. CMS also supports pharmacist final release of the product through access to the patient's notes, blood results and dose reduction rules.

5. Administration



Once the product is released from pharmacy and reaches the ward, the nurse will then prepare for the administration. The administration screen is intuitive and easy to follow. Nurses can have access to the patient notes and administration history and can add comments and general observations. Alongside SACT, pre-medications, flushes, antiemetics, pre and post-hydration regimes are all included in the administration section, and all relevant actions can be added. All administrations and actions are sequential and notes can be entered for each individual step. Actual administration is recorded, in real-time, by scanning a patient bar code and the product barcode in turn.

CMS Closed-Loop support

GMP strict quality validation requirements and the increasing complexity of drug therapies involved in cancer treatment means that it is no longer sufficient to optimise just the preparation process; instead the entire process from prescribing to administration must be controlled ensuring patient safety.

Within CMS, there is full support - from the moment a request is made until the time of administration - through specific workflows determined by the organisation. Each step is logged (and auditable) with the date, time and user, that the process is conducted in accordance with the appropriate procedural guidelines.

CMS Quality Validation

As part of the purchase of CMS, validation (based on the GAMP5 validation framework) of processes being implemented within the customer's environment is offered as an option.

Good Automated Manufacturing Practice (GAMP) is both a technical subcommittee of the International Society for Pharmaceutical Engineering (ISPE) and a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry. More specifically, GAMP describes a set of principles and procedures that help ensure that pharmaceutical products are of the required quality.

The following documentation will be provided as part of the validation process:

- Validation Plan (VP)
- User Requirement Specification (URS)
- Risk Analysis (RA)
- Combined installation & Operational qualification protocol (CIOQ) for the test environment.
- Combined installation & performance qualification protocol and report (CIPQ) for the production environment.
- System Management Plan (SMP)
- Traceability Matrix (TM)
- Validation Report (VR)

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