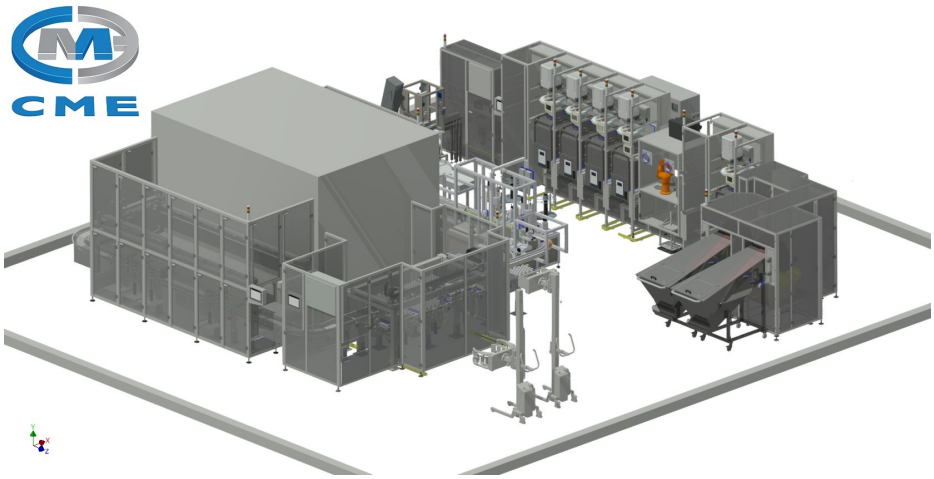
CME's Prescription For Innovative Medicines Manufacturing

Scotland's new Medical Manufacturing Innovation Centre will soon take delivery of CME's Just In Time (JIT) Clinical Trials Manufacturing System, a disruptive technology which will reduce the time taken to bring new medicines to market.

Once delivered, this system will provide the MMIC with the flexibility to fill pill bottles with different types of drugs, in tablet or capsule form, without the risk of cross contamination, whilst maintaining complete traceability throughout the system. The Multi-Million Pound turnkey system, designed and manufactured by CME Limited, comprises a number of individual stations each of which is used to perform discreet operations including: handling, filling, sealing, weighing, marking, labelling and packing.

A unique feature of this system is its ability to meet the stringent pharmaceutical hygiene and cleanliness standards without the complete system being located in an ISO class clean room environment.



CME's contribution to this prestigious project began when the company secured an initial contract for the design element of a complete bespoke system capable of receiving on-demand orders, filling pill bottles with the appropriate number of tablets or capsules of the requisite drug, labelling bottles and consolidating those orders all whilst ensuring full product tracking and traceability.

CME's innovative design solution for the JIT system, whilst vastly reducing the risk of cross contamination of the bottles and the surrounding equipment and environment was instrumental in securing both the initial design contract, and the subsequent contract for the manufacture of the automated clinical trials line.

The system build project required not only the specification and integration of a wide range of proprietary technologies, but also innovative design solutions to a series of technical challenges across the various elements of the system.

System Capability

The system handles and processes 2 different sizes of pill containers – 60cc and 150cc, supplied in bulk form and which are fed to the system from bulk hoppers. Each hopper has a capacity for 1,000 or 2,000 bottles depending upon the bottle size, and the bottles pass through bowl feeding, orientation and singulation systems ready for loading to the line individually.

Product traceability is an essential element in any medical or pharmaceutical environment, this begins with each bottle being laser marked with a unique 2D matrix code which is used for tracking and verification purposes throughout the automated processes.

The first of the "filling" operations involves the loading of a desiccant capsule into each bottle. This is achieved in a humidity and temperature controlled fill station environment. To verify that the correct amount of desiccant has been added, precise tare and fill weights are taken and validated against the product matrix code identifier to ensure it is as expected for the particular bottle and size.

A **series of subsequent humidity and temperature controlled drug filling stations**, each configured as a fully functioning independent unit, and designed to allow quick changeover of pharma product types, are used to dispense tablets or capsules of differing drug types and strengths. Tablets or capsules pass through the feeding system in a controlled manner with accurate counts populated into a holding chamber. Prior to the drugs being fed into the pill bottle, the bottle ID marker is again checked to verify the correct correlation between container and product. . The processes performed within these stations relating to locating the bottles, feeding the drugs, controlling the environment and preventing cross contamination, eliminates the need for the complete system to be housed in an ISO classed controlled clean room. This element of the system is subject to patent applications.

Pill containers, now containing desiccant plus tablets or capsules once again have the 2D ID code read prior to being check weighed, and if correct they are passed to the next station where a foil seal is secured to the top of the bottle by induction heating. This is followed by each bottle having a cap fitted and tightened to a pre-determined torque at the next station in the line.

In addition to the bottle handling, filling, sealing and capping operations described, the system also **incorporates comprehensive bottle and tray storage, retrieval and labelling facilities.** This allows completed product to be handled, stored and processed in a number of different ways including: transferring finished product from the bottle infeed system to trays, transferring bottles from a white stock infeed to trays and also to pick bottles from previously populated and stored trays for transfer to the bottle labelling unit. Bottles can also be picked and loaded into shipping trays, which when populated to the correct level are transported to the dispatch area. The storage element of the system has capacity for in excess of 17,000 bottles.

Bottle labelling is carried out in a separate, self-contained system, which is capable of accepting both sizes of bottle and applying either a single panel label or wrap around panel label as required. The 2 D code on each bottle is read prior to its unique label being printed, verified by machine vision and then applied.

This comprehensive and flexible system controls and maintains traceability throughout manufacture, and secure reject areas are incorporated at each manufacturing stage, ensuring that only good and verified product passes to the next operation. The system has also been designed to allow scale up to meet future capacity requirements, and for the future introduction of alternative pack formats and component variants.

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