



Exciting new filling line concept

We have been awarded a consultancy contract for a confidential client in Europe, to incorporate within its existing site a new grassroots building, dedicated to formulation and finishing of injectable cytotoxic liquid and freeze-dried products.

Aseptic processing will be within sterile rooms, and primary containment will be guaranteed by closed processing within barrier systems. The project is being managed from our Paris office, with process engineering in Milan.

Great emphasis has been placed by the client on the requirement for a compact filling line that can be run and controlled by the minimum number of operators.

This is a new concept and we approached several vendors. IMA SpA has agreed to work with us in meeting this new challenge.

IMA is currently developing this highly innovative filling line, devised as one very compact module for continuous or batch processing of aseptic vials from 2 to 100 ml, for liquid or lyo products, up to 120 vials per minute.

We plan to complete all testing at the IMA factory, to ship the assembled line in one truck, and then to install at site and complete qualification in under two months from arrival at site. The module includes a linear vial washing machine, a depyrogenating tunnel, a filling/stoppering machine, a capping machine and is equipped with 21CFR11 interface and interactive training.

An important key feature is that the module is not intended to be customized. Eliminating customization ensures cost and time savings not only during installation and validation but during facility design specification, as well as repeatability of project scope, minimized risk, technical support and spare part availability.

The first prototype will be ready at the end of 2005; the first machine could be delivered 6-7 months later and, when fully in production, will be a stock item with a delivery time of 2-3 months. This is an innovative concept that could lead to a new era of filling lines.