



**Germana Molinari**  
Senior finishing & formulation engineer

In the absence of a 'one size fits all' solution to the containment of fill finish operations, a logical approach to the design of effective protection is required. Key to success is the correct combination of working area confinement and personnel gowning.

Previous solutions often relied on personal protective equipment (PPE) together with contained rooms or departments to protect the environment. Now, more and more, the approach is to use primary containment at the very source of product exposure, using secondary containment as a back up solution and PPE as an emergency/short-term intervention protective device.

The essential first step is identification of the critical operations, typically:

| Injectables Facility | Oral Solid Dosage Facility |
|----------------------|----------------------------|
| Dispensing           | Dispensing                 |
| Formulation          | Product transfer           |
| Filling              | Tabletting/capsule filling |
| Lyos unloading       | Blistering/bottle filling  |

The range of containment devices applicable to the different operations is wide and includes:

- contained connection - split valve, high containment valve, rapid transfer port, continuous liner
- glovebox isolator
- closed restricted access barrier system (C-RABS)

Crucial is the awareness that there are no universal solutions applicable to every situation. The selection of the proper containment solution should include an analysis of the key features of the operation to be contained, typically:

- product potency - low, medium, high
- product form - liquid or solid
- product diffusion capability - aerosol generation, powder spread
- activity duration - occasional or shift-based
- product exposure - open or closed activity
- aseptic processing requirements - meeting HSE and GMP requirements
- product potency issue or only cross-contamination prevention

Three possible indicative decision trees are below:

