



Contract Manufacturing according to your needs

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Your experienced Biotechnology Partner

The Boehringer Ingelheim Pharma GmbH & Co. KG campus in Biberach/Riss, Germany, is not only one of the major Boehringer Ingelheim research and development centers, but also the home of one of the largest facilities dedicated to biopharmaceuticals. This facility provides the entire value chain from cell line and process development to commercial cell culture manufacturing and, finally, to the aseptic production of various dosage forms of finished drug products.

In addition to manufacturing drug products in liquid and lyophilized vials, Boehringer Ingelheim can provide patient-friendly application forms like pre-filled syringes.



Figure 1: Syringes

Syringes in Contract Manufacturing

Syringe filling takes place in ‘Biopharma Manufacturing 4 (BPM 4),’ which is equipped with a Restricted Access Barrier System (RABS).

Ready-to-use syringes from 1 mL to 10 mL can be processed in tub sizes from 160 to 42 pieces per tub.

BPM 4

Filling capabilities	0.5 – 10 mL
Batch size	25,000 – 150,000 units

Table 1: Filling capabilities of syringe filling line BPM 4

The ready-to-use stoppers are transferred into class A by means of an alpha/beta port system. Unpacking the tub and detaching the lid is fully automated. The nested syringes are removed from the tub for filling. Immediately after the dosing process with rotary piston or peristaltic pumps, the plungers are inserted mechanically. The fill volume is monitored automatically in a non-destructive way by tare-gross weighing. Stopper position is checked and documented semi-automated with a camera.



Figure 2: Syringe filling line BPM 4

Vials in Contract Manufacturing

In 'Biopharma Manufacturing 6 (BPM 6)', a modern isolator line (2017) for vials is connected to two identical large scale lyophilizers with 20.4 m² total shelf surface area each.

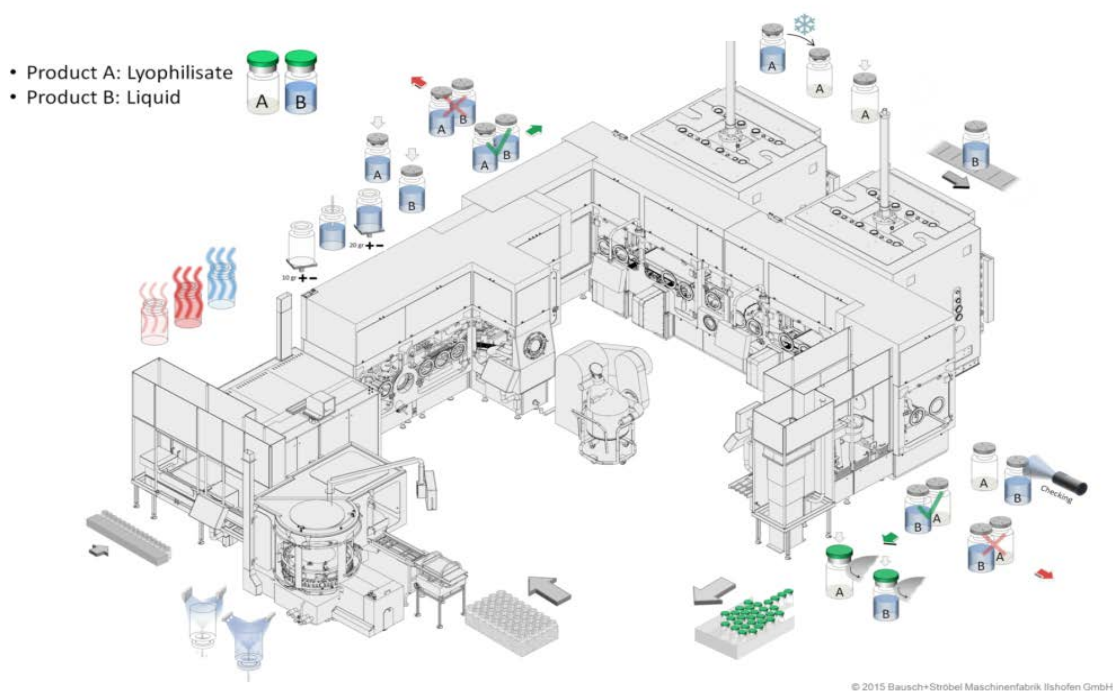


Figure 3: Schematic presentation of BPM 6

On the filling lines, vials from 0.5 mL to 100 mL, can be processed. Table 2 summarizes typical filling capabilities for line BPM 6.

BPM 6	
Filling capabilities	0.5 - 100 mL
Batch size (liquid vials)	2,000 - 96,000 units
Batch size (lyo vials)	10,000 - 87,500 units

Table 2: Filling capabilities of BPM 6

Security for your product

All filling lines are integrated filling lines with vial washer, depyrogenation tunnel and filling line.

Filling lines are designed in RABS (Restricted Access Barrier Systems) or in Isolator technology thus providing maximum protection of the aseptically filled product.

Filling is performed by rotary piston pumps or by peristaltic pumps. To allow flexible utilization disposable equipment is used and can be integrated.

The protein formulation is transferred to the filling line via a filter skid that allows in-line filtration, integrating the final filtration step as close as possible to final dosing. The filter skid as well as all other fill equipment parts with direct product contact are cleaned and sterilized in place (CIP/SIP), to ensure sterility of the product path down to the filling needle.

Plungers and closure parts are sterilized and dried by a processing system which can be connected to the isolator via an alpha/beta port. For bulk components, washing and siliconization steps can be included in the preparation process.

Loading and unloading of the freeze-dryer is fully automated and cooling is performed by liquid nitrogen, a technology that allows transfer of complex lyophilization cycles.

The use of specific decontamination cycles of the separate isolator units, allows flexible usage of individual processing units, e.g. liquid vial filling, or freeze-dried vial production.