New
Small Scale API Facility
at EXCELLA

FAREVA
HOLDING

About Us

Excella Pharma Source (formerly Heumann PCS GmbH) located in Feucht, Germany has been serving the pharmaceutical industry for more than 35 years. We are known as a high quality source for API's and finished dosage forms that are complex and difficult to manufacture. We are offering a full range of services including process development services, analytical method development and validation, a unique reference standards program and an outstanding regulatory support.

New Small Scale API Facility Operational

Excella's latest investment is the small scale high containment API facility described in this brochure. Construction of this facility at our site was started in April 2008 shortly after the acquisition of our company by the Fareva group. After only 15 months the new unit was completed well in the budget of 17.4 million Euros. Qualification and validation of the equipment installed and the complete facility followed and in July of 2009 the plant became operational. It was started in a three shift mode with two teams and will be driven up to full capacity usage in 2010.

Excellence in High Containment Production up to OEB 5

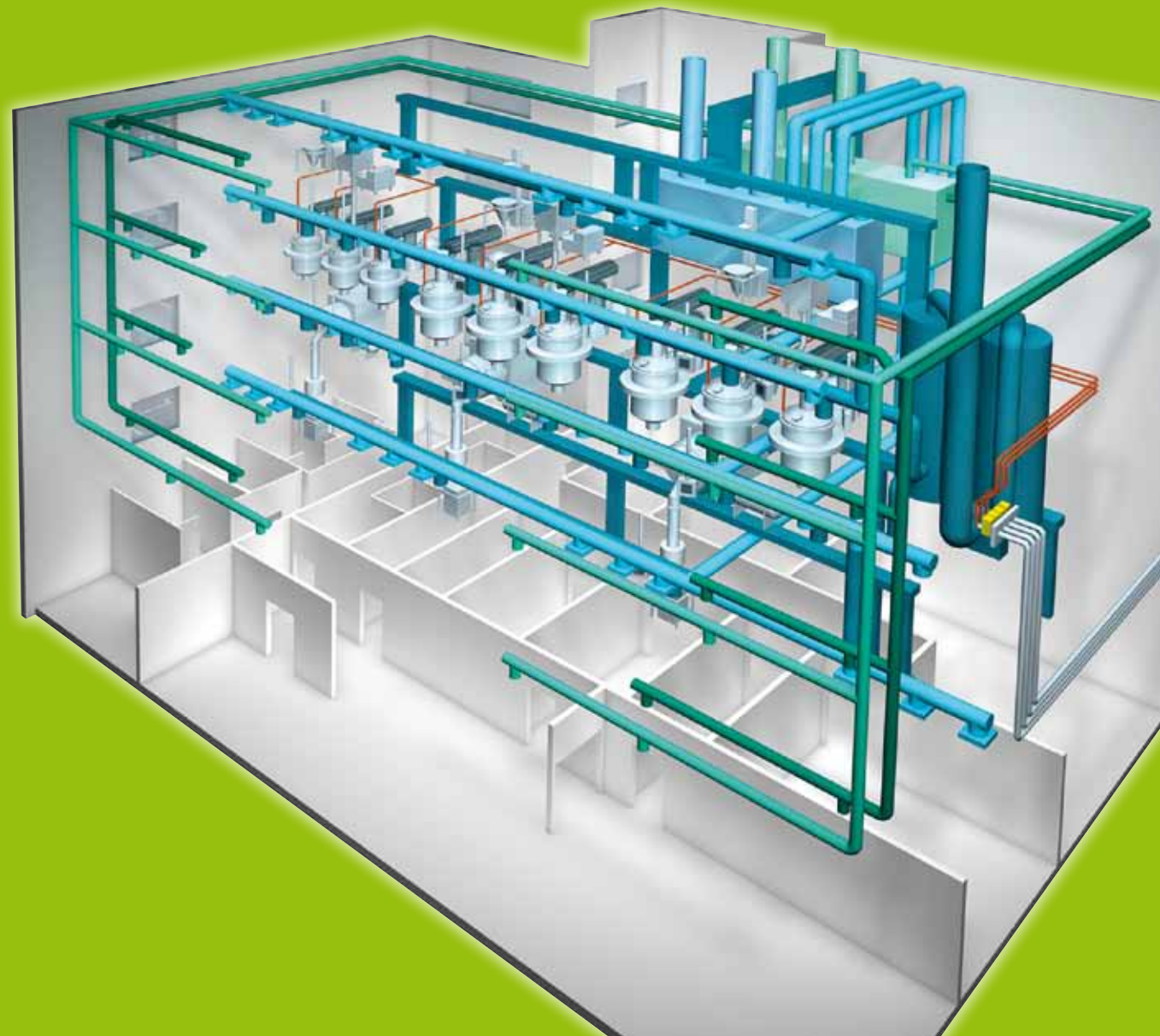
Two main drivers were behind the construction of the new Small Scale Facility ("SSF") :

- to increase Excella's capacity for small volume API's. Newer molecules are consistently more potent and/or more selective and, therefore, volumes to be manufactured are small.

- to add the long sought for capability to manufacture OEB 4 and OEB 5 substances in small scale. OEB 4 substances are substances with an occupational exposure level between 10 and 1 µg/m3 and OEB 5 substances have an OEL below 1 µg/m3.

Consequently, the new facility has three compartments which are completely independent of and separated from each other with separate air handling systems, separate access, etc. Two of the compartments are designed for handling highly active API's and are OEB 5 compliant, with reactors in the size of 250 and 800 liters, respectively. The third compartment, again with 800 liter reactors, is used for standard substances. In addition, a kilo lab is available with 60 liter reactors installed. This allows for batch sizes from a few up to 150 kg.

Each compartment extends over four floors, with a top-down product flow, i.e. with charging done from the top floor, the reactors located on the next level, centrifuges and pressure filters again one floor lower and the harvesting rooms on the ground level. Separate airlocks on every floor for each compartment with a higher pressure than in the surrounding rooms give access for personnel and materials.



Safety and Product Quality

The team at Excella is fully committed to manage the risks associated with handling and producing highly potent and toxic substances. Safety and quality considerations include our personnel, the environment and our neighbourhood but also our customers and the patients using the products. Our management and our staff are dedicated to maintain and improve safety and environmental and health systems beyond current standards. Extensive worker training ensures that safety and product quality are never compromised.

A validated strict and sophisticated cleaning regime encompassing CIP systems, decontamination procedures and multi-step cleaning processes designed for the respective equipment warrants that no residues of highly active or toxic components are carried over into the next product.

Occupational health monitoring and dust exposure measurements assist the team to keep the awareness for potent compound handling at the highest level and to prove the consistent compliance with the OEL protection levels defined.

Closed Systems for Protection of Product and Environment

All handling of materials is done in completely closed systems. For charging of raw materials and intermediates on the top floor and discharging of intermediates and final API stages on the ground floor, Frewitt containment systems like glove boxes, big bag handling devices and powder transfer systems have been installed. They ensure perfect protection of our co-workers from toxic and highly active substances as well as they avoid any contact of the substances to the environment.

Separated Technical Area

In order to minimize the risk of cross contamination and to make the manufacturing compartments easily cleanable, the new facility follows the concept of a clear separation of manufacturing areas and technical areas. Major equipment, like centrifuges, is installed “through the wall”, the technical parts as motor and drive units being accessible from the technical area for easy maintenance and repair, while only the parts used during the manufacturing process extend into the manufacturing area.

One-Stop-Shopping

Our Offer with the New Facility

Excella's new facility provides state-of-the-art containment services. The facility operates to current Good Manufacturing Practices and can produce material for preclinical testing, clinical trials and commercial use as it serves Excella as a pilot plant and a small scale manufacturing unit.

… one step further

Highly potent molecules produced in Excella's new high containment API facility can seamlessly flow into Excella's drug product manufacturing division on site.

Our Pharma colleagues are specialized in the manufacture of solid dosage forms of highly active or toxic substances with particular claims for product, staff and environmental protection. We are a market leader in high containment tablet and capsule production with two units that are OEB 4 and OEB 5 compliant.

So, if requested by the customer, Excella can offer a one-stop-shopping solution ranging from process development through API production to the packed finished dosage form.

Key Features of the New Facility

- Facility houses three independent manufacturing compartments and a kilo lab to support production of API's in small scale
- Fully cGMP compliant and capable of handling high potent substances up to OEB 5
- Glass lined and Hastelloy reactors with capacities from 60 to 800 liters for multi-step syntheses
- Temperature range from - 40 °C to 165 °C
- Latest cGMP centrifuges with automatic heel removal and WIP
- Commercial batch sizes ranging from a few kilos up to 150 kg
- Airlock systems to prevent cross contamination and pollution of the environment
- Entirely closed production lines
- Strict control systems for equipment and personnel in order to meet lowest OEB's
- Validated sophisticated cleaning procedures to avoid cross contamination

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