Freeze drying experts BTL announce new cytotoxic capability

With the construction of a new standalone cytotoxics laboratory, UK-based BTL are now able to provide R&D services in freeze drying for cytotoxic products.

Cytotoxic therapies are drugs that work by preventing the rapid growth and division of cells. This makes them particularly useful against cancers with high growth factors such as acute leukemias and lymphomas. However, their effects are not specific to tumours. Normal cells can also be damaged both in patients and anyone else exposed, such as healthcare professionals and laboratory technicians. Cytotoxics are highly potent which means that throughout their development and production journey from R&D to actual administration there is a constant need for secure handling.

Handling cytotoxics

In the development laboratory, the safe and responsible handling of cytotoxic drugs requires measures that are significantly more stringent than standard practice. Staff must be protected through use of restricted access and protective clothing such as Tyvek suits. Cleanroom containment including room pressure differentials and single-pass HVAC systems are used to prevent product from escaping from the laboratory and to prevent cross-contamination with any other products that may be under investigation. Procedures for additional training, waste disposal, cleaning and validation must also be in place.

All of these factors make it common for cytotoxics to be handled separate from other products, in a separate suite specifically for handling cytotoxic material.

Rather than take on the costs of building and running additional laboratory space, many drug developers benefit from partnering with contract research organizations with existing facilities and additional expertise.

About Freeze Drying

Freeze drying is a complex operation used to turn unstable therapeutic actives into stable pharmaceutical and biopharmaceutical products. The objective of freeze drying is product stabilization and this process imparts higher stability, broader temperature tolerance and longer shelf-life than formulations that remain in solution. The process of freeze drying avoids high temperatures, which makes the procedure ideal for products which are often sensitive to heat or which are chemically or biologically unstable, as is the case with many biopharmaceuticals. Unlike other drying methods, freeze drying avoids processes such as crystallization, filtration, and precipitation. This helps preserve chemical and biological potency in the dried product. For these reasons freeze drying is common in the pharmaceutical and biopharmaceutical industries.

However, freeze drying can be an expensive process.

“When freeze drying cycles are inefficient they become long and costly,” says BTL’s Commercial Director Dr Laura Ciccolini. “This is why many developers choose to partner with an organization with expertise in this field like BTL, to ensure that product and process are optimized. However there are a limited

number of companies with freeze drying expertise, and of these, few have the capability to handle cytotoxic compounds safely. This is the reason for the construction of this new facility."

About the new facility

BTL's new standalone cytotoxics laboratory has been built to provide both an outsourcing capability to smaller developers, and specific product development expertise to more established enterprises. The suite contains a full range of characterization and analysis equipment as well as a pilot-scale freeze dryer. This enables BTL to offer its full range of freeze drying product and process development services and small scale production runs for cytotoxic products that may not be safe to handle in other facilities.

Dr Ciccolini says,

"BTL are now able to provide a really exceptional combination of world-wide reputation for freeze drying expertise and safe cytotoxic processing."

About BTL

UK-based BTL (Biopharma Technology Ltd) have been freeze drying specialists since 1997. They have developed products and processes for over 1000 types of product for companies worldwide, including small drug molecules, large complex biomolecules, living organisms, tissues, foods, and more. They have also developed their own specialist analytical instruments for characterizing products for freeze drying, which are used in both laboratories.

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