Fig. 7 Contained transfer of freeze-dried powder product to the LDPE bag by means of a hopper. *LDPE* low-density polyethylene (Image courtesy: ATMI Life Sciences)

Once the drying cycle is completed, the freeze-dried material from each tray is carefully transferred to a "pre-sterile" bag by means of a sterile polypropylene/stainless steel hopper (Fig. 7). The transfer operation has to be done as quickly as possible under optimal humidity conditions due to the possible hygroscopic nature of the product.

The product in the bag is then mixed uniformly and samples withdrawn for quality control. The bags offer the flexibility for a short-term storage of bulk product for considerable periods thereby minimizing the storage space. Studies evaluating the suitability of the bag material for a particular product, storage stability studies, and stress testing, need to be performed before selecting such bags as an interim storage system for bulk freeze-dried material. Eventually, the bulk product can be stored in USP type I glass bottles for long term under suitable temperature and humidity conditions, protected from light. For safe and easy transfer of freeze-dried powders, ATMI Life Sciences developed contained powder transfer bags (Fig. 8a, b) with tri-