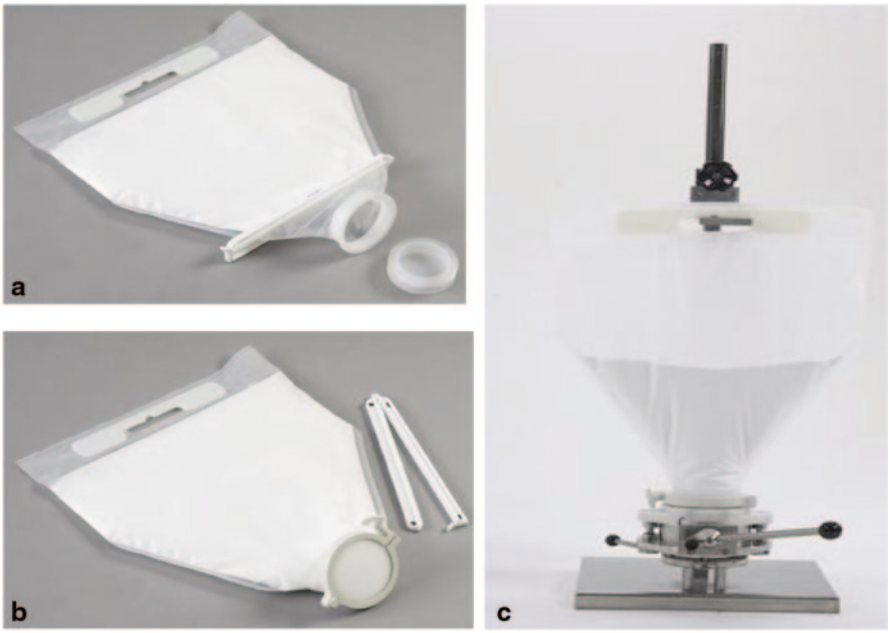

Fig. 8 **a** and **b** Newsafe contained powder transfer bags and accessories. **c** Transfer bag attached to tri-clamp connector (Image courtesy: ATMI Life Sciences)

clamp connectors (Fig. 8c) sealed onto ultra clean LDPE film. Newsafe contained powder transfer bags have antistatic properties, which prevent the buildup of electrostatic charge, thereby permitting safe and efficient handling of hygroscopic and fluffy freeze-dried powders.

Industrial scale-up of bulk freeze-drying process is optimized and performed on similar lines as that for other lyophilization-based processes. Production scale freeze-driers are typically available as single chamber or double chamber types. Cleaning and sterilization (cleaning in place, CIP/sterilization in place, SIP), which may not be essential considerations in laboratory freeze-dryers, are integral aspects of production scale freeze-dryers.

Freeze-drying validation involves validation of three aspects of the operation:

CIP Validation During the product loading and unloading steps and also during drying step, (particularly secondary drying when high vacuum is applied), it is possible that traces of product material builds up on the surface of the condenser and the surface of the drying chamber. The objective of CIP validation is to demonstrate the effectiveness of the cleaning step to remove product traces from the condenser and the drying chamber. Typically, CIP step involves a recipe with low-concentration acid wash or solvent wash (in which the product is soluble) followed by several rinses with water for injection.