

Summary - Hose Management

GMP sites should have procedures defining the use, specification, storage, handling, cleaning and maintenance of hoses used in cleaning and production of intermediates and APIs in accordance with cGMP guidelines. Flexible hoses should be adequately identified, maintained, and cleaned

When developing site hose specifications, considerations should be given to dedicated hose vs. multi-purpose hose. If conditions allow, the preference should be for dedicating hoses to a specific use to prevent risk of cross-contamination. Dedicated or not, hoses should be tracked with unique identification and cleaned appropriately. Cleaning should always be made a requirement even if hoses are dedicated.

The hose length is typically restricted by the storage and handling procedure. It should be small enough for use but not so short to prevent excessive hose bends/kinks that can lead to premature mechanical fatigue/failure. It should be long enough for use but not so long to avoid impact on the effectiveness of cleaning. Avoid using multiple hoses, which are connected in series in order to extend hose lengths.

Only gaskets that meet or exceed the requirements of the chemical process and hose assembly specifications should be used for chemical transfer hoses.

A good hose preventive maintenance program should include the following:

- An SOP that sets processing requirements to ensure hose integrity;
- A program that provides documented tracking of the age and conditions throughout the life cycle of the hose;

Hydrostatic test – performing this test will help remove leaking hose assemblies from service.

A reliable hose preventive maintenance program will promote a longer hose life cycle and establish hose replacement frequency in the most economical way.

A written procedure for tracking hose maintenance including the use of tracking software, logbook or alternatives is recommended. This will assure monitoring on the proper maintenance, inspection, and testing throughout the service life of a hose.

Use and status of cleaning of hoses need to be traceable. Essential hose label information could be a combination of the following: serial/tag number, vendor name, manufactured date, hose materials, key hose design specs, unit/location assignment, last inspection/test dates, and first use date, etc.

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