FORM KK-2: Single-Use Technical Communication Guide for Mechanical Hose Barb Connection Qualification

Introduction

The purpose of this questionnaire is to serve as a communication tool between assembly manufacturer and owner/user to detail methods by which mechanical hose barb connections are qualified by the assembly manufacturer as part of single-use products including assemblies and systems. The information provided herein by the assembly manufacturer is meant solely as a guide.

KK-2.1 General Questions

1. This questionnaire applies to the following: (*please specify pressure range or a subset of tubing sizes, types, or retention device types etc.*):

   _____

2. Is there a documented procedure for joining the hose barb, flexible tubing, and retention device? ☐ Yes or ☐ No
   a. If yes, are there controls in place to ensure repeatable connections are made such that qualification results are representative of everyday manufacturing operations? (*please specify*):

      _____

3. Is there an established testing program to substantiate performance of the mechanical connection? ☐ Yes or ☐ No
   a. If yes, what method(s) is used? (*list all standards/test methods that apply, otherwise please specify refer to SJ-2.3 Qualification*):

      _____

KK-2.2 Test Parameters

1. Test Type (*check all that apply*)
   - ☐ Burst Pressure (*indicate range, set value, ramp rate, test to failure, other*): _____
   - ☐ Tensile (Pull-off) Test
   - ☐ Leak Test:
     - ☐ Dye penetrant
     - ☐ Bubble emission (*indicate range, set value, ramp rate, test to failure, other*):

       _____
     - ☐ Pressure hold/Decay (*indicate range, set value, ramp rate, test to failure, other*):

       _____
     - ☐ Tracer gas (*please* specify gas type and indicate range, set value, ramp rate, test to failure, other):

       _____
     - ☐ Other (please specify): _____
2. Temperature of Test Fluid (*indicate unit*):
   ☐ Ambient ☐ Other (*please specify*): _____
3. Test Duration:
   - ☐ Range (*e.g., time-based pressure hold, or dependent on ramp rate; explain*):

     _____
   - ☐ Set Value: _____
   - ☐ N/A
4. Test Fluid:
   ☐ Air ☐ Water ☐ Other (*please specify*): _____
5. Sample Sterilization Method:
   - ☐ No Treatment
   - ☐ Ionizing Irradiation (*add detail, e.g., dose*): _____
   - ☐ Thermal Sterilization (*add detail, e.g., Temperature °C and duration*): _____
   - ☐ Other (*please specify*): _____

6. Additional Considerations (*please specify, e.g., accelerated aging, manipulation details, any test method that emulates e.g., pump pulsations*):
   a. External Environment (*generally mimics target application conditions*):
      ☐ Temperature *(indicate units*): _____
      ☐ Pressure (*e.g., ambient, vacuum; indicate units*): _____
      ☐ pre-conditioned (*e.g., accelerated aging, maximum irradiation dose; please describe*):
      _____
   b. Mechanical Test Constraints:
      ☐ Dynamic / Force Applied (*please describe*):
      _____
      ☐ Static / No Force Applied
      ☐ Other (*please specify*): _____

KK-2.3 Acceptance Criteria

1. Quantitative:
   ☐ Maximum Allowable Leakage Limit (*indicate units*): _____
   ☐ Mass Flowrate: _____
   ☐ Pressure Drop: _____
   ☐ Other (*please specify*): _____
   ☐ Minimum Pressure Requirement (*please describe, indicate units*): _____
   _____
   ☐ Minimum Pull-off Force (*please describe, indicate units*): _____
   _____
   ☐ Other (*please specify*): _____
   ☐ N/A
2. Qualitative (*passing observation, check all that apply*):
   ☐ No Visible Leak (*please describe; e.g., no bubbles indicating leak locations at 30psi (2 bar) underwater during manipulation*):
   _____
   ☐ All other acceptance criteria met (*please describe all other acceptance criteria; e.g., positive engagement of tubing to hose barb, appropriately applied retention device, reinforcing filament intact, etc.*):
   _____
3. Minimum Sample Size: _____
4. How is failure or performance defined in the scope of this assessment? *(please describe)*:
   _____

KK-2.4 Other Notes/Additional Considerations *(e.g., is this initial qualification or a time-based system, lot-based, or 100%?):*