

# Q1: I am a representative of

- Pharmaceutical company: 11
- Packaging component manufacturer: 2
- Testing Equipment manufacturer: 6
- Contract testing lab: 2
- Other: 2

## Q2: CCIT method

- Probabilistic: 1
- Deterministic: 9
- Both Probabilistic and Deterministic: 11
- Not familiar: 0
- N/A: 1

# Q3: New USP 1207 triggered changes

- Yes, and established new methods: 6
- Yes, will establish new methods: 2
- No: 11
- N/A: 6

# Q4: Do you perform 100% leak detection in commercial product

- Yes, on all or nearly all injectable products: 3
- Yes, on selected injectable products: 5
- No: 5
- N/A: 7

Q5: In our pharma company, CCIT methods are validated using artificial leaks down to the following size

- Less than 2um: 6
- 2-20 um: 10
- 20-50 um: 2
- More than 50 um: 1
- Our company does not use leaks: 1
- N/A: 3

# Do you use positive controls

- No: 3
- Yes, but only in selected scenarios: 7
- Yes, in all CCIT runs: 9
- N/A: 2

# What type of statistical sampling plan do you use to determine how many samples to test

- USP Sterility Testing : 4
- Acceptable Quality Limits: 5
- Other: 7
- N/A: 5