



PROCESSOR TRAINING QUESTIONNAIRE

Thank you for partnering with us to collect your in-process samples! We are excited to join your sampling team and want to start your training off right. This document has a checklist of videos and Standard Operating Procedures (SOPs) to review, as well as a questionnaire to complete to check your understanding

Who Should Use This Questionnaire?

Operators, lab technicians, or anyone responsible for sampling should use this checklist and questionnaire.

More Questions?

If there are any remaining unanswered questions, please visit our website QualiTru.com or email sales@qualitru.com.

END TO END SAMPLE DATA FOR PROCESS CONTROL



CHECKLISTS:

Video Checklist:

1. Silo Sampling: <https://youtu.be/bTq5DBF5qYk>
2. Inline/ Representative Sampling: <https://youtu.be/wbaLux5VN8Q>
3. Needle Insertion: <https://youtu.be/1xAgXPxhBXI>
4. Tri-clamp Installation: <https://youtu.be/EGGQcf7Nh1o>

SOP Checklist:

1. [QualiTru Needle-Only Sampling](#)
2. [System Diagnostic Sampling and Process Verification](#)
3. [QualiTru Line Sampling](#)
4. [Silo or Bulk Tank Peristaltic Inline Sampling](#)
5. [Sampling and Maintenance of the QualiTru Side Mount Truck Sampler](#)
6. [Proper Needle Insertion into QualiTru Septum](#)
7. [Use of the TruDraw Single Sampler](#)
8. [Proper Agitation of a Sterile Collection Bag](#)

Technical Spec Sheet

QUESTIONNAIRE

Sampler Questions:

- 1. What are the first steps to sampling?**
 - a. Wipe (or spray) the septum with a sanitizer and insert the needle.
 - b. Remove the dust cover, wipe (or spray) the septum with a sanitizer, and insert the needle.
 - c. Wash hands, put on gloves, remove the dust cover, wipe (or spray) the septum with a sanitizer, insert the needle, and cover the port with the dust cover.
- 2. When do I need to replace the septum?**
 - a. Not until you need to start the next CIP cycle.
 - b. When I'm finished sampling for the week.
 - c. After each channel is used once, or 30 days after being placed in the stainless port.
- 3. How should you insert the needle into the outside channels?**
 - a. Turn the bevel of the needle inward.
 - b. Turn the bevel of the needle outward.
 - c. The direction doesn't matter.
- 4. How should you tighten the nut?**
 - a. Hand tighten, then use a wrench to tighten another 1/4 of a turn.
 - b. Hand tighten, then use a wrench to tighten another 1/8 of a turn.
 - c. Hand tighten only.
- 5. When do you replace the septum?**
 - a. Before CIP.
 - b. After CIP.
 - c. You can replace it before or after CIP.
- 6. What is the proper method for placing a new septum into the stainless-steel port?**
 - a. Remove the dust cover and nut, put the septum in the port and replace the nut and dust cover.
 - b. Wash hands, put on gloves, remove the dust cover, wipe (or spray) the septum and stainless-steel port with a sanitizer, insert the septum, replace the nut, and cover the port with the dust cover.
 - c. It doesn't matter – just make sure it is secure
- 7. How do you remove the septum from the packaging?**
 - a. Wearing gloves grab the bottom of the septum.
 - b. Wearing gloves grab the top or cap of the septum. DO NOT touch the bottom or soft material of the septum.
 - c. Grab the top or cap of the septum. DO NOT touch the bottom or soft material of the septum.
- 8. How do I know if I used a channel?**
 - a. There is a pen mark on the used channels.
 - b. A visible puncture on the sticker reveals a used channel.
 - c. You need to keep a journal of the used channels.
- 9. How long should I sanitize the top of the septa for prior to inserting needle?**
 - a. 15-20 seconds.
 - b. 10 seconds.
 - c. 30 seconds.
- 10. Which gauge needle is NOT recommended for use on PN110011?**
 - a. 14 gauge
 - b. 21 gauge
 - c. 18 gauge
 - d. 16 gauge
- 11. When should you wash your hands?**
 - a. Only when using needles
 - b. Before removing the nut.
 - c. Before putting on gloves, before removing the nut to change the septa and when using a needle.
- 12. When are the blue dust covers used?**
 - a. It should remain in place unless sampling or replacing septum.
 - b. Just during installation.
 - c. It does not need to be used.

Quality Management Bonus Questions:

The following questions are for Quality Management to optimize your sampling program. Answers can be provided by your local service provider or on the technical spec sheets.

- 1. How do I ensure a complete sterile fluid path?**
 - a. You wash your hands and wear gloves when sampling.
 - b. The septa and collection unit both undergo sterilization and aseptic technique are used to collect the sample.
 - c. You sanitize all surfaces and wash your hands.
- 2. What is the difference between a grab and a representative sample?**
 - a. A grab sample is taking the final product, and a representative is taking many of the final product samples.
 - b. A grab sample is using a manual tool, and a representative is using an automatic system.
 - c. A grab sample is a 'snapshot' of the product quality from a silo or inline product. Representative sampling is a small amount of liquid that is pulled continuously throughout the process that represents the batch.
- 3. What is aseptic technique?**
 - a. The product is heated up to 130-150 Celsius.
 - b. Practice or procedure to prevent contamination from pathogens, and environmental cross-contamination.
 - c. The result of sanitizing products and surfaces.
- 4. How long are the septa validated (PN110011 & PN110021) to, at max temp and max pressure?**
 - a. 50 hours
 - b. 100 hours
 - c. 200 hours
- 5. What is the maximum temperature for (PN110011 & PN110021)?**
 - a. 250F & 300F or 121.1C & 148.9C
 - b. 200F & 350F or 93.3C & 176.6C
 - c. 250F & 350F or 121.1C & 176.6C
- 6. What is the maximum pressure rating for the standard septa (PN110011)?**
 - a. 75 psi or 5.17 bar
 - b. 100 psi or 6.89 bar
 - c. 150 psi or 10.34 bar