

Outsourcing Water System Validations: Key Points from a Microbiological Perspective

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Overview

- Managing the water system validation
- Characterizing your water system
- Evaluating contract services
- Selecting appropriate microbiological tests
- Communicating effectively with your team
- Reviewing and acting on the data
- Handling change control
- Moving from validation to routine testing

Managing the Validation

■ Critical items

- 💧 Assign a responsible person for the system.
 - 💧 Select an individual or small group to act as your internal “system owner” or expert for trouble-shooting.
 - 💧 Ensure that individual has the resources to keep the validation moving if questions or problems arise.
- 💧 Understand your water system.
 - 💧 Know the current water purity required for operations.
 - 💧 Ensure the system design meets your requirements.
 - 💧 Consider future water purity needs.

Managing the Validation

■ Critical items (continued)

- 💧 Identify the tests required for the water.
 - 💧 Define the chemical and microbiological testing.
 - 💧 Set up systems to handle the data generated.
- 💧 Determine if outsourcing is needed.
 - 💧 Assess internal staffing and resources.
 - 💧 Identify areas of expertise needed.
 - 💧 Calculate the laboratory capacity required.
 - 💧 Evaluate the timeline.

Managing the Validation

■ Critical items (continued)

- 💧 Set up solid communication systems.
 - 💧 Touch base regularly with all parties involved in the validation processes.
 - 💧 Provide instructions for processing OOS results, organism identifications, and other information *before* data generation begins.
- 💧 Clarify how the data will be processed.
 - 💧 Deal with data promptly to avoid problems.

Characterizing your system

- Set realistic sampling schedules.
- Select appropriate chemical and microbiological tests.
- Consider seasonal impact.
- Remember that a water system, even a validated one, is still a dynamic system.

Selecting microbiological tests

- Heterotrophic plate counts should give a representative result.
 - 💧 Match the sensitivity of the test with your expected results or known limits.
 - 💧 Low bioburden water and WFI-quality water would be tested by membrane filtration methods using larger sample volumes.
 - 💧 Purified water with higher bioburden can be tested using standard plate count methods.

Selecting microbiological tests

- If you don't know which tests are most appropriate, ask an "expert".
 - 💧 Talk with your in-house laboratory personnel that have experience in water analysis, if that resource exists.
 - 💧 Work with contract service providers (e.g., laboratories, consultants and vendors) that have experience in water validation and testing.

Outsourcing your validation

- Select the services that can provide expertise in your areas of need.
 - 💧 Do you need experts in system validation?
 - 💧 Do you need experts in water collection and testing only?
 - 💧 Do you have staff that can interpret the data, or will you need external support?
 - 💧 Do your service providers have experience?

Outsourcing your validation

- Ensure any independent consultants or providers have the knowledge and skills to perform the tasks requested.
 - 💧 Check your needs and complexity of the validation with the provider's experience.
 - 💧 Make sure you are comfortable with the level of expertise that can be provided.
 - 💧 Don't assume experts in one area (design) can take on tasks in another area (testing).

Working with contract laboratories

- Plan in advance with your laboratory.
 - 💧 Provide sample schedules, sites and other information to familiarize the laboratory with your project before submission starts.
 - 💧 Set test parameters, notification limits and contact requirements in advance.
- Work *with* your lab and listen to them.
 - 💧 An OOS water result is not always lab error!

Working with multiple providers

- Assign an individual as your contact point with providers.
 - 💧 Maintain communication (e.g., weekly for large or complex projects).
 - 💧 Share important information, schedule changes, personnel changes, and system changes.
- Welcome expert advice from providers.
 - 💧 Your success is their success.

Handling change control

- Document all your changes.
- Communicate system changes to everyone involved (including your lab).
 - 💧 Changes could impact the tests needed and how the results are interpreted.
 - 💧 Subtle microbiological impacts on the system may be picked up if the lab knows a change was made - even if result is not out of limit.

Handling change control

- Assess the effect of any change on contract services, including sampling.
 - 💧 Did you move or delete a port?
 - 💧 Will a new sanitization schedule interfere with sample collection schedules?
 - 💧 Can your contract laboratory handle "extra" sample volume resulting from a change?

Moving to routine testing

- Keep everyone informed of the validation schedule, especially the lab.
- Establish the routine monitoring frequency for the validated system.
- Evaluate the routine monitoring data in a timely manner.

Summary

- Plan the validation.
 - 💧 Know your system and your outsourcing options.
- Communicate consistently.
 - 💧 Share information; take responsibility.
- Manage the data.
 - 💧 Review and act on data quickly to keep the process moving.