



Process Liquid Preparation Services

Simplify process liquid and buffer manufacturing

Focus on producing life-changing therapeutics and vaccines

Regardless of your stage of development, your focus is on improving patients' lives. Creating better patient outcomes starts by making the right decisions that enhance your processes so you can achieve your business goals. When you partner with Thermo Fisher Scientific, your productivity is our priority.

Imagine breaking through pre-production bottlenecks

- Readily prepared chemicals reduce the necessary preparation steps
- Skilled employees concentrate on core manufacturing activities
- Workflow simplification eliminates time and resources wasted on problematic raw material sourcing

Imagine getting more out of existing investments

- Dedicated equipment primarily on core manufacturing activities
- Increased productivity within cGMP space
- Reduced need for significant capital investments

Imagine mitigating operational risks

- Ready-to-use materials alleviate environmental, health, and safety (EH&S) concerns
- Readily prepared chemicals decrease operating errors associated with mis-formulation and contamination



Thermo Scientific Process Liquid Preparation Services

simplifies pre-production workflows—for both upstream and downstream—by delivering fit-for-purpose process liquid and buffer preparation solutions that enable you to produce life-changing therapeutics and vaccines, faster.

Since your workflow is unique to you, we can help build solutions that meet your facility's specifications. Through collaboration, Process Liquid Preparation Services can simplify your process liquid and buffer manufacturing workflow to enable your resources to focus more on accelerating production.



Open architecture design

Satisfy your unique workflow specifications with flexible options for chemical grade, format, and container type



Global manufacturing network

Access a broad portfolio of chemicals and capabilities through our global manufacturing network

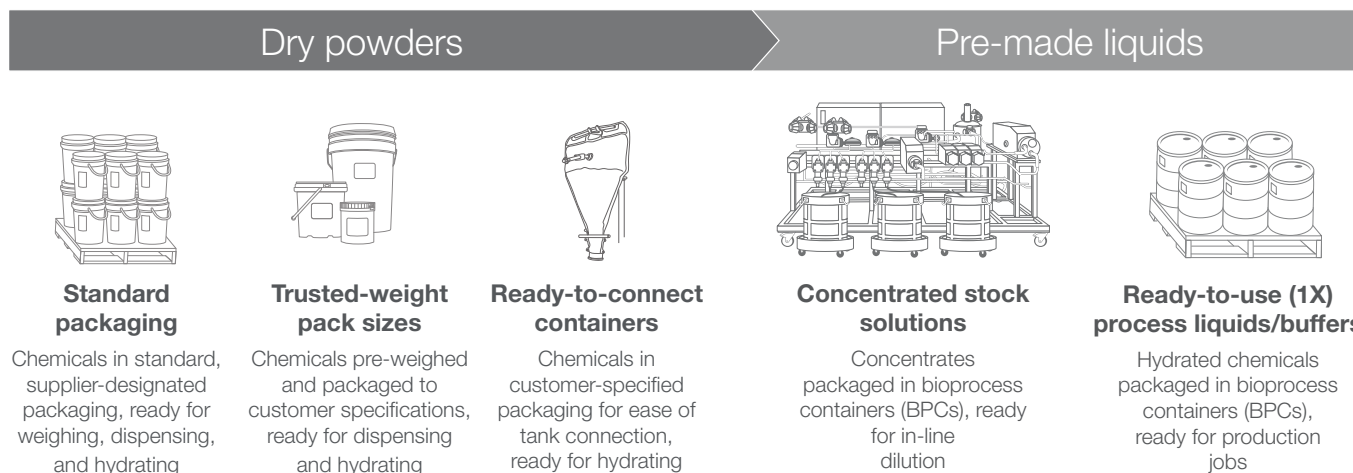


Expertise & experience

Manage your process liquid and buffer manufacturing confidently with a trusted partner

Developing a solution that meets *your* manufacturing needs

Solutions can range from ready-to-hydrate dry powder chemicals, ready-to-use process liquids, or a combination of both. Once your Lean assessment and workflow analysis are complete, chemical configurations for your facility can be better determined—one-size solutions will not fit all.



Our collaborative approach is based on a foundation of Lean principles combined with industry best practices that are applied to your process liquid and buffer preparation steps.

1 Lean assessment

Through an engagement of assessment exercises, we help uncover areas of waste.

2 Workflow analysis

We then analyze the current state process flow wastes and risks.

3 Solution design

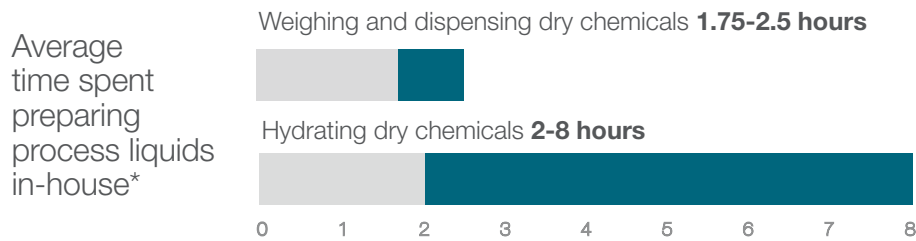
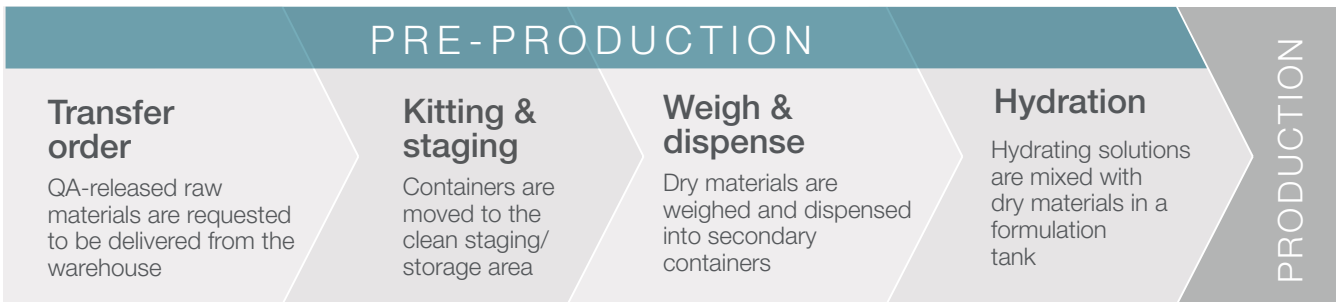
Based on your unique specifications and manufacturing needs, we collaborate to create a fit-for-purpose solution that can improve productivity, reduce total costs, and mitigate risks.

Access to our global manufacturing network provides flexible options:



In-house vs. outsourcing preparation

Process liquid and buffer manufacturing for upstream and downstream bioprocessing requires weighing, dispensing, and hydrating a wide range of chemicals to support multiple bioproduction unit operations. In-house process liquid manufacturing requires significant investments in dedicated cGMP space, equipment, and resources to execute its pre-production workflow.



| | | In-house preparation | Outsourcing preparation |
|--------------|--|----------------------|-------------------------|
| PRODUCTIVITY | Resources required | ● | ● |
| | Raw material rejection variability | ● | ● |
| INVESTMENTS | Manufacturing equipment, space, and resources | ● | ● |
| | cGMP space required | ● | ● |
| | Transportation costs | ● | ● |
| | Material waste disposal fees | ● | ● |
| | Storage space for finished process liquids and buffers | ● | ● |
| | Chemical handling, ergonomics, safety | ● | ● |
| RISKS | Mis-formulations | ● | ● |

Key: ● High ● Medium ● Low

CASE STUDY

Overcoming rapid growth challenges

Situation

A biologic manufacturer was challenged with the need to quickly expand their process liquid and buffer preparation capacity to meet the demand for a recently approved therapeutic.

They estimated the demand would exceed the capacity of the site's existing resources within two months; thereby resulting in production delays that impact the supply of finished drug product and the potential need to expand the warehouse by 10,000ft².

Lean assessment & workflow analysis

We conducted a Process Walk of the company's weigh-dispense-hydration workflow to analyze the current state of the process liquid and buffer preparation area. The team found:

- Limited availability and size of mixing equipment, which created bottlenecks in process liquid and buffer preparation area
- Inefficient sterile connection technology resulted in wasted time and effort, as well as adding additional costs for expensive equipment

Solution design

Process Liquid Preparation Services helped maximize productivity and outputs by streamlining the pre-production workflow, enabling the customer:

- Source their highest volume buffers in the bioprocess containers specified
- De-bottleneck the workflow with ready-to-use process liquids, which optimized their production schedule
- Avoid capital and operational expenditures totaling \$5.1 million in the first year

"By outsourcing common chemical solution formulations, we reduced our buffer prep load by 56% which gives us a chance to keep up with the projected growth."

Operational Readiness
Program Manager

Results

\$2.7M
CapEx avoidance
Space & equipment

\$2.4M
OpEx annual savings
Manufacturing & maintenance resources

\$330.8K
Annual savings
Raw material costs

56%
Time savings
With process improvements



How to get started

- 1 Contact your Thermo Fisher bioproduction sales representative for a workflow assessment.** Coordinate a Process Walk or Gemba Walk to identify potential areas of waste and risk within your current workflow.
- 2 Determine your workflow challenges.** Analyze current state process flow and identify future state process flows that can improve productivity, reduce total costs, and mitigate risks.
- 3 Design your solution.** Collaborate with Thermo Fisher to create a fit-for-purpose solution based on your unique specifications and needs.

Driving performance through collaboration

To meet the increasing demands for biologics worldwide, you need to expect more from partners and suppliers.

With a collaborative approach grounded in Lean principles and industry-leading best practices, we work with you to achieve optimal bioprocessing outcomes. Committed to addressing your needs, from pre-clinical trials through large-scale commercial production, we provide integrated solutions that are fit-for-purpose. If a solution does not exist, we will build it—together.

And while we are flexible in our approach, we are uncompromising in our pursuit of performance so that you can have complete confidence in the efficiency and speed of your biologics development and manufacturing processes.

That's our commitment to you.

Thermo Scientific™ Production Chemicals and Services works with biologic developers and manufacturers who want to do what matters most, innovate and produce life-changing therapeutics. With over 30 years of experience delivering production chemicals and direct material supply chain solutions, we deliver risk mitigation, improved operational efficiencies, and reduced total cost of ownership so our customers can accelerate their speed to market, speed to clinic, and improve productivity.

Find out more at: thermofisher.com/simplifybufferprep

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*Data supplied by Thermo Fisher Scientific.

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