

# Production Chemical Custom Packaging Services

Simplify process liquid and buffer manufacturing



# Process liquid and buffer manufacturing workflow

Process liquid and buffer manufacturing for upstream and downstream bioprocessing requires weighing, dispensing, and hydrating (formulation) a wide range of chemicals to support all aspects of bioproduction unit operations. In-house process liquid manufacturing requires significant investments in dedicated cGMP space, equipment, and resources to execute the workflow, including regulatory oversight and quality management.

## Weigh-Dispense-Hydration Steps

#### **Transfer Order**

QA released raw materials are requested in the Enterprise Resource Planning (ERP) system via a Transfer Order to be delivered from the warehouse to the production area.

#### **Kitting & Staging**

Raw material containers are cleaned and moved into the the clean staging/ storage area within the cGMP manufacturing space. Detailed labeling, organizing, and kitting of raw materials to support specific formulations or production runs are conducted.

#### Weigh & Dispense

Raw materials are weighed and dispensed into secondary containers. Problematic raw materials often require extra handling (de-clumping). Changeovers require extensive cleaning to prevent contamination.

### Hydration (Formulation)

Pre-weighed chemicals are mixed with a hydrating solution in a formulation tank. Tank time bottlenecks due to the demand for process liquids vs. production must be effectively managed in order to meet manufacturing demands.

#### Production Jobs

Cell Culture, Harvest, Purification, and Fill/Finish of the final drug product.







# Challenges in the workflow

## Resources focused on non-core, non-value-added activities

### **Operational Inefficiencies**

- Time and resources required to execute the workflow and for changeover
- Extra time associated with problematic materials
- Unnecessarily rejected raw materials based on operator variability
- Poor stability and/or short shelf life for mixed liquid solutions

#### **Financial Burdens**

- Cost of resources dedicated to non-core manufacturing activities
- cGMP space requirements to support weigh, dispense, and hydration (WDH) workflow vs. core manufacturing
- Ongoing CapEx and OpEx requirements for building and maintaining
  WDH capacity to support core manufacturing

#### Risks

- Environmental, Health and Safety (EH&S) related restrictions and requirements (e.g., chemical handling, ergonomics, and safety)
- Manufacturing risk due to operator errors (e.g., contamination, mis-formulation, etc.)





## Production Chemical Custom Packaging Services Solving process liquid challenges together

Production Chemical Custom Packaging Services offered by Thermo Fisher Scientific is a service designed to help biologic manufacturers accelerate innovation and improve productivity. By supplying ready-to-hydrate (dry powders) and ready-to-use (pre-made liquids) chemicals, the process liquid manufacturing workflow can be simplified through the reduction or elimination of previously resource-intensive steps.



## **Open Architecture**

Dry powder and liquids solutions customized to specifically meet your bioprocessing requirements—any chemical (specification, brand, format) and any container (specification, brand, type).



## Manufacturing Network Flexibility

Global manufacturing network with broad chemical dry powder and liquid manufacturing capabilities and capacities to efficiently address your unique needs.



## **Expertise & Experience**

Years of dry powder and liquid manufacturing experience combined with bioprocessing container expertise to simplify your workflow.

# Tailored solutions for your unique needs

Through a collaborative engagement, leveraging Lean tools, Thermo Fisher will work with you to uncover areas of waste and risk within your weigh, dispense, and hydration (formulation) workflow. This process driven approach is designed to ensure a fit-for-purpose solution.



# Chemical format flexibility

The unique challenges within your workflow will determine whether trusted-weight dry powders or pre-made liquid solutions are required. Often a hybrid approach, involving both trusted-weight dry powders and pre-made liquid solutions, results in the most effective workflow solution.

## Comparison: liquids vs. powders Outsourcing advantages over in-house manufacturing

	Pre-made liquids	Trusted-weight dry powders
Operational Efficiency Optimization		
Time and resources for weigh-dispense steps	+++	+++
Time and resources for hydration steps	+++	+
Chemical raw material rejection variability	+++	+++
Product stability and shelf life	_	N/A
Equipment cleaning between chemical components	+++	+++
Raw material transportation and inventory handling costs	_	N/A
Expenditure Avoidance		
WFI system investment and maintenance	+++	N/A
Manufacturing space and equipment for weigh-dispense	+++	+++
Manufacturing space and equipment for hydration	+++	N/A
Operating resources for non-core manufacturing activities	+++	++
Material waste and disposal fees	+++	+++
Risk Mitigation		
EH&S ergonomics and safety	++	+++
EH&S chemical handling	+++	+++
Operator errors (misformulations, contamination, etc.)	+++	++

Key: + Advantage, - Disadvantage, N/A Not Applicable

#### Maximize your workflow efficiencies with a fit-for-purpose solution.

# Bioprocessing workflow: chemicals commonly used (monoclonal antibody production)

	Æ	5		
	Mixing, cell culture, and fermentation	Harvest and collection		
	Media Hydration and Supplementation	Cell Handing & Harvest	Filtration	Capture Chromatography
			Proces	s liquids and buffers are
<b>Chemicals Used</b>	Amino Acids, Biological Buffers, Buffering Salts, Cell Culture Media & Supplements, Carbohydrates, Glucose Solutions, Minerals & Vitamins, WFI	Biological Buffers, Buffering Salts, Denaturants, Detergents, WFI	Biological Buffers, Buffering Salts, WFI	Acid/ Base Solutions, Biological Buffers, Buffering Salts, WFI
<b>Process Liquid Examples</b>	Cell line specific pre-mixed media (e.g., CHO, Insect, Bacterial, etc.), Cell line specific feed solutions (e.g., CHO, Insect, Hybridoma, etc.), Glucose Solutions, Sodium Bicarbonate, DMSO (for cell banks)	Tris HCl 20-50 mM, Triton X-100, Tween, 5M Sodium Chloride, Phosphate Buffered Saline (PBS)	Buffers (e.g., Tris HCI 20-50 mM), Phosphate Buffered Saline (PBS)	Custom chromatography- running buffers and elution buffers, including components such as Tris, Tris HCl, HEPES, etc.
				Column Cleaning,
				Denaturants, Ethanol, Sodium

System Cleaning

Detergents: Alkaline, Acidic, Neutral; Disinfectants and

## Questions to consider

- How are bioproduction manufacturing demands impacting your weigh, dispense, and hydration (formulation) workflow?
- What chemicals or solutions are presenting the biggest challenges to your workflow?
- What strategies are you pursing to improve and streamline your process liquid manufacturing processes?

	Purification			Bulk storage and final fill			
Viral Inactivation	Polish Chromatography	Viral Filtration	UF / DF	Fill / Finish			
used across the entire workflow.							
Solvents, Acids, Detergents, Surfactants	Acid/ Base Solutions, Biological Buffers, Buffering Salts, WFI	Acid/ Base Solutions, Biological Buffers, Buffering Salts, WFI	Acid/ Base Solutions, Biological Buffers, Buffering Salts, WFI	Amino Acids <i>(some),</i> Biological Buffers, Buffering Salts, Carbohydrates, WFI			
Triton X-100, Hydrochloric Acid Solutions, Acetic Acid Solutions	Custom chromatography- running buffers and elution buffers, including components such as Tris, Tris HCI, HEPES, etc.	Buffers (e.g., Tris HCl 20-50 mM), 5M Sodium Chloride	Buffers (e.g., Tris HCl 20-50 mM), 5M Sodium Chloride	5M Sodium Chloride, Citric Acid Solutions, Custom Tris Buffer Formulations, Concentrated Sugar Solutions (e.g., mannitol, sorbitol, trehalose), Amino Acid Solutions (e.g., methionine, arginine, lysine, phenylalanine), Polysorbate 80, Polysorbate 20			
Regeneration, Storage	9						
Hydroxide, and Sodium Chloride Solutions							
and Sanitization							
Sporicides; Water, Ethanol, and Sodium Hydroxide Solutions							

## Collaborate with us to design a solution

Engage with your Thermo Fisher bioproduction sales representative to conduct a site assessment consisting of a Process Walk or Gemba Walk to help identify potential areas of waste or risk within your current workflow. Together, we will identify and design solutions that meet your workflow needs.

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#### **CHEMICALS**

Any specification Any brand Any format

**CONTAINER** 





Any weight Any formulation



**YOUR SOLUTION** 

# Eliminate non-core, non-value-added manufacturing activities

When you outsource all – or a portion – of your weigh, dispense, and hydration process to Thermo Fisher through our Production Chemical Custom Packaging Services, you can simplify your process liquid manufacturing and make core manufacturing a priority.

Increase Productivity



Reduce Costs



Minimize Risks



## How to get started

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.

H Determine your workflow challenges. Analyze current state process flow waste and risk and identify future state process flows that can improve productivity, reduce total cost, and/or mitigate risks.

> Design your solution. Collaborate with Thermo Fisher to create a custom – fit for purpose – solution based on your unique specifications and needs.

**USA** U.S. Customer Service: +919-598-1986

Europe EU Customer Service: +00353 1 899 1880

Find out more at thermofisher.com/processliquidsimplification

Service and product availability may vary by country and are subject to varying regulatory requirements. Please contact your local sales representative for availability.

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