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From Bench to GMP – Organizing and Scaling Your Buffer Supply

By PAN-Celltech R&D · Rev 1.0 · 4 Aug 2026 · a practical guide for monoclonal antibody developers

KEY TAKEAWAYS

- Almost every antibody programme starts by making its own buffers - the right call at the bench, but it quietly stops working at GMP scale.
- The real cost of an in-house buffer is not materials and labour - it is five hidden burdens: QC and release on every batch, documentation (the batch record is part of the product), batch-to-batch consistency, supply security resting on one or two people, and the scientific capacity it consumes.
- The question stops being "can the team make the buffer" and becomes "should it" - buying from a qualified GMP partner turns a fixed internal burden into a variable, documented, de-risked supply.
- The buffers are unremarkable (Tris-HCl, NaCl, MgCl2, EDTA stocks, Water for Injection) - the difficulty is making them consistently, documentably and at scale.
- What to demand from a partner so the switch reduces risk: matched RUO -> GMP grades, a Certificate of Analysis on every lot, documentation that carries your filing, DMF support where needed, and an audit-ready quality system.

A practical guide for monoclonal antibody developers approaching the make-versus-buy decision for process buffers and reagents.

In brief. *Almost every antibody programme begins by preparing its own buffers at the bench. As volumes rise and the programme moves toward GMP, in-house preparation quietly becomes a constraint on quality, capacity, and compliance rather than a convenience. This paper sets out how to recognise that inflection*

> *point, how to organise the transition to an external GMP supplier, and what to demand from a partner so the change reduces risk instead of adding it.*

1. Why developers start in-house - and why it stops working

In the early life of a monoclonal antibody programme, making your own buffers is the obvious choice. The volumes are small, the formulations are standard, and a competent process-development team can weigh out a Tris-HCl buffer, a sodium chloride elution solution or an EDTA stock between experiments without a second thought. In-house preparation feels free, fast, and fully under the team's control. For bench-scale screening and early process development, it usually is the right answer.

The difficulty is that the conditions which made in-house preparation sensible do not survive contact with scale and with GMP. Three things change at once. Volumes grow from litres to tens and hundreds of litres. The regulatory bar rises sharply as the programme approaches the clinic, where buffers used in manufacturing become part of a controlled, documented, auditable process. And the team's time becomes the scarcest resource in the company, far too valuable to spend weighing salts and filtering water.

What had been a quiet background task becomes a recurring source of cost, risk, and distraction. The buffers themselves have not changed - a 2 M Tris-HCl stock at pH 8 is still a 2 M Tris-HCl stock - but everything around them has. The question is no longer whether the team can make the buffer. It is whether the team should.

> *The buffers in question are unremarkable; that is precisely the point. Concentrated Tris-HCl and sodium chloride stocks for chromatography wash and elution, magnesium chloride and EDTA for conditioning and chelation, and Water for Injection across pack sizes from bottles to bulk bags for dilution and final formulation. None is difficult to make. All of them, at GMP scale, are difficult to make* ***consistently, documentably, and without consuming scientific capacity.***

2. The hidden cost of staying in-house at GMP scale

The visible cost of an in-house buffer - raw materials and a few hours of labour - is only a fraction of the real cost. The burden that actually accumulates sits in five places, none of which appears on a per-litre price comparison.

Quality control and release become a project of their own

A buffer used in a GMP process must be tested, specified, and released against defined acceptance criteria. pH, conductivity, concentration, bioburden, endotoxin and appearance all need methods, instruments, qualified analysts, and a release decision for every batch. The analytical load grows with the number of formulations and the number of batches, and it competes directly with product testing for the same QC capacity.

Documentation is the deliverable, not the buffer

Under GMP, the batch record, certificate of analysis, raw-material traceability and change history are not paperwork around the product - they are part of the product. An in-house buffer programme means owning all of it: writing and maintaining specifications, qualifying suppliers of the underlying chemicals, recording every preparation, and being able to reconstruct the full history of any batch years later during an inspection. Few early-stage teams have the documentation infrastructure this implies.

Batch-to-batch consistency is harder than it looks

Manual preparation introduces variation - in weighing, in water quality, in pH adjustment, in filtration - that is tolerable in research but corrosive in a validated process. Inconsistent buffers translate into variable chromatography performance, shifting yields, and investigations that consume far more time than the buffer ever saved.

Supply security rests on one or two people

In-house supply is only as resilient as the individuals who run it. A key analyst leaving, an instrument failing, or a water system going down can halt buffer preparation and, with it, manufacturing. There is rarely a qualified second source, because the team is the source.

The real cost is the opportunity cost

The scientists capable of preparing GMP buffers are the same scientists who should be developing the process, characterising the product, and preparing the regulatory dossier. Every hour spent on buffer logistics is an hour not spent on the work that only they can do. For a company racing toward a first clinical filing, that trade is rarely worth making.

> ***A useful test:*** *if your most experienced process scientists are spending measurable time each week on buffer preparation, QC, and documentation rather than on the antibody itself, the in-house model is already costing more than it appears to.*

3. Recognising the make-versus-buy inflection point

The shift from in-house to outsourced buffer supply is not a single decision taken on one day. It is an inflection that most programmes reach at a recognisable stage - typically as they move from process development into clinical manufacturing, when both volume and regulatory expectation step up together. The signals below tend to appear in combination. Any one of them is worth noting; several together mean the inflection has arrived.

Signal	What it indicates
Buffer volumes have moved from litres to tens or hundreds of litres	Manual preparation no longer scales; the time and consistency cost is climbing steeply.
The programme is approaching IND / IMPD filing or first GMP manufacturing	Buffers now sit inside a regulated, documented, auditable process and must meet a far higher quality and traceability standard.
QC capacity is increasingly consumed by buffer release	Internal analytical resource is being diverted from product testing to raw-material support.

Signal	What it indicates
testing	
Investigations or yield variability are being traced back to buffer preparation	Manual variation is now affecting process performance - a quality, not just a logistics, problem.
Hiring is focused on MSAT, process development, and QA roles	The organisation is professionalising toward manufacturing; the make-versus-buy question is on the table whether or not it has been named.
A new GMP facility or suite is being built or qualified	A natural moment to design buffer supply as an external, qualified input rather than recreate in-house preparation at larger scale.

A short readiness check

If you can answer yes to most of the following, outsourcing GMP buffer supply will almost certainly reduce your total cost and risk:

- Are buffers consumed in volumes that make manual preparation a recurring scheduling problem?
- Will the buffers be used in a GMP process within the next 12-18 months?
- Is buffer QC and documentation competing with product-related work for the same people?
- Would the loss of one or two staff disrupt your buffer supply?
- Would your process scientists add more value working on the antibody than on reagent logistics?

4. What GMP-ready buffer supply actually requires

Outsourcing buffer supply only reduces risk if the external buffer arrives with everything a GMP process demands. A cheaper buffer with thin documentation is not a saving; it is a liability transferred downstream to your QA team. When evaluating an external supply, the following elements are what separate a genuine GMP-ready product from a research-grade reagent in a larger bottle.

> ***A worked example - the water you take for granted.*** *Water for Injection is the most-used item in the whole process: it is the base of nearly every buffer and the vehicle for the final formulation, so its quality cascades into everything downstream. It is also the input teams most underestimate - "just water," until you need it RNase-free, at an ultra-low endotoxin level, and backed by a qualified DMF, batch after batch. If even the most ordinary component in your process must meet that standard, it sets the bar for the whole supply - and that combination of purity and documentation is precisely what is hard to guarantee in-house and straightforward to source from a qualified partner.*

- **Certificate of Analysis and Certificate of Conformity** for every batch, against a defined, agreed specification - so your release decision rests on the supplier's tested data, not your own re-testing.
- **Regulatory support via a Drug Master File (DMF)** or equivalent documentation, allowing the supplier's quality and manufacturing information to support your own filings without exposing proprietary detail in both directions.
- **Stability data** establishing a justified shelf life under defined storage conditions, so the buffer's quality is assured across its in-use period rather than assumed.
- **Full raw-material traceability** from the underlying chemicals through to the finished solution, with controlled change notification when anything in the chain moves.
- **A clear qualification and audit path** - including the ability to audit the supplier efficiently - because a buffer you cannot qualify is a buffer you cannot use.
- **Scalable, GMP-grade pack sizes** from development volumes through to production, so the same qualified product follows the programme as it grows rather than forcing a re-qualification at each scale-up.

> ***The documentation is the product.*** *For a lean clinical-stage team, the decisive advantage of a good supplier is not the litre of buffer - it is the CoA, the DMF support, the stability file and the audit access that arrive with it, removing work the team has no capacity to do.*

5. Organising the transition from bench to first production

Handled well, the move to external supply is a controlled, phased qualification - not a leap of faith. The following sequence keeps risk low and avoids the two failure modes that catch teams out: switching too late, under manufacturing pressure with no time to qualify; and switching carelessly, without the documentation to defend the change later.

Phase 1 - Map and specify

List every buffer and reagent in the process, with its formulation, the volume consumed, the process step it serves, and the quality attributes that matter. This inventory is the foundation of every later step and often reveals consolidation opportunities - several near-identical stocks that can be standardised.

Phase 2 - Find a supplier with off-the-shelf GMP products

Approach potential suppliers well before the manufacturing deadline, while there is still room to evaluate calmly. Give preference to a partner that already offers off-the-shelf GMP catalogue products - a standard buffer, DPBS or Water for Injection, for example. A ready, qualified product lets you test the supplier and their documentation quickly and at low risk before committing to anything customised. Assess the product together with its documentation package - the CoA, specification, and stability information - not the liquid alone.

Phase 3 - Qualify the supplier and the product

Run supplier qualification in parallel with product qualification. Ask the supplier upfront for their supplier qualification guide - a good partner will have one ready - as it sets out the certificates, regulatory documentation, and audit options available and lets a lean QA team plan the qualification efficiently. Audit the supplier - increasingly this can be done by electronic or

video audit rather than a full on-site visit - and confirm the buffer meets specification across the relevant pack sizes. Document the qualification so it stands up to later inspection.

Phase 4 - Transition and standardise

Move the qualified buffers into routine supply, retiring in-house preparation step by step rather than all at once. Where appropriate, keep a defined contingency. Standardise on the qualified pack sizes that match each scale, from development through production.

Phase 5 - Grow with the programme

As volumes increase, the same qualified product and supplier should scale with you seamlessly - from 500 ml and 1000 ml bottles, through 5 to 20 litre canisters, to bag sizes of 2, 10, 20, 50, 100, 500 and 1000 litres - all under the same documentation framework, so growth does not mean re-qualifying the supply chain from scratch at every step.

> ***Timing is the single biggest controllable risk.*** *Teams that begin qualification early treat the switch as routine. Teams that wait until in-house supply is already failing inherit all the cost of the change with none of the time to manage it.*

6. Choosing a supply partner for a lean team

Not every buffer supplier is built for an early-stage antibody company. The large catalogue houses are optimised for standard products at volume and can be reluctant to engage on small, customised GMP batches or to make qualification easy for a small QA function. The criteria that matter most at this stage are therefore as much about fit and friction as about the product itself.

Criterion	Why it matters at the make-versus-buy stage
Customisation of your own formulation	The single most valuable capability: a partner able to take your self-formulated buffer and reproduce it as a customised GMP production - not only sell standard catalogue lots. This lets you outsource your whole

Criterion	Why it matters at the make-versus-buy stage
	buffer portfolio, including your bespoke formulations, from one qualified source.
Low qualification friction	With limited QA capacity, the documentation and audit experience is decisive. DMF support, stability data, and efficient electronic or video audits let a small team qualify quickly.
Scalability of pack sizes	A partner who supplies the same qualified product from development volumes to production scale lets you grow without re-qualifying the supply chain at each step.
Supply security	Reliable delivery and short lead times for the products you depend on remove the single-point-of-failure risk that in-house preparation carries.
Experience and track record	A supplier with a long history in bioprocess reagents brings settled quality systems and the judgement that only comes from decades of manufacturing - reassurance a first-time outsourcer needs.

> ***Strong recommendation.*** *Above every other criterion, prioritise a partner with the ability to take your own self-formulated buffer and produce it under a customised GMP production process. Off-the-shelf standards such as DPBS get you started and qualified quickly; the ability to transfer your specific formulations into qualified, documented production is what lets you hand over the entire buffer portfolio - generic and bespoke alike - to a single source you have already qualified.*

7. The PAN-Celltech approach

PAN-Celltech has spent close to four decades manufacturing cell culture media, reagents and buffers for bioprocessing. That experience is built directly around the make-versus-buy moment described in this paper: helping antibody developers move from in-house preparation to a qualified external supply without inheriting new risk.

- **Your own buffer, produced under GMP.** Beyond off-the-shelf standards, PAN-Celltech can take your self-formulated buffer and reproduce it as a customised GMP production. Moving a formulation into GMP production calls for a higher level of professionalism, and the regulatory workload rises sharply at this point - so we provide the full package it demands, from the master batch record through the supporting process documentation, letting your bespoke formulations come from the same qualified source as the standard items.
- **Off-the-shelf GMP catalogue products.** Standard buffers, DPBS, Tris-HCl and sodium chloride stocks, magnesium chloride, EDTA and Water for Injection - ready, qualified products that let you start fast and at low risk. Our WFI, for example, is RNase-free, sterile (0.2 µm filtered) and at an ultra-low endotoxin level, supplied with a TSE/BSE-free declaration and a qualified DMF, in single-use, gamma-irradiated packaging.
- **A complete documentation package.** Certificate of Analysis and Conformity per batch, DMF-supported regulatory information, stability data, and full traceability - the work your QA team would otherwise have to do.
- **Low-friction qualification.** Electronic and video audits make supplier qualification fast and practical for lean teams, without the burden of a full on-site programme before you can begin.
- **Pack sizes that grow with you, seamlessly.** From 500 ml and 1000 ml bottles, through 5 to 20 litre canisters, to bag sizes of 2, 10, 20, 50, 100, 500 and 1000 litres - the same qualified product scales with the programme, with no re-qualification at every step.
- **Higher security of supply.** Reliable delivery and short lead times on highlighted, available products, backed by settled quality systems and 38 years of bioprocess manufacturing experience.

> ***The result:*** *your scientists return to the antibody, your QA team gains a qualified, documented supply it did not have to build, and your buffer supply scales with the programme instead of constraining it.*

8. Conclusion

Making your own buffers is the right decision early and the wrong one eventually. The point at which it changes is predictable: it arrives as volumes climb and as the programme moves toward GMP, when the cost of preparation, QC, documentation, and lost scientific time quietly overtakes the cost of a qualified external supply. Recognising that moment, and planning the transition as a controlled qualification rather than a last-minute scramble, turns a potential bottleneck into a strengthening of the whole process.

The right partner does not simply sell you a buffer. They hand your lean team the documentation, the regulatory support, and the supply security it lacks the capacity to build alone - and they grow with you as the programme scales. That is the difference between outsourcing as a cost and outsourcing as a strategic advantage.

Talk to us about your buffer supply

If your antibody programme is approaching the make-versus-buy inflection point, PAN-Celltech can help you map your buffer requirements and qualify a customised GMP supply - starting with an off-the-shelf standard product. Contact us at **info@pan-celltech.com** or visit **www.pan-celltech.com**.

Frequently asked questions

When should we stop making buffers in-house?

At the inflection point where volumes grow from litres to tens and hundreds of litres and the programme approaches the clinic - where buffers become part of a controlled, documented, auditable GMP process. That is when the QC, documentation and capacity burden of in-house prep outweighs its convenience.

What are the hidden costs of in-house buffer prep at GMP scale?

Five, none of which appears on a per-litre price: (1) QC and release testing on every batch, (2) documentation - the batch record, CoA and traceability are part of the product, (3) batch-to-batch consistency, (4) supply security resting on

one or two people, and (5) the scientific capacity consumed weighing salts instead of advancing the molecule.

Is not buying buffers more expensive per litre?

The per-litre price is only a fraction of the real cost. Buying from a qualified partner converts a fixed internal burden - QC, documentation, capacity - into a variable, documented, de-risked supply, and frees your QA and your scientists for the work only they can do.

What should we demand from a GMP buffer supplier?

Matched RUO -> GMP grades so you qualify once; a Certificate of Analysis on every lot; documentation that carries your filing rather than burdening it; DMF support where a product genuinely needs it; and a demonstrated, audit-ready quality system.

Which buffers does this apply to?

The standard chromatography and formulation stocks - concentrated Tris-HCl and sodium chloride for wash and elution, magnesium chloride and EDTA for conditioning and chelation, and Water for Injection across pack sizes from bottles to bulk bags.

Can PAN also make custom buffers?

Yes - a standard product can become a fully customized GMP formulation to your own recipe, manufactured by PAN-Celltech, without switching supplier or restarting qualification.

Move your buffer supply from bench to GMP

Ask for a qualified GMP buffer, a Certificate of Analysis, or a custom GMP formulation - and take the make-or-buy burden off your team.

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Manufactured to GMP in an EU Annex 1 facility within an ISO 9001 quality system. A Certificate of Analysis is released on every lot; DMF support is available where a product needs it.