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# CASE STUDY

**CASE STUDY · MAB**

## FROM IN-HOUSE BUFFER PREP TO A QUALIFIED GMP SUPPLY PARTNER

Prepared by **PAN-Biotech**

Author:
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6 Aug 2026 · Anonymised customer story

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# FROM IN-HOUSE BUFFER PREP TO A QUALIFIED GMP SUPPLY PARTNER

**How a growing monoclonal-antibody developer moved from preparing its own process buffers to a qualified external GMP supply partner – starting with a cell-dissociation reagent and GMP-grade DPBS, and actively expanding the scope across its buffer and Water for Injection supply under one audited source.**

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## Results at a glance

- **Audit passed** · on-site audit qualified PAN-CellTech as a GMP supplier
- **GMP DPBS in routine supply** · DPBS CT-36500, scaled to larger volumes
- **Scope actively expanding** · across process buffers and Water for Injection
- **One qualified source** · in-house prep to a single audited GMP partner

This story is published with the customer **anonymised**. It describes a real, active PAN-CellTech engagement with a growing monoclonal-antibody developer; the customer's name is withheld.

THE CONTEXT

## A growing antibody programme

Like most antibody developers, the customer began by preparing its own process buffers. At bench scale that was the obvious choice: the volumes were small, the formulations standard, and in-house preparation felt fast and fully under the team's control.

As the programme grew, that calculus changed. Buffer volumes climbed from litres into far larger quantities, and as the process moved toward GMP those buffers became part of a controlled, documented and auditable manufacturing chain.

THE CHALLENGE

## When in-house prep becomes a constraint

In-house preparation quietly turned from a convenience into a constraint. It competed for QC capacity, demanded documentation the team had limited bandwidth to maintain, and rested on the availability of one or two people. The developer needed a qualified external partner who could carry that burden without adding risk – and do it in a way that scaled with the programme rather than forcing a re-qualification at every step.

THE SOLUTION

## A step-by-step qualification, not a leap

The relationship grew in exactly the way a careful make-versus-buy transition should:

- **An established working relationship.** The customer was already using an Accumax cell-dissociation reagent in its upstream workflow – a known, trusted product that opened the door to a wider conversation about GMP supply.
- **A low-risk, off-the-shelf entry point.** The developer moved first to GMP-grade DPBS (CT-36500, DMF Type IV MF044371), a ready catalogue product, scaling up to larger quantities.
- **Supplier qualification by audit.** The customer's QA team audited PAN-CellTech's manufacturing and quality systems first-hand and confirmed PAN-CellTech as a qualified GMP supplier.
- **Actively expanding the project scope.** With the supplier qualified, PAN-CellTech and the developer are now **actively working to expand the project scope** beyond DPBS across the core process buffers and Water for Injection – bringing reagents, buffers and water under one audited partner.

THE SCOPE

## The scope now being brought in

| CATEGORY | EXAMPLES | ROLE IN THE PROCESS |
|---|---|---|
| Concentrated buffer stocks | Tris-HCl, sodium chloride solutions | Chromatography wash and elution |
| Conditioning & chelation reagents | Magnesium chloride, EDTA | Process conditioning and chelation |
| Water for Injection | Various pack sizes (WFI Beyond on request) | Buffer preparation and final formulation |
| Already in supply | Accumax cell-dissociation reagent, GMP-grade DPBS (CT-36500) | Upstream dissociation; wash / conditioning |

Pack sizes scale with the programme – from 500 ml and 1000 ml bottles to bulk bags – so the developer can grow without re-qualifying its supply chain at every step.

THE RESULT

## One qualified, documented, scalable source

Consolidating with PAN-CellTech lets the developer convert a growing internal burden into a qualified, documented and scalable external supply. The relationship already delivers on this through cell-culture reagents and GMP DPBS; as the project scope actively expands across the buffer and water package, the same advantages carry across the rest of the process:

- **One qualified source.** Bringing the cell-dissociation reagent, GMP DPBS, process buffers and Water for Injection under one audited supplier simplifies qualification and procurement.
- **Documentation the team does not have to build.** Each product comes with its quality documentation, keeping QA capacity focused on the antibody.
- **Ready for a rising regulatory workload.** As the process matures, PAN-CellTech can take self-formulated buffers into customised GMP production with the full package.
- **A supply that scales with the programme.** Pack sizes from bottles to bulk bags let the developer grow without re-qualifying its supply chain at every step.

FAQ 1

## When should a monoclonal antibody developer stop preparing process buffers in-house?

When volumes climb from litres into far larger quantities and the process moves toward GMP, in-house preparation turns from a convenience into a constraint – competing for QC capacity, demanding documentation, and resting on one or two people. That is the point to qualify an external GMP supplier.

FAQ 2

## How does a company qualify PAN-CellTech as a GMP buffer supplier?

By audit – on-site, virtual or paper (documentation) audit, supported by PAN-CellTech's Supplier Qualification Guide. In this case the customer's QA team audited the manufacturing and quality systems on-site, which confirmed PAN-CellTech as a qualified GMP supplier.

FAQ 3

## What is a low-risk way to start moving buffer supply to an external partner?

Start with a qualified, off-the-shelf catalogue item – here GMP-grade DPBS (CT-36500, DMF Type IV MF044371) – to test both the product and the documentation before committing to anything customised, then expand the scope toward a single qualified source.

FAQ 4

## Which buffers and reagents can be consolidated under one GMP supplier?

Concentrated stocks such as Tris-HCl and sodium chloride, conditioning and chelation reagents such as magnesium chloride and EDTA, and Water for Injection across pack sizes – alongside cell-culture reagents and GMP DPBS already in supply.

### Facing the same decision?

If your antibody programme is outgrowing in-house buffer preparation, PAN-CellTech can help you start with a qualified off-the-shelf product and grow into a fully customised GMP supply.

**Start a Custom & GMP Project Enquiry:** pan-biotech.com/custom-gmp-project-enquiry/ · **info@pan-celltech.com**

PAN-Biotech GmbH · Manufacturer of record for GMP supply: PAN-CellTech GmbH (EU Annex 1) · Customer anonymised. GMP-compliant, audit-proven manufacture; EU Annex 1 is a capability, not a certification.