

IN-DEPTH · INDUSTRY EDITION A02· MONOCLONAL ANTIBODIES · FOR  
PHARMA, BIOTECH & CDMO

# Standardizing and De-risking the Monoclonal Antibody Program

**One partner from research to GMP – the antibody program as thirteen process bundles: five upstream (research-grade), seven downstream (ready-to-use GMP) and one QC & stability service, from cell bank to drug substance**

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**In brief.** The monoclonal antibody is the most mature modality in modern medicine – and the one whose process is best understood, which is exactly why it rewards **standardisation**. A typical mAb program runs to **thirteen steps**, and PAN delivers all thirteen as **process bundles: five upstream (USP)** bundles, from cell bank to clarified harvest; **seven downstream (DSP)** GMP bundles, from Protein A capture to a formulated drug substance; and **one QC & stability service bundle** – five plus seven plus one. This briefing shows how PAN-Biotech and its GMP arm PAN-Celltech cover the whole journey with **one coherent toolkit** – media, supplements, buffers and stock solutions – built so that a **handful of universal stock solutions recur step after step** (WFI-quality water in twelve steps, DPBS in seven, NaCl 5 M and phosphate in five, Tris in four). The offering follows a **research-to-GMP continuum**: the five upstream (USP) bundles (S1-S5) are **research-grade today** across the three platforms – **CHO, HEK293 and hybridoma** – the same product qualified to GMP on request with no reformulation; and the seven downstream (S6-S12) ship as **ready-to-use GMP bundles**, one labelled box per step, manufactured to GMP in an **EU Annex 1 facility and held on stock**. The key water and wash utilities – **DPBS and WFI Beyond** – are backed by filed **FDA Type IV (excipient) Drug Master Files**, and every downstream buffer is available **beyond-compendial** with WFI Beyond on request.

**HOW TO READ THIS** · a shared story, then a section written for your role – jump to yours:  
**Developers & Researchers** · **Production & Manufacturing** · **Procurement** ·  
**Quality Assurance** · **Regulatory Affairs** · **Decision-makers, BD & Project leads** ·  
**CDMOs & CMOs**

## SECTION 1

### Where the cost and the risk sit in a mAb program

Antibody manufacturing is a solved problem in outline and a demanding one in detail. The upstream titre battle has largely been won – modern CHO fed-batch routinely reaches multi-gram-per-litre – which has **moved the cost and the risk downstream**, into the purification and formulation train that turns a clarified harvest into an injectable drug substance. By widely cited estimates, **roughly half of a mAb's production cost sits in the downstream**, led by the Protein A capture resin and the buffer volumes a chromatography train consumes.

And the risk concentrates there too. A low-pH viral-inactivation hold is a **mandatory ICH Q5A safety step**, not an optional one; a late polishing or formulation error destroys a batch that already carries almost its entire value; and the finished antibody must stay stable – free of aggregation and oxidation – through months in a vial. The prize, then, is not only a higher titre but a **faster, simpler, better-documented process** that de-risks the expensive end. That is what a single qualified toolkit is for.

**Dozens of different buffers, built from a small set of recurring stock solutions. The complexity is in the combinations, not the ingredients.**

## SECTION 2

### The antibody journey in thirteen steps

A typical mAb process can be written as thirteen steps – **five upstream (USP)**, taking cells from the bank to a clarified harvest; **seven downstream (DSP)**, taking that harvest to a formulated drug substance; and a thirteenth **QC & stability** step. PAN supplies the process liquids for **every one of them**, and delivers all thirteen as ready-to-use process bundles.

| Step                                                   | Stage                      | What happens                                                                 |
|--------------------------------------------------------|----------------------------|------------------------------------------------------------------------------|
| <b>UPSTREAM (USP) - CELL BANK TO CLARIFIED HARVEST</b> |                            |                                                                              |
| <b>S1</b>                                              | Cell bank & thaw           | Thaw of MCB/WCB, DMSO removal, viability check.                              |
| <b>S2</b>                                              | Screening & selection      | Clonal expansion; hybridoma selection (HAT/HT); early seed train.            |
| <b>S3</b>                                              | Expansion & seed train     | Step-wise expansion to bioreactor inoculum (CHO / HEK293 / hybridoma).       |
| <b>S4</b>                                              | Bioreactor production      | Fed-batch / perfusion, 1-1000 L; the core titre phase.                       |
| <b>S5</b>                                              | Harvest & clarification    | Centrifugation → depth filtration → 0.2 µm; clarified harvest fluid.         |
| <b>DOWNSTREAM (DSP) - CAPTURE TO DRUG SUBSTANCE</b>    |                            |                                                                              |
| <b>S6</b>                                              | Protein A capture          | Affinity capture of IgG; >99% removal of host-cell protein, DNA, media.      |
| <b>S7</b>                                              | Viral inactivation         | Low-pH hold (pH 3.5-4.0, 30-60 min) - mandatory ICH Q5A step.                |
| <b>S8</b>                                              | Ion exchange (CEX + AEX)   | Polishing: aggregate, HCP, DNA, endotoxin and viral clearance.               |
| <b>S9</b>                                              | HIC (optional)             | Aggregate removal; bispecific mispair separation.                            |
| <b>S10</b>                                             | SEC polishing              | Aggregate and fragment removal by size.                                      |
| <b>S11</b>                                             | UF/DF                      | Concentration (1-50 mg/mL) and buffer exchange into the formulation buffer.  |
| <b>S12</b>                                             | Drug-substance formulation | Final concentration and excipients; 0.2 µm fill of final bulk.               |
| <b>S13</b>                                             | QC & stability             | Endotoxin, sterility, pH, osmolality, SEC-HPLC, identity; ICH Q1A stability. |

### SECTION 3

## One toolkit – a handful of stock solutions

Look closely at those thirteen steps and the dozens of working buffers they need, and a pattern appears: they are built from a **small set of concentrated stock solutions that recur again and again**. Qualify a handful of stocks once, and they serve step after step – so a team carries **fewer SKUs to qualify** while keeping full flexibility to prepare its own working buffers.

The recurrence is striking across a standard mAb train:

- **WFI-quality water** – used in **twelve** of the production steps (the base of every buffer and the final formulation).
- **DPBS (w/o Ca & Mg)** – **seven** steps, from cell washing to a ready-to-use SEC running buffer.
- **NaCl 5 M** and **phosphate** – **five** steps each; **Tris 1 M** – **four**; **acetate** and **histidine** – **three** each; **citrate** – **two**.

Two economies fall out of this. **Citrate 100 mM pH 3.0** is dual-use – the Protein A elution buffer *and* the low-pH viral-inactivation buffer – and **histidine 100 mM** is one unified SKU across SEC, UF/DF and final formulation, the most widely used mAb formulation buffer. Fewer qualified materials, doing more of the work.

#### SECTION 4

### The Antibody Process Bundle – one box per step

PAN delivers the whole program the way the process runs it – as **step-specific process bundles, one box per step, thirteen in all: five upstream (USP) bundles, seven downstream (DSP) GMP bundles** and **one QC & stability service bundle**. For each of the **seven downstream steps (S6–S12)** there is **one box**, the *Antibody Process Bundle*, holding the exact set of **GMP-grade** liquids that step needs, each bottle labelled with its name, article number, lot, volume, storage and production date. A team orders the **bundle for its process step** rather than assembling a list of individual items and reconciling them on receipt – the toolkit arrives on the dock the way the process actually uses it.

The **five upstream (USP) bundles (S1–S5)** are offered **research-grade today** – the same media, feeds and supplements ship **custom GMP on request, with no reformulation** – so a program runs research today and moves to GMP tomorrow on the identical products.



The Antibody Process Bundle line: one labelled, GMP-grade box per downstream step, filled with PAN-Celltech's square single-use buffer and stock-solution bottles.

**Order the box for your step, not a shopping list of buffers. Each bundle is the toolkit, pre-assembled and labelled for the bench.**

Each box carries the same anatomy: the downstream step it serves, a **GMP grade** mark, a product count, and a printed table of every component with its PAN article number – so the person receiving it can check contents against the label without opening a system. The seven GMP bundles that make up the downstream train:

| GMP bundle                                            | Step | Process                                           | Products    |
|-------------------------------------------------------|------|---------------------------------------------------|-------------|
| <b>DOWNSTREAM (DSP) · S6-S12 · GMP GRADE</b>          |      |                                                   |             |
| <b>Protein A Capture Bundle</b>                       | S6   | Capture chromatography (Protein A affinity)       | 7 products  |
| <b>Viral Inactivation Bundle</b>                      | S7   | Low-pH hold (ICH Q5A)                             | 4 products  |
| <b>Ion Exchange (IEX) Bundle</b>                      | S8   | Charge polishing (CEX + AEX)                      | 6 products  |
| <b>Hydrophobic Interaction (HIC) Bundle</b>           | S9   | Hydrophobic-interaction chromatography (optional) | 6 products  |
| <b>Size Exclusion (SEC) Bundle</b>                    | S10  | Size-exclusion polishing                          | 6 products  |
| <b>Ultrafiltration / Diafiltration (UF/DF) Bundle</b> | S11  | Concentration & buffer exchange                   | 9 products  |
| <b>Final Formulation Bundle</b>                       | S12  | Drug-substance formulation & final bulk           | 13 products |

Every one of the seven is built from the same universal stocks – Tris, acetate, phosphate, NaCl 5 M, citrate and histidine on a WFI base – so the bundles share chemistry as well as a packaging standard, and any buffer in them can be produced on the **WFI Beyond** water base as an added **safety standard** – a made-to-order option for larger quantities, described in Section 7. The thirteenth bundle, **S13 (QC & stability)**, is a **service bundle**, not a supply step: PAN-Celltech supports it with CoA per lot, endotoxin, bioburden and sterility, ICH Q1A stability studies and DMF-backed regulatory support. With the **five research-grade upstream bundles** (S1-S5) that come before, the seven downstream bundles and this service bundle complete the **thirteen-bundle program**; full component-and-article-number listings for all thirteen are in the appendix.



Every bundle box states its step, its GMP grade and a full component list with article numbers; the buffers ship in labelled single-use bottles – here the Protein A Capture and Size Exclusion (SEC) bundles with Phosphate Buffer, Sodium Acetate and WFI Beyond.

## SECTION 5

### Upstream: cell bank to clarified harvest

The first five steps take cells from the bank to a clarified harvest, across the three major antibody platforms – **CHO, HEK293 and hybridoma**. PAN's upstream range carries the media, feeds and supplements for each: the **PANcell CHO Feed Kit** for chem-defined CHO fed-batch, **HybridBoost** for serum-free hybridoma production, and **Panserin 293** for HEK293 – with **Cryopan II / III** for cryopreservation (DMSO and DMSO-free), **stable glutamine** to hold down ammonia in long runs, **Pluronic F-68** for shear protection, and ITS, HAT/HT and non-essential amino acids where a protocol needs them.

Underneath it all run the two universal utilities – **WFI-quality water** for every media and buffer preparation and **DPBS** for cell washing, counting and system flushing – so the upstream suite already shares its foundation with the downstream train that follows. The upstream range is offered **research-grade today**; the identical products are available **custom GMP on request, with no reformulation**, so the material a team screens and selects on is the material it scales and files with – research today, GMP tomorrow.

## SECTION 6

### Downstream: from capture to drug substance

The downstream phase is where the antibody is purified and formulated, and it is built almost entirely on the recurring stock solutions. **Protein A capture (S6)** equilibrates on a Tris/NaCl base and elutes at low pH with **citrate** or **glycine**; that same low-pH eluate flows straight into **viral inactivation (S7)**, the mandatory ICH Q5A hold, then is neutralised with Tris. **Ion exchange (S8)** polishes on acetate/Tris/phosphate bases with a NaCl gradient – CEX and AEX from the same stocks – with an **optional HIC (S9)** on an ammonium-sulfate high-salt base for aggregate and bispecific-mispair removal.

Final polishing runs by **SEC (S10)** on a ready-to-use DPBS or histidine buffer; **UF/DF (S11)** concentrates to dose and exchanges into the formulation buffer – most often **histidine pH 6.0**; and **formulation (S12)** adds the stabilisers a mAb needs to survive storage: **sucrose or trehalose** as cryo/lyo protectant, **polysorbate 20 or 80** against aggregation, NaCl for tonicity. CIP/SIP between batches uses **NaOH 1 M**. One qualified set covers the journey from capture to final vial.

## SECTION 7

### Water, and the WFI Beyond Standard for antibodies

Water is the base of every buffer and the vehicle for the final formulation, so it sets the quality ceiling for the whole train – and antibodies are sensitive to exactly the attributes an ordinary water monograph does not screen for. The pharmacopoeial Water for Injection monograph (Ph. Eur. 0169, its core dating to 1969) is a floor: it limits conductivity, organic carbon and endotoxin, but it sets **no limit at all on the trace metals** and other impurities that quietly degrade a biologic. And water is not a minor input here: **WFI-quality water is the base of twelve of the thirteen bundles** – every one except the QC & stability service – so whatever the water carries, it carries into almost the entire program. WFI Beyond starts from that gap.

**What WFI Beyond is.** WFI Beyond is PAN's beyond-compendial Water for Injection – water that first meets the monograph and then goes past it, proven lot by lot on the Certificate of Analysis:

- **Beyond compendial on the monograph attributes** – endotoxin more than 50x below the limit, total organic carbon 10x below, conductivity more than 5x below (typical batch results lower still).
- **All 24 ICH Q3D elemental impurities specified and measured** by ICP-MS on every lot – a first for a water, since the WFI monograph tests none of them. Each element is reported against its parenteral limit, not as a pass/fail.
- **Nuclease-free** (RNase and DNase not detected), **sterile** (0.1 um filtered, filled into gamma-irradiated single-use containers), and **animal-component-free** with a signed BSE/TSE and ICH Q3 declaration.
- **DMF-backed** – a filed FDA Type IV (excipient) Drug Master File (MF044505), referenceable in an IND/BLA through a Letter of Authorization.
- **The impurity classes the monograph never named, answered up front** – residual solvents (ICH Q3C), **nitrosamines** (current EMA guidance, the class that forced global recalls from 2018) and elemental impurities (ICH Q3D), risk-assessed across every product-contact material.

**Why it matters for an antibody.** Oxidative damage to a monoclonal antibody is overwhelmingly **metal-catalysed** – Fenton chemistry, in which trace **copper** and **iron** generate radicals that attack methionine, histidine and tryptophan and drive the aggregation, charge variants and potency loss that surface late, deep in CMC. Copper and iron are the two catalysts, and here is the gap WFI Beyond closes: **the water monograph tests neither, and ICH Q3D – a toxicity framework – includes copper but not iron.** WFI Beyond measures both; on the reference lot copper and iron were both below the limit of quantification. Controlling the water controls the metals at the source, upgrading every buffer and the final formulation built on it. (*The full water story is In-Depth · Industry Edition D02 · Water. The WFI Beyond Standard.*)

## Built on WFI Beyond: a safety standard for every bundle

**BUILT ON WFI BEYOND** the mark for the water beneath a molecule that earns it.

Because every buffer in every Antibody Process Bundle is built on a water base, the same upgrade is open to all of them. On request, the buffers in any bundle – or across the entire downstream train – can be produced on the **WFI Beyond** water base instead of standard WFI-quality water, giving the finished buffers the same beyond-compendial, metal-controlled foundation. For a sensitive or high-value antibody headed for the clinic, this is the **recommended safety standard**: it removes trace copper and iron – the two oxidation catalysts – as an upstream contributor to instability, at the layer where it is cheapest to control. A process built this way carries the mark **Built on WFI Beyond**.

**How to get it.** The WFI Beyond bundle upgrade is **opt-in and made to order** – not the stocked default, but a build option for **larger, process-scale quantities**, produced through PAN-Celltech's existing **Custom Solutions / custom GMP program**, the same route that already delivers customer-specific formulations and pack sizes, with a Certificate of Analysis per lot and DMF-backed regulatory support. Ask your PAN contact to build any bundle, or the whole train, Built on WFI Beyond.

## SECTION 8

### The DMF advantage

Two of the universal utilities are backed by filed FDA **Type IV Drug Master Files – DPBS (MF044371)** and **WFI Beyond (MF044505)**. Type IV is the FDA's category for **excipients**, which is exactly what these materials are in a finished antibody drug product, so you reference them in your IND/BLA through a Letter of Authorization rather than re-proving or reconstructing them – taking months of independent testing off the critical path, with PAN's proprietary detail protected in the FDA's confidential file. (DMF and stability support are optional, on-request services.)

## SECTION 9

### The proof at commercial scale

The GMP downstream bundles are filled by the PAN-Celltech GMP liquid operation that has proven itself at commercial scale – GMP-compliant and audit-proven manufacture in an EU Annex 1 facility (a capability, not a certification):

#### 13 of 13 steps

Media, supplements, buffers and stock solutions across the entire mAb process – cell bank to drug substance.

#### ~150,000 L • zero rejections

~300,000 bottles supplied to a contract/OEM customer over ~2 years, with zero rejections.

#### up to ~1.8M L / year

Combined manufacturing output; the GMP facility alone runs up to ~1.0M L/year.

#### 2 filed FDA DMFs

DPBS (Type IV, MF044371) and WFI Beyond (MF044505); CoA on every lot.

#### Top 10 CMOs in Europe • 2024

PAN-Biotech recognised among Pharma Tech Outlook's "Top 10 Contract Manufacturing Organizations in Europe" (2024).

A representative case: an antibody developer moving from in-house buffer preparation to a qualified GMP partner consolidated onto PAN's DPBS, WFI and downstream buffers and passed an on-site audit – read the anonymised story in the Knowledge Hub at

**[pan-biotech.com/knowledge-hub](https://pan-biotech.com/knowledge-hub)**.

Track-record figures are anonymised; no customer names are disclosed. Capacity figures are stated as "up to".

#### AUTHOR'S INSIGHT

### The antibody that passes release and fails later

The fear that came back most often in the interviews behind this series applies with particular force to antibodies: a molecule that **clears every release test on the day it is filled and still degrades in storage**. For a mAb the mechanism is specific – **oxidation and aggregation**, seeded by parts-per-billion of a trace metal the water carried in, or by an excipient a hair out of specification – surfacing months later as lost potency or a failed stability time-point, sometimes deep into a Phase 1-3 study.

That is why the formulation end of the train – the **histidine buffer, the polysorbate, the sucrose or trehalose, and above all the water** – is not a commodity to be bought on price. Controlling those inputs up front, and upgrading to WFI Beyond where a molecule earns it, is among **the cheapest insurance an antibody program can buy** against its most expensive kind of late failure.

*– A personal note from the author, drawn from the interview programme behind this In-Depth series.*

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## SECTION 10 • READ BY FUNCTION

### What the one-toolkit approach means for you – by function

The story above is shared. The sections below translate it into the terms of a specific role – read yours, skip the rest.

#### A • DEVELOPERS & RESEARCHERS

### Develop the whole antibody process on one foundation

An antibody process touches media, feeds, cryo, a dozen chromatography buffers and a formulation – and a developer usually assembles them from a scattered supplier base, each with its own qualification and paper trail. PAN lets you build the whole thing on **one coherent toolkit**: CHO/HEK293/hybridoma media and supplements upstream, and downstream a set of concentrated stocks from which you prepare your own working buffers with full flexibility. Because the recurring stocks are already qualified, you develop faster and carry less of the downstream worry back to the bench.

The chemistry is built for the way antibodies actually behave – **citrate that doubles as Protein A eluent and viral-inactivation buffer, histidine as the one formulation SKU** across SEC, UF/DF and drug substance, PS20/PS80 and sucrose/trehalose for stability – and every buffer can be built on **WFI Beyond** where a fragile molecule earns it. (See the technical paper [The monoclonal antibody process, end to end](#) in the Knowledge Hub.)

## Ready-made buffers off the shelf – fewer stock-outs mid-campaign

On the floor, an antibody campaign burns through buffer volume – equilibration, wash, elution, viral-hold, polishing, diafiltration and formulation – and every litre made in-house is weighing, mixing, QC-checking and vessel cleaning that isn't making product. Ordering the concentrated stocks and ready-to-use buffers **from stock, in GMP grade with a CoA per lot** takes that off the floor, in one packaging standard from a single qualified source; fewer manual steps mean fewer contamination entry points and fewer deviations mid-run. And you can order them **by the process step** – as an *Antibody Process Bundle*, one labelled box carrying exactly the components that step needs, article numbers printed on the label – instead of picking each buffer off a catalogue line and reconciling the shipment yourself.

It also keeps the campaign moving. **On-stock dispatch** replaces custom-manufacturing slots and multi-week lead times, so a re-order doesn't stall a batch, and the range scales from a small prep to process volumes (up to 1000 L single-use bags) without re-qualifying the supply. Consistent lot-to-lot chemistry across the recurring stocks means the working buffers behave the same, campaign after campaign.

## Qualify a handful of stocks, not a fragmented basket

The stock-solution principle is a procurement story before it is a technical one: because a **handful of universal stocks** recur across twelve of thirteen steps, you qualify and carry far fewer SKUs than a buffer-by-buffer basket implies – fewer vendors, fewer audits, one documentation and packaging standard. The right lens is **total cost of ownership**, where the hidden tail – qualification labour, incoming QC, the cost of a stalled campaign or a failed batch – dwarfs the unit price, and a single on-stock, GMP-grade, DMF-supported source collapses most of it. Packaging the toolkit as **step-specific process bundles** – one ordered SKU per stage instead of a line-by-line basket – collapses the ordering, goods-in and reconciliation overhead as well.

Held stock is insurance against the demand you cannot forecast – a campaign brought forward, a titre surprise – absorbed without a fresh qualification. The reliability is proven at scale: an entire specialty portfolio bridged at **~150,000 L over ~2 years with zero rejections** (see the Knowledge Hub). And key inputs are DMF-supported today, turning a sourcing decision into a regulatory asset.

## D · QUALITY ASSURANCE

### One audited source across the whole antibody train

Consolidating media, buffers and utilities to **one audited GMP source** collapses the QA load a fragmented antibody supply creates – a single set of documentation and specifications, one packaging standard, one site to assess **on-site or remotely, in full or in part**. Manufacture is **GMP-compliant and audit-proven in an EU Annex 1 facility**, with a **Certificate of Analysis on every lot**, and – because DPBS and WFI Beyond are excipients in the finished drug – that documentation is already on file with the FDA as a Type IV (excipient) DMF your regulatory team can reference.

Consistency is built in: the recurring stocks mean fewer distinct materials to control, fewer deviations and out-of-specification surprises, and – for the fragile formulation end – the impurity classes a modern filing must clear (elemental impurities to ICH Q3D, residual solvents, nitrosamines, TSE/BSE from non-animal materials) documented ahead of the questions. Stability support is available on request.

## E · REGULATORY AFFAIRS

### Reference our filings; document the antibody dossier once

The two universal utilities most likely to sit in your antibody submission – **DPBS and WFI Beyond** – are backed by filed FDA **Type IV (excipient) Drug Master Files** (MF044371, MF044505). You cross-reference them through a Letter of Authorization, so the water and the wash/formulation base are referenceable as exactly what they are in the drug product, without your team rebuilding a dossier or re-proving the material – months off the critical path.

Because a small set of qualified stocks carries across the whole train, the material named in your control strategy is **consistent from capture to drug substance**, and the beyond-compendial dossier answers the modern impurity questions (ICH Q3D, Q3C, nitrosamines, TSE/BSE) before they are asked. Where a specific product you rely on is not yet filed, PAN-Celltech will write and file a custom DMF on request.

## F · DECISION-MAKERS, BD & PROJECT LEADS

### Compress the antibody timeline; de-risk the asset

For the most competitive modality in the industry, **time to clinic is the asset**. One qualified, on-stock toolkit across all thirteen steps plus DMF-backed references takes weeks-to-months out of qualification and filing, and standardising the recurring stocks removes the buffer-by-buffer sourcing that quietly slows a program. Every month saved is cash preserved and data reached sooner.

The larger prize is **de-risking the asset itself** – removing the avoidable Phase 1-3 failure modes a fragmented, under-documented supply invites (a late material change, a stability surprise, a supply gap) – which is exactly the CMC and supply-chain diligence investors and partners look for. It reframes PAN from a vendor of liquids into a partner that takes time and risk out of the path to the clinic, backed by external recognition (Pharma Tech Outlook's "Top 10 CMOs in Europe", 2024) and a proven continuity record.

## A standard antibody toolkit you can run – and offer to your clients

For a contract manufacturer running many antibody programs, one qualified toolkit – **five research-grade upstream bundles** plus **seven ready-to-use GMP downstream bundles** (and a QC & stability service), all with a CoA per lot – lets you **standardise incoming materials across every client** rather than re-qualifying a different buffer set for each. And because DPBS and WFI Beyond are filed as **Type IV (excipient) DMFs your clients can reference directly**, it is a regulatory asset you pass straight through to the sponsor.

As a capacity partner, PAN-Celltech runs custom-formulated GMP (EU Annex 1) production, including private-label lines and single-use fill from 500 mL to 1000 L, with scale to match – combined output **up to ~1.8 million litres a year** – and a continuity record to underwrite it (~150,000 L / ~300,000 bottles over ~2 years, zero rejections). The same GMP material serves a client's program from early development through to commercial supply.

### In one arc

Thirteen steps, from cell bank to drug substance → three platforms (CHO, HEK293, hybridoma) → a handful of universal stock solutions recurring step after step → GMP manufacture in an EU Annex 1 facility, held on stock → water engineered beyond the monograph → DMF-backed regulatory confidence. One qualified toolkit for the whole antibody program, from a single partner whose reason for building it is to take risk and time out of *your* path to the clinic.

## Working with PAN

There are two ways in. **Develop with us:** start research-grade upstream and move to GMP on the **same materials, with no reformulation** – the seven downstream steps available as ready-to-use GMP bundles you will scale and file with. Or **switch to us:** qualify one audited GMP source across your downstream and retire a fragmented supplier base. Specifications, Certificates of Analysis, samples and DMF reference letters are available through your PAN sales contact. For custom and GMP project enquiries: [info@pan-celltech.com](mailto:info@pan-celltech.com).

### What to ask your PAN contact for – by function:

**Developers & Researchers** – the mAb process toolkit, matched stocks and samples, and product specifications.

**Production & Manufacturing** – ready-to-use buffers and pack sizes, single-use formats, and stock & lead-time commitments.

**Procurement** – price and framework terms, a qualified-SKU list, and a TCO comparison for your antibody buffer basket.

**Quality Assurance** – specifications and CoA samples, audit access and a quality agreement.

**Regulatory Affairs** – DMF numbers and Letters of Authorization, the impurity dossier, and custom-DMF scoping.

**Decision-makers, BD & Project leads** – partnership, custom GMP and project work.

**CDMOs & CMOs** – OEM / private-label supply, custom GMP fill, and second-source / continuity arrangements.

## APPENDIX

### The monoclonal-antibody toolkit – by process step

Products by step, with article numbers – the **thirteen bundles: five upstream (S1–S5), seven downstream (S6–S12) and one service (S13)**. The five upstream bundles are **research-grade today (P- numbers)** – the same products available custom GMP on request with no reformulation. The seven downstream bundles are **GMP (CT- numbers)**; each downstream row is what that bundle box contains, pre-assembled and labelled. The thirteenth, **S13 (QC & stability)**, is a **service bundle**. Every downstream buffer is available **beyond-compendial**, produced with **WFI Beyond (CT-981500)** instead of standard WFI, on request.

| Step                                                                                | Key products                                                                                                                                                                                                                                                                             | Article no.                                                                                                                                                       |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>UPSTREAM (USP) · S1–S5 · FIVE RESEARCH-GRADE BUNDLES (CUSTOM GMP ON REQUEST)</b> |                                                                                                                                                                                                                                                                                          |                                                                                                                                                                   |
| S1 · Cell bank & thaw · 7                                                           | Cryopan II, with DMSO · Cryopan III, DMSO-free · DPBS w/o Ca & Mg · Penicillin-Streptomycin · L-Glutamine 200 mM · RNase/DNase Neutralizer · WFI Quality Water                                                                                                                           | <b>P07-93100 · P07-96100 · P04-36500 · P06-07100 · P04-80100 · P10-61500 · CT-991500</b>                                                                          |
| S2 · Screening & selection · 8                                                      | DMEM, stable Gln · RPMI 1640, stable Gln · HAT Supplement 50× · HT Supplement 50× · Accutase · Penicillin-Streptomycin · DPBS w/o Ca & Mg · WFI Quality Water                                                                                                                            | <b>P04-04500 · P04-18500 · P07-02100 · P07-01100 · P10-21500 · P06-07100 · P04-36500 · CT-991500</b>                                                              |
| S3 · Expansion & seed train · 10                                                    | PANcell CHO Feed Kit · HybridBoost · Panserin 293S / 293A · L-Glutamine 200 mM · Stable Glutamine 200 mM · ITS Solution I 100× · Pluronic F-68 10 % · Sodium Bicarbonate 7.5 % · DPBS w/o Ca & Mg · WFI Quality Water                                                                    | <b>P04-71102K · P04-995910 · P04-710609 / P04-710608 · P04-80100 · P04-82100 · P07-03100 · P08-02100 · P04-44100 · P04-36500 · CT-991500</b>                      |
| S4 · Bioreactor production · 13                                                     | PANcell CHO Feed Kit · HybridBoost · Glucose 20 % Stock · MEM NEAA 100× · Insulin human recombinant · Sodium Pyruvate 100 mM · HEPES Buffer 1 M · Pluronic F-68 10 % · ITS Solution I 100× · L-Glutamine 200 mM · Stable Glutamine 200 mM · Sodium Bicarbonate 7.5 % · WFI Quality Water | <b>P04-71102K · P04-995910 · CT-00331 · P08-32100 · P07-04300 · P04-43100 · P05-01100 · P08-02100 · P07-03100 · P04-80100 · P04-82100 · P04-44100 · CT-991500</b> |
| S5 · Harvest & clarification · 6                                                    | DPBS w/o Ca & Mg · DPBS 10× w/o Ca & Mg · Sodium Chloride 0.9 % · Accutase · RNase/DNase Neutralizer · WFI Quality Water                                                                                                                                                                 | <b>P04-36500 · P04-53500 · P05-39500 · P10-21500 · P10-61500 · CT-991500</b>                                                                                      |

| Step                                                 | Key products                                                                                                                                                                                                                                                                                                       | Article no.                                                                                                                                                     |
|------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>DOWNSTREAM (DSP) · S6-S12 · SEVEN GMP BUNDLES</b> |                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                 |
| S6 · Protein A Capture Bundle · 7                    | NaCl 5 M Stock · Tris-HCl 1 M Stock, pH 8.4 · Citrate Buffer 100 mM, pH 3.0 · Glycine 100 mM, pH 3.0 · Sodium Chloride 0.9 % · Ethanol 20 % · WFI Quality Water                                                                                                                                                    | <b>CT-77055 · CT-05500 · CT-62500 · CT-69500 · CT-39500 · CT-89500 · CT-991500</b>                                                                              |
| S7 · Viral Inactivation Bundle · 4                   | Citrate Buffer 100 mM, pH 3.0 · Tris-HCl 1 M Stock, pH 8.4 · Triton X-100 10 % · WFI Quality Water                                                                                                                                                                                                                 | <b>CT-62500 · CT-05500 · CT-01001 · CT-991500</b>                                                                                                               |
| S8 · Ion Exchange (IEX) Bundle · 6                   | Sodium Acetate 100 mM, pH 4.5 · NaCl 5 M Stock · Tris-HCl 1 M Stock, pH 8.4 · Phosphate Buffer 100 mM · NaOH 1 M Stock · WFI Quality Water                                                                                                                                                                         | <b>CT-76451 · CT-77055 · CT-05500 · CT-18810 / CT-18850 · CT-55105 · CT-991500</b>                                                                              |
| S9 · HIC Bundle · 6 · optional                       | Ammonium Sulfate 1 M · Ammonium Sulphate 3 M Stock · Phosphate Buffer 100 mM · Tris-HCl 1 M Stock, pH 8.4 · NaCl 5 M Stock · WFI Quality Water                                                                                                                                                                     | <b>CT-67500 · CT-68500 · CT-18810 / CT-18850 · CT-05500 · CT-77055 · CT-991500</b>                                                                              |
| S10 · Size Exclusion (SEC) Bundle · 6                | DPBS w/o Ca & Mg · Histidine 100 mM, pH 6.0 · Phosphate Buffer 100 mM · NaCl 5 M Stock · DPBS 10× w/o Ca & Mg · WFI Quality Water                                                                                                                                                                                  | <b>CT-36500 · CT-69510 · CT-18810 / CT-18850 · CT-77055 · CT-53500 · CT-991500</b>                                                                              |
| S11 · UF/DF Bundle · 9                               | Histidine 100 mM, pH 6.0 · Sodium Acetate 100 mM, pH 4.5 · Phosphate Buffer 100 mM · Sucrose 30 % Stock · Trehalose 30 % Stock · Polysorbate 20 (PS20) 1 % · Polysorbate 80 (PS80) 1 % · DPBS w/o Ca & Mg · WFI Quality Water                                                                                      | <b>CT-69510 · CT-76451 · CT-18810 / CT-18850 · CT-00131 · CT-00231 · CT-00211 · CT-00311 · CT-36500 · CT-991500</b>                                             |
| S12 · Final Formulation Bundle · 13                  | Histidine 100 mM, pH 6.0 · Sucrose 30 % Stock · Trehalose 30 % Stock · Polysorbate 20 (PS20) 1 % · Polysorbate 80 (PS80) 1 % · NaCl 5 M Stock · Phosphate Buffer 100 mM · Sodium Acetate 100 mM, pH 4.5 · DPBS w/o Ca & Mg · EDTA 0.5 M, pH 8.0 · L-Arginine 1 M, pH 7.0 · Mannitol 10 % (w/v) · WFI Quality Water | <b>CT-69510 · CT-00131 · CT-00231 · CT-00211 · CT-00311 · CT-77055 · CT-18810 / CT-18850 · CT-76451 · CT-36500 · CT-10500 · CT-69520 · CT-00401 · CT-991500</b> |
| <b>SERVICE · S13 · ONE SERVICE BUNDLE</b>            |                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                 |
| S13 · QC & stability · service bundle                | Release testing (not a supply step): CoA per lot · endotoxin (LAL) · bioburden & sterility · ICH Q1A stability · Type IV DMF / Letter of Authorization                                                                                                                                                             | -                                                                                                                                                               |

**Universal utilities.** WFI Quality Water (CT-991500) recurs in twelve steps and DPBS (CT-36500) in seven; NaCl 5 M and phosphate in five, Tris in four, acetate and histidine in three, citrate in two. **WFI Beyond** (CT-981500) is Water for Injection engineered beyond Ph. Eur. monograph 0169 – endotoxin < 0.005 EU/mL (>50× below limit), TOC < 0.05 mg/L, conductivity < 0.2 µS/cm, nuclease-free – and, with DPBS, is backed by a filed FDA Type IV (excipient) DMF (MF044505, MF044371). Downstream (S6-S12) is GMP grade, manufactured by PAN-Celltech; upstream (S1-S5) is research-grade today, the same products custom GMP on request with no reformulation, across the CHO, HEK293 and hybridoma platforms. Full specifications and current article numbers on request.

## APPENDIX B

### Every mAb product, mapped to every process step

The process-step matrix below shows which of the recurring products each of the thirteen steps uses – a dot marks a product used in that step: upstream S1-S5 in red, downstream S6-S12 in blue, and QC & stability (S13) as release testing, not a supply step. It is the recurrence made visible: **WFI-quality water and WFI Beyond each recur in twelve of the thirteen steps**, DPBS in seven – which is why a handful of qualified stocks cover the whole program. Every buffer is available beyond-compendial with WFI Beyond, on request; custom GMP to your recipe.

## Process-step matrix – every product, every step

**Steps.** S1 Thaw · S2 Screen · S3 Seed train · S4 Reactor · S5 Harvest (upstream) | S6 Protein A · S7 Viral inact. · S8 IEX · S9 HIC · S10 SEC · S11 UF/DF · S12 Formulation (downstream). S13 QC & stability is release testing, not a supply step, so it has no column. ● upstream use · ● downstream use.

| Product                       | Article no.                   | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 | S10 | S11 | S12 | Steps |
|-------------------------------|-------------------------------|----|----|----|----|----|----|----|----|----|-----|-----|-----|-------|
| WFI Quality Water             | CT-991500                     | ●  | ●  | ●  | ●  | ●  | ●  | ●  | ●  | ●  | ●   | ●   | ●   | 12    |
| WFI Beyond                    | CT-981500                     | ●  | ●  | ●  | ●  | ●  | ●  | ●  | ●  | ●  | ●   | ●   | ●   | 12    |
| DPBS w/o Ca & Mg              | P04-36500 / CT-36500          | ●  | ●  | ●  |    | ●  |    |    |    |    | ●   | ●   | ●   | 7     |
| DPBS 10× w/o Ca & Mg          | P04-53500 / CT-53500          |    |    |    |    | ●  |    |    |    |    | ●   |     |     | 2     |
| Sodium Chloride 0.9 %         | P05-39500 / CT-39500          |    |    |    |    | ●  | ●  |    |    |    |     |     |     | 2     |
| Cryopan II, with DMSO         | P07-93100 / CT-94100          | ●  |    |    |    |    |    |    |    |    |     |     |     | 1     |
| Cryopan III, DMSO-free        | P07-96100 / CT-96100          | ●  |    |    |    |    |    |    |    |    |     |     |     | 1     |
| Penicillin-Streptomycin       | P06-07100 / CT-07110          | ●  | ●  |    |    |    |    |    |    |    |     |     |     | 2     |
| L-Glutamine 200 mM            | P04-80100 / CT-80100          | ●  |    | ●  | ●  |    |    |    |    |    |     |     |     | 3     |
| Stable Glutamine 200 mM       | P04-82100 / CT-82100          |    |    | ●  | ●  |    |    |    |    |    |     |     |     | 2     |
| RNase/DNase Neutralizer       | P10-61500                     | ●  |    |    |    | ●  |    |    |    |    |     |     |     | 2     |
| DMEM, stable Gln              | P04-04500 / CT-04500          |    | ●  |    |    |    |    |    |    |    |     |     |     | 1     |
| RPMI 1640, stable Gln         | P04-18500 / CT-18500          |    | ●  |    |    |    |    |    |    |    |     |     |     | 1     |
| HAT Supplement 50×            | P07-02100 / CT-02100          |    | ●  |    |    |    |    |    |    |    |     |     |     | 1     |
| HT Supplement 50×             | P07-01100 / CT-03100          |    | ●  |    |    |    |    |    |    |    |     |     |     | 1     |
| Accutase                      | P10-21500                     |    | ●  |    |    | ●  |    |    |    |    |     |     |     | 2     |
| PANcell CHO Feed Kit          | P04-71102K                    |    |    | ●  | ●  |    |    |    |    |    |     |     |     | 2     |
| HybridBoost                   | P04-995910 / CT-995905        |    |    | ●  | ●  |    |    |    |    |    |     |     |     | 2     |
| Panserlin 293S / 293A         | P04-710609 / P04-710608       |    |    | ●  |    |    |    |    |    |    |     |     |     | 1     |
| Pluronic F-68 10 %            | P08-02100 / CT-02110          |    |    | ●  | ●  |    |    |    |    |    |     |     |     | 2     |
| Sodium Bicarbonate 7.5 %      | P04-44100                     |    |    | ●  | ●  |    |    |    |    |    |     |     |     | 2     |
| ITS Solution I 100×           | P07-03100 / CT-03110          |    |    | ●  | ●  |    |    |    |    |    |     |     |     | 2     |
| Glucose 20 % Stock            | CT-00331                      |    |    |    | ●  |    |    |    |    |    |     |     |     | 1     |
| HEPES Buffer 1 M              | P05-01100 / CT-01100          |    |    |    | ●  |    |    |    |    |    |     |     |     | 1     |
| MEM NEAA 100×                 | P08-32100 / CT-32100          |    |    |    | ●  |    |    |    |    |    |     |     |     | 1     |
| Insulin human recombinant     | P07-04300                     |    |    |    | ●  |    |    |    |    |    |     |     |     | 1     |
| Sodium Pyruvate 100 mM        | P04-43100 / CT-43100          |    |    |    | ●  |    |    |    |    |    |     |     |     | 1     |
| Ethanol 20 %                  | CT-89500                      |    |    |    |    |    | ●  |    |    |    |     |     |     | 1     |
| Triton X-100 10 %             | CT-01001                      |    |    |    |    |    |    | ●  |    |    |     |     |     | 1     |
| NaCl 5 M Stock                | CT-77055                      |    |    |    |    |    | ●  |    | ●  | ●  | ●   |     | ●   | 5     |
| Tris-HCl 1 M Stock, pH 8.4    | CT-05500                      |    |    |    |    |    | ●  | ●  | ●  | ●  |     |     |     | 4     |
| Citrate Buffer 100 mM, pH 3.0 | CT-62500                      |    |    |    |    |    | ●  | ●  |    |    |     |     |     | 2     |
| Glycine 100 mM, pH 3.0        | CT-69500                      |    |    |    |    |    | ●  |    |    |    |     |     |     | 1     |
| Sodium Acetate 100 mM, pH 4.5 | CT-76451                      |    |    |    |    |    |    |    | ●  |    |     | ●   | ●   | 3     |
| Phosphate Buffer 100 mM       | CT-18810 / CT-18850           |    |    |    |    |    |    |    | ●  | ●  | ●   | ●   | ●   | 5     |
| NaOH 1 M Stock                | CT-55105                      |    |    |    |    |    |    |    | ●  |    |     |     |     | 1     |
| Ammonium Sulfate 1 M          | CT-67500                      |    |    |    |    |    |    |    |    | ●  |     |     |     | 1     |
| Ammonium Sulphate 3 M Stock   | CT-68500                      |    |    |    |    |    |    |    |    | ●  |     |     |     | 1     |
| Histidine 100 mM, pH 6.0      | CT-69510                      |    |    |    |    |    |    |    |    |    | ●   | ●   | ●   | 3     |
| Sucrose 30 % Stock            | CT-00131                      |    |    |    |    |    |    |    |    |    |     | ●   | ●   | 2     |
| Trehalose 30 % Stock          | CT-00231                      |    |    |    |    |    |    |    |    |    |     | ●   | ●   | 2     |
| Polysorbate 20 (PS20) 1 %     | CT-00211                      |    |    |    |    |    |    |    |    |    |     | ●   | ●   | 2     |
| Polysorbate 80 (PS80) 1 %     | CT-00311                      |    |    |    |    |    |    |    |    |    |     | ●   | ●   | 2     |
| EDTA 0.5 M, pH 8.0            | CT-10500                      |    |    |    |    |    |    |    |    |    |     |     | ●   | 1     |
| L-Arginine 1 M, pH 7.0        | CT-69520                      |    |    |    |    |    |    |    |    |    |     |     | ●   | 1     |
| Mannitol 10 % (w/v)           | CT-00401                      |    |    |    |    |    |    |    |    |    |     |     | ●   | 1     |
| Custom GMP Buffer             | PAN-Celltech · to your recipe |    |    |    |    |    | ●  | ●  | ●  |    |     |     |     |       |
| PRODUCTS PER STEP             |                               | 7  | 8  | 10 | 13 | 6  | 7  | 4  | 6  | 6  | 6   | 9   | 13  |       |

Process-step matrix – every mAb product mapped to every process step, with the per-step product count along the foot. Every buffer is available beyond-compendial with WFI Beyond, on request; custom GMP to your recipe.