

IN-DEPTH · INDUSTRY EDITION D01 · FOR PHARMA, BIOTECH &amp; CDMO

# Standardizing and De-risking the Biomanufacturing of Modern Medicine

**Why the bottleneck moved from discovery to supply – and how one partner de-risks it**

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**In brief.** The hard part of a modern medicine is no longer discovering it – it is manufacturing it reliably, at quality, on time. This briefing sets out how PAN-Biotech and its GMP arm PAN-Celltech remove the supply and downstream bottlenecks that delay biologics: **38 years of upstream cell-culture expertise**; top products **manufactured to GMP in an EU Annex 1 facility and held on stock**; **water engineered beyond the compendial monographs**; **FDA Type IV (excipient) Drug Master File support** that de-risks your filing; and a complete on-stock downstream portfolio – **The Open Downstream**, a foundation of 31 products serving four applications. Combined output up to **~1.8 million litres a year**, with an **award-winning track record** at commercial scale.

**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 really sit

The discovery of a modern medicine is no longer what holds it back – the manufacturing is. This edition does not rest on one company's opinion. It distils what we have heard, analysed and summarised across the industry: **hundreds of interviews, insights and data points** with pharma, biotech of every size (small, mid and large), CDMOs, CMOs and CROs, and start-ups – and at **every level of the organisation**: researchers and developers, procurement and buyers, production, QA,

regulatory affairs, and the CEO / business-development table. One pattern comes back everywhere.

For the last **two decades the industry poured its energy into upstream (USP)** – lifting **titre and yield** from cell-culture media, feeds and process control. That work succeeded: upstream productivity has climbed dramatically. But it quietly moved the problem downstream. By widely cited estimates, **roughly half of the total production cost of a modern biologic – and often more for antibodies – is incurred not in the bioreactor, but downstream:** in the purification, viral clearance, polishing and formulation that turn a vat of complex biological fluid into a safe, injectable product. The part the industry optimised least is the part that now carries the most cost.

And the two halves fail very differently. A failed **upstream** batch is painful but recoverable: you lose the media, the bioreactor time and a few weeks, and you restart – at clinical scale that can still mean losses running into the millions or tens of millions, but the value lost is mostly time and inputs. A failure **downstream** is far worse, because by then almost the entire value of the batch is already invested in the product. A single bad buffer or reagent at a final polishing step can destroy a nearly-finished, high-value batch outright – **illustratively three to four times the cost of the equivalent upstream loss** – with no way to restart that material. Risk, like cost, concentrates at the very end of the line.

Underneath both sits the cost everyone feels but few put on a line item: **time**. Every delayed or repeated step – a re-order that isn't on the shelf, a custom batch waiting for a manufacturing slot, a revalidation, a failed lot – pushes the whole programme back, and in this industry a month of delay is a month of cash burned against the clinic and the market. **Time of process is cost of process.**

That reframes the goal. The prize is no longer only a higher titre; it is a **faster, easier, more reliable end-to-end process. Ease of process is cost of process – and more:** a simpler, standardised, well-documented process also **de-risks failure and makes the programme far more reliable for QA and regulatory affairs**. That is what the rest of this briefing is about – how PAN-Biotech and PAN-Celltech make the whole production chain faster, easier and safer, from cell culture to the open downstream.

## SECTION 2

### Thirty-eight years upstream: the foundation

PAN-Biotech, founded in 1988, has spent 38 years on the **upstream (USP)** side of bioproduction – the media, sera, supplements and reagents that keep cells alive, productive and consistent. Consider a 2,000-litre bioreactor of CHO cells, the workhorses of the industry. They need a precisely balanced milieu – defined gradients of amino acids, vitamins, glucose and lipids, down to trace elements such as zinc and iron. A fraction off and the cells stress: they misfold protein, or mis-attach the sugar chains (glycosylation) the drug depends on. The result underperforms – or provokes an immune response in the patient.

Mastering those liquid recipes for four decades is the foundation everything else builds on. When we extend into downstream processing, we do it from **deep upstream chemistry, not from a standing start**. PAN-Biotech is the master brand; **PAN-Celltech** is its dedicated GMP arm – a branded house, not a rename. Combined manufacturing output runs to **up to ~1.8 million litres a year**.

**"We don't lead our customers; we follow them – from the first research vial to commercial supply."**

### SECTION 3

## Into GMP: PAN-Celltech and EU Annex 1 (2022)

In 2022, PAN-Celltech's **EU Annex 1** facility came on line. Annex 1 is among the most stringent frameworks in the world for the manufacture of sterile medicinal products, and it is demanding on the floor: continuous environmental monitoring; HEPA filtration with particulate limits counted per cubic metre; multi-stage gowning and sterile airlocks; and pressure cascades so that air always moves outward from the core, never inward. It is a purpose-built environment for sterility – a capability and a standard, which is why we describe our manufacture as **GMP-compliant and audit-proven** rather than "certified."

PAN-Celltech began the way the whole industry does. A GMP-grade medium or buffer is traditionally a bespoke, made-to-order affair: the supplier clears a line, sources the raw materials, manufactures that one batch, runs a full battery of quality-control tests, and ships months later. That was our starting point too – and running it, batch after batch, was the learning curve. Set that experience against the industry insight above – that **cost and risk concentrate downstream, that time is cost, and that ease of process is itself cost and de-risking** – and the innovation follows: take the **universal denominators** (the products almost every biologic manufacturer needs), manufacture them to GMP, and **hold them on stock**, each lot released with its **Certificate of Analysis**. These are held on stock as **GMP-grade catalogue products (CT-series)**, used from development through commercial supply; where a programme wants a research-grade (RUO) version – for cost at higher development volumes, say – PAN-Celltech can produce one as a custom build on request.

The effect is decisive. The bespoke wait becomes an **off-the-shelf order**; the variables and delays of custom manufacturing – a scheduling slot, raw-material lead time, a 14-day sterility hold, a fresh revalidation on every reorder – fall away. Holding the finished formulation on stock lets you **develop on the very same GMP-grade material you will scale and file with** – so there is no RUO → GMP switch and no comparability gap to close later, because **the chemistry of the liquid never changes** from bench to commercial fill. This is not a cheap compromise – it is excellence, held on the shelf.

## Standard on stock, custom where it counts

Standardising the catalogue does not replace bespoke manufacturing – it makes room for it. Where a project genuinely needs a **custom formulation, grade or packaging**, PAN-Celltech continues to **build to order**, as we always have.

Standardising everything that *can* be standardised is precisely what frees the capacity to do that well: the routine comes off the critical path, so new, non-standard and complex projects get the development attention, line time and speed they deserve. The on-stock foundation carries the universal; custom manufacturing carries the rest – and having the standard building blocks already qualified makes each new bespoke project faster to stand up, too.

### SECTION 4

## Water: the quality ceiling, and WFI Beyond

Everything in bioproduction begins with water. Every medium, every buffer, every final formulation is overwhelmingly water – so water sets the **quality ceiling** for everything built on top of it. You can source the purest amino acids on the planet, but if the water is compromised, the batch is compromised.

Compendial **Water for Injection** (Ph. Eur. / USP) sets limits for conductivity, total organic carbon and bacterial endotoxin – monographs framed decades ago, largely for simpler or robust molecules. PAN-Biotech's argument – the thinking behind **WFI Beyond** – is that for the most fragile modern biologics the compendial minimum is no longer sufficient. WFI Beyond is deliberately **controlled past the monograph** on the attributes that decide fitness for those products.

**Think of a small molecule as a single-storey house – standard concrete is fine. A modern biologic is a hundred-storey tower: invisible cracks in the foundation bring the whole structure down. In biomanufacturing, water is the concrete.**

The "cracks" are specific. An mRNA lipid nanoparticle is a fragile strand of genetic code inside a shell of fat, exquisitely sensitive to **trace metal ions** – parts-per-billion of certain metals can catalyse oxidation and degrade the lipid; to **nucleases**, enzymes that exist precisely to chew up loose RNA; and to **micro-variations in pH** over months of cold storage. Standard WFI need not screen for these; WFI Beyond targets them, so the foundation holds however complex the molecule on top. And this is measured, not asserted: WFI Beyond **specifies and quantifies all 24 ICH Q3D elemental impurities** by ICP-MS on every Certificate of Analysis, alongside the core Water-for-Injection parameters (**conductivity, total organic carbon, bacterial endotoxin**) and attributes the monograph never screened (**nuclease activity and sterility**). Bacterial endotoxin runs **>50× below** the Ph. Eur. Water-for-Injection limit, and TOC to a spec **~10× below** it – with the reference lot measured ~45× below; the water is **nuclease-free** (RNase & DNase not detected) and **animal-component-free**.

The following is our water-product portfolio for the needs and applications of modern medicine:

- **Sterile Water for Cell Culture** – cell-culture-grade water, research use (P-series).
- **WFI Quality Water** – WFI-quality water to EP/USP, GMP grade (CT-991500).
- **WFI Beyond** – beyond-compendial Water for Injection, backed by a filed FDA Drug Master File (MF044505); the CT-98 series, from 500 mL / 1000 mL bottles to single-use, gamma-irradiated bags up to 1,000 L. Opt-in, available on request.

The full water story – WFI Beyond's beyond-compendial specification, its filed FDA Drug Master File and the science behind it – is the subject of its own companion briefing, **In-Depth • Industry Edition D02 • Water**.

→ [Read In-Depth Edition D02 • Water](#)

## SECTION 5

### The DMF advantage: a regulatory skeleton key

Sometimes the most valuable thing a supplier can give a regulated customer is not a chemical in a bottle – it is a document. A **Drug Master File (DMF)** is a confidential dossier filed with the FDA that captures exactly how a product is made and controlled: raw-material sourcing, equipment, cleaning validations, quality-control limits, stability data. The customer references it in their own submission through a **Letter of Authorization** – and never has to re-prove, reverse-engineer or reconstruct the material to satisfy the regulator.

PAN currently holds **two filed FDA DMFs: DPBS (Type IV, MF044371) and WFI Beyond (MF044505)**. Both are filed as **Type IV DMFs – the FDA's category for excipients**, which is exactly what these materials are in a finished drug product, so they are referenceable as precisely what your submission uses them as. The mechanism works in both directions. It protects our proprietary know-how – the detail stays in the FDA's confidential file, disclosed to neither customers nor competitors – and it removes months of independent testing and validation from the customer's critical path. For a regulated buyer, a DMF-backed input is continuity you can build a filing on. On request, PAN-Celltech will also write and file a DMF for the specific PAN products a customer uses. (DMF and stability support are optional, on-request services.)

## SECTION 6

### The Open Downstream: consolidating the most expensive step

As Section 1 set out, **roughly half of a biologic's total production cost – and a disproportionate share of its risk – sits downstream**: not in the bioreactor where the cells grow, but in recovering the therapeutic, often less than 1% of the harvest, from a

complex process fluid (host-cell DNA and protein, spent media, and possibly endogenous viruses). And the failure is **asymmetric**: upstream, a batch that fails early costs time and materials and you restart; downstream, a single bad buffer or reagent at a final polishing step can irreversibly destroy a nearly-finished, highest-value batch – illustratively three to four times the cost of the equivalent upstream loss, with no way to restart that material. The sequence – capture, viral inactivation, chromatographic polishing and final formulation – is exactly where cost, quality and regulatory risk concentrate, at the very end of the line.

Historically this meant a **scattered, fragmented supplier base** – one supplier for the sodium chloride, another for the Tris buffer, another for the detergents – each with its own lead times, QC standards, packaging and regulatory documentation; each carrying its own procurement handling effort of qualification, contracting, ordering, goods-in and invoicing; and each a separate audit for your quality team. **The Open Downstream** replaces that with a coherent, GMP-grade **foundation of 31 on-stock products** – buffers, stock solutions, reagents and excipients – from a **single qualified source**.

### One toolkit, four applications – and the freedom to pivot

The 31 products are deliberately built as a **shared foundation**, not four separate sections. They serve **four applications – monoclonal antibodies, vaccines, mRNA / pDNA, and cell & gene therapy** – because the chemical levers underneath diverse biologics are largely the same: how you manipulate pH, drive a separation, inactivate a virus, and stabilise a molecule for shipping. The monoclonal-antibody programme is live; the others follow on the same foundation.

The practical payoff is **two-fold**. First, **standardisation is the starting point for customisation**: any of the 31 standard products – or a **combination of two or more** of them – can serve as the qualified basis for a customized formulation where a project needs one, so bespoke work begins from proven, in-stock building blocks rather than a blank sheet. Second, it **protects the pipeline**: a programme can move from a mAb into an mRNA product **without rebuilding and re-qualifying its whole downstream supply base** – the same qualified materials are already on the shelf and already in the quality system. And where the industry is shifting – for example the EU **REACH** phase-out of Triton™ X-100 – the range already stocks the compliant, **animal-free** option (PANclear APG), so a required change doesn't force a re-sourcing scramble.

### And one upgrade that lifts the whole range: WFI Beyond

There is a further advantage that runs through everything above. Every one of the 31 standard products – *and* every customized product derived from them – can be built on **WFI Beyond**, our beyond-compendial Water for Injection. Because water is the single largest component of almost every buffer, stock solution and final formulation, **upgrading the water upgrades everything made from it**. It is one decision that raises the quality ceiling of an entire downstream train at once – standard or

bespoke, from first buffer to final fill – taking the whole foundation a measured step beyond the monograph on trace metals, endotoxin, TOC and nucleases. A single, qualified water standard you can grow with, whatever you are making. (The full water story is told in **In-Depth • Industry Edition D02 • Water.**)

→ **Read In-Depth Edition D02 • Water**

#### **AUTHOR'S INSIGHT**

### **The failure everyone fears most – and how we engineered against it**

Across the interviews behind this edition, one fear came back more than any other – from founders, QA leads and programme directors alike: that a promising therapy **fails in the clinical phases**, after years of work and enormous sums are already committed. It is the industry's most common and most feared failure mode – and it is exactly why our research team put **extraordinary attention into de-risking these dangers**.

What makes it so feared is that it can hide. A finished biologic can clear every quality criterion on the day it is filled and still **degrade silently in storage**, over the months or years it sits in a vial or a frozen bag. The culprits are the very trace impurities a release test tolerates: **parts-per-billion of a metal ion** can catalyse oxidation that unfolds a protein or breaks down a lipid nanoparticle; a **residual nuclease keeps chewing at an mRNA payload**; a small pH drift tips a formulation out of its stability window. None of it shows up on day one – it surfaces *later* as lost potency, aggregation or a failed stability time-point, sometimes deep into a **Phase 1–3 study**, where a single time-point can stall or sink the whole programme.

So we treat **de-risking the inputs as de-risking the programme**. The purity of the water, buffers and excipients a product is built and formulated in decides not just whether it passes today, but whether it *survives to the patient* – which is why controlling them up front, and upgrading to **WFI Beyond** where a molecule earns it, is among the cheapest insurance a programme 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 edition.*

## **SECTION 7**

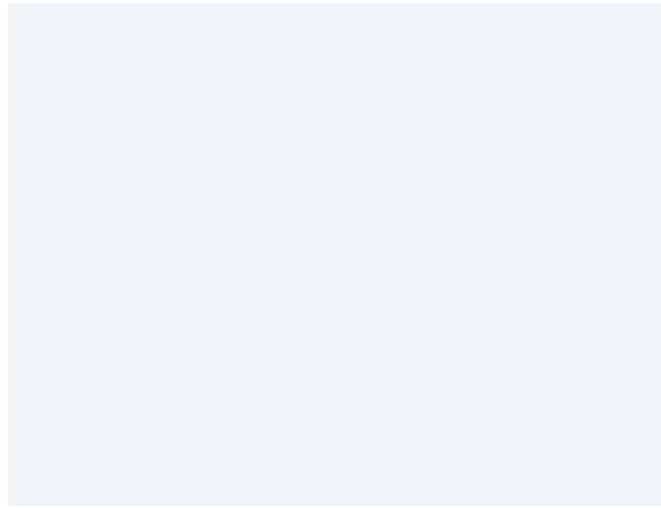
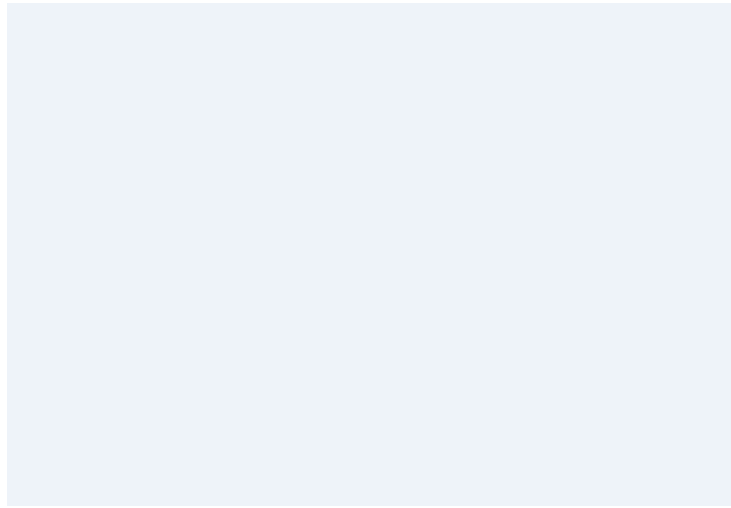
### **The proof at commercial scale**

#### **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 (MF044501) Annex 1 GMP manufacture; CoA on every lot.



The ~50,000 L and ~150,000 L stories above are anonymised customer case studies – read them in full 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".

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## **SECTION 8 • READ BY FUNCTION**

### **What the Open Downstream 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.

## Develop and scale without changing the chemistry

The most important de-risking move for a research team happens quietly: it lets them **stay on the science**. Because the Open Downstream is one **open, flexible and well-established biological system** – a single set of **GMP-grade formulations you develop on and scale with**, the identical material from bench to commercial fill – a developer no longer has to carry the downstream worries that usually reach back to the bench: the **QA burden, audits, the documentation and paper trail, switching suppliers, and the re-testing or revalidation** that a late material change sets off. Because you can develop directly on the GMP material, the classic RUO → GMP transition simply isn't there to manage. That weight is absorbed by the platform, not the person.

It starts with the everyday grind. Researchers still lose hours hand-weighing salts, mixing, titrating and QC-checking routine buffers and stock solutions – skilled time spent on **preparation instead of science**, and a quiet source of lot-to-lot variability. Now they can simply **order those buffers ready-made, from stock**, in GMP grade (with a research-grade build on request) – consistent, documented and ready to use. (See the technical paper [From Bench to GMP: organizing and scaling your buffer supply](#) in the Knowledge Hub.)

Concretely, you **develop on the same GMP-grade material you will scale and file with** – the liquid never changes, so there is no grade switch to revalidate and no fresh round of surprises; and where a research-grade (RUO) version is wanted for higher-volume early work, PAN-Celltech can build it on request. On top of it sits **WFI Beyond**, controlled past the monograph for the sensitivities that actually break fragile modalities (ppb trace metals, nucleases, cold-storage pH drift).

Downstream, the 31-product foundation is a coherent toolkit of shared chemical levers, for example: high-salt **ammonium sulfate** for hydrophobic-interaction capture/polishing; **magnesium chloride** as an IVT cofactor for mRNA; **SDS / alkaline lysis** for pDNA recovery; **low-pH citrate** or a **detergent** for viral inactivation; **histidine** for high-concentration mAb formulation and **neutral sodium citrate** for mRNA-LNP storage; and **sucrose, trehalose, mannitol, PS20/PS80 and recombinant HSA** for cryo/lyo, anti-aggregation and animal-free stabilisation. One qualified set covers the journey from capture to final vial.

## Ready-made buffers off the shelf – less prep, fewer stoppages

On the manufacturing floor, buffer and stock-solution preparation is quiet, constant work – weighing salts, mixing, titrating, QC-checking and cleaning vessels – skilled time that isn't making product, and a steady source of lot-to-lot variability. Ordering the Open Downstream range **ready-made, from stock, in GMP grade with a Certificate of Analysis per lot** takes that off the floor: consistent, documented buffers delivered ready to use, in **one packaging standard from a single qualified source**. Fewer manual steps mean fewer contamination entry points and fewer deviations to work through mid-run.

It also keeps the line moving. **On-stock dispatch** replaces custom-manufacturing slots and multi-week lead times, so a re-order doesn't stall a batch; the modular range **scales from a small prep to process volumes** – up to single-use bags of 1000 L – without re-qualifying the supply; and where a molecule needs it, the whole train can be built on **WFI Beyond**. Less time spent making and checking buffers, more time running the process.

## One audited source instead of a fragmented supplier base

Consolidating the downstream base to a single qualified GMP supplier removes duplicated effort at every level – **fewer vendors to qualify, fewer purchase orders, fewer audits, one set of documentation and one packaging/label standard**. Because the foundation is held **on stock**, you get predictable dispatch rather than custom-manufacturing slots and multi-week lead times.

The right lens is **total cost of ownership (TCO)**, not the unit price on the quote. A cheaper litre carries a long hidden tail: vendor qualification and audit labour, purchase-order and goods-in handling, incoming QC, inventory carrying – and the big ones, the cost of a **delay or a failed batch** (where a nearly-finished, high-value product is at stake) and the **revalidation** any change triggers. Put a value on the de-risking at each of those levels and the "expensive" option is usually the fragmented one; standardising to a single on-stock, GMP-grade, DMF-supported source collapses most of the tail.

**Time is the largest hidden line of all.** On-stock dispatch replaces custom slots and multi-week lead times, and one qualified source removes weeks of repeated qualification and paperwork per vendor, per year. In a business where a month of delay is a month of cash burned against the clinic and the market, that recovered time is often worth more than the unit-price line it sits beside.

Held stock is also **insurance against the future you cannot forecast**. If a forecast is exceeded, demand suddenly spikes, or an incumbent supply is disrupted, an on-stock GMP range absorbs it – no scramble, no fresh qualification, supply protected. And because the foundation is **modular** – 31 building blocks that combine and scale across four applications – you can flex volumes and move between programmes without re-sourcing. That flexibility has a cash value: fewer write-offs, fewer stock-outs, fewer emergencies.

The reliability is proven at scale: when an incumbent supply was disrupted, PAN bridged an entire portfolio and delivered **~150,000 L / ~300,000 bottles over ~2 years with zero rejections** – read the anonymised story in the Knowledge Hub at [pan-biotech.com/knowledge-hub](https://pan-biotech.com/knowledge-hub). Procurement can also turn a sourcing decision into a **regulatory asset**: key inputs are DMF-supported today, and PAN-Celltech will file a DMF for the specific PAN products you use on request – de-risking the filing from the supply side.

## Comparability preserved, audits made easy

The heaviest QA burden in a fragmented downstream is the audit and documentation load – a different vendor, specification, packaging and paper trail for every buffer. Consolidating to **one audited GMP source** collapses it: a single set of documentation and specifications, one packaging standard, and a manufacturing site your team can assess **on-site or remotely, in full or in part**. Manufacture is **GMP-compliant and audit-proven in an EU Annex 1 facility** (a capability, not a certificate), with a **Certificate of Analysis on every lot** – WFI Beyond, for instance, released against a 27-attribute panel. And if a programme needs a higher quality level or a lower-risk water, a switch to **DMF-backed WFI Beyond** is always a possibility – a very good option, and a fast one to implement. For the DMF-backed inputs (DPBS and WFI Beyond), that documentation is already filed with the FDA as a **Type IV (excipient) Drug Master File** your regulatory team can reference – the QA record and the regulatory dossier are one and the same.

Comparability is preserved by design. Because you **develop on the same GMP-grade material you scale and file with**, there is no RUO → GMP grade switch to revalidate, and you avoid the comparability studies a late material change forces – exactly where they hurt most in the lifecycle. Consistent lot-to-lot chemistry also means **fewer deviations, investigations and out-of-specification surprises** to work through.

The modern impurity dossier is prepared ahead of you. Beyond the compendial minimum, PAN documents the classes a current filing actually has to clear – elemental impurities (ICH Q3D), residual solvents (Q3C), nitrosamines (EMA guidance) and TSE/BSE from non-animal materials – so the questions are answered before they are asked. (See the technical paper [Beyond Compendial: buffers & reagents](#) in the Knowledge Hub.)

And material-change risk is managed for you as the ground shifts: the **REACH phase-out of Triton™ X-100** is met with a stocked, **animal-free** option (PANclear APG); recombinant HSA reduces adventitious-agent risk, and formal change notification keeps your control strategy current. Stability support is available on request.

## Reference our filing instead of re-proving the material

The centrepiece is the **Drug Master File**. PAN holds **two filed FDA DMFs – DPBS (Type IV, MF044371) and WFI Beyond (MF044505)**. You cross-reference them in your IND/BLA through a **Letter of Authorization**, so you neither re-prove nor reverse-engineer the material, and PAN's proprietary detail stays in the FDA's confidential file – protected on both sides. Both are **Type IV DMFs – the FDA's category for excipients**, the correct classification for these materials in a finished drug, so you reference them as exactly what your submission uses them as, rather than building a dossier of your own; in practice, cross-referencing one can take **months** of independent testing and validation off the critical path.

The wider dossier is built to survive review, not just to pass it. Beyond the compendial minimum, PAN documents the impurity classes a modern filing actually has to clear – elemental impurities (ICH Q3D), residual solvents (Q3C), nitrosamines (EMA guidance) and TSE/BSE freedom from non-animal materials – so agency questions are answered before they are asked and **information requests are fewer and faster to close**. (See the technical paper [Beyond Compendial: buffers & reagents](#) in the Knowledge Hub.)

Continuity is a regulatory property too. Because you **develop on the same GMP-grade material you file with**, the material referenced in your control strategy doesn't change under you late in development, and formal **change notification** keeps that strategy current as the ground shifts – the **REACH phase-out of Triton™ X-100**, for instance, is already met with a stocked, animal-free option rather than a scramble and a variation. Fewer unplanned material changes means fewer comparability studies and post-approval variations.

Where a product you rely on isn't yet filed, **PAN-Celltech will write and file a custom DMF on request** – a maintained, living dossier (annual updates, change control), which is why it signals a long-term supply relationship rather than a spot buy. DMF and stability support are optional, on-request services.

## Compress the timeline; keep the option to pivot

The strategic case is simple: cost and risk concentrate **downstream**, so standardizing that step is where timelines are won. On-stock GMP inputs plus DMF-backed references can take **months** out of qualification and filing – and in this industry, time is capital. Every month cut from the path to clinic is a month less cash burned and a month earlier to data, to the next raise, or to market.

The larger prize is **de-risking the asset itself**. The fear voiced across the industry is not a slow buffer order – it is a **Phase 1-3 programme that fails on something avoidable**: a material change forcing comparability work, a storage or stability surprise in a nearly-finished, high-value batch, a supply gap at the worst moment. Standardizing and de-risking the hardest, most expensive part of manufacturing removes exactly those failure modes – which is also the story that **diligence teams and investors want to see** on the supply and CMC side of a programme.

Just as important is **optionality**. Because one qualified foundation serves four modalities, a pipeline can pivot (mAb → vaccine → mRNA → cell & gene) **without supply-chain whiplash** – the materials, documentation and DMF backing are already in place – and held stock absorbs the upside case if demand or a forecast is exceeded. You keep the freedom to change direction without re-sourcing, re-qualifying and restarting the clock.

That reframes PAN from a vendor of liquids into a **partner that removes time and risk from your path to the clinic** – upstream to downstream, bench to commercial fill – backed by external recognition (Pharma Tech Outlook's "Top 10 CMOs in Europe", 2024) and a proven continuity record. And by standardizing the most expensive part of manufacturing, it lowers the barrier for smaller and specialised developers to bring therapies – including for rarer diseases – faster to patients who would otherwise wait.

## A supply partner you can build on – and offer to your own clients

For a contract manufacturer, PAN sits on both sides of the equation. As **your** supplier, one qualified GMP foundation – media, sera, supplements, water and the 31-product downstream range, all with a CoA per lot and DMF-backed key utilities – lets you **standardise incoming materials across every client programme** rather than re-qualifying a different buffer set for each. Fewer vendors, one documentation and packaging standard, one audit story to maintain: the same consolidation your clients value, applied to your own supply base.

It also gives you something to **resell to your clients**. A DMF-backed, EU Annex 1, audit-proven input train – with WFI Beyond and the on-stock downstream foundation behind it – is a regulatory and continuity story you can carry into your own pitches and audits, strengthening the case a sponsor hears when they choose you. And because the key inputs (DPBS and WFI Beyond) are filed as **Type IV (excipient) Drug Master Files**, your clients can reference them directly in their own submissions – a regulatory asset you pass straight through to the sponsor. Standardised, well-documented incoming material is one less variable in every programme you run. More than that, the open, modular range lets you **help your own clients standardise and de-risk** – putting the full set of options in front of them (GMP-grade material from bench to commercial, DMF backing, on-stock flexibility, and research-grade or custom formulation on request) as part of the service you wrap around their programme.

As a **capacity partner**, PAN-Celltech runs custom-formulated GMP (EU Annex 1) production, including **private-label lines and custom single-use packaging**, with scale to match: combined output **up to ~1.8 million litres a year**. Because the foundation is held on stock and modular, it also gives you room to **absorb demand swings** – a forecast exceeded, a client's programme accelerating – without a fresh qualification cycle each time.

The continuity record matters most here. When an incumbent supply was disrupted, PAN bridged an entire specialty portfolio end-to-end – standing up roughly two dozen products and supplying **~150,000 L / ~300,000 bottles over ~2 years with zero rejections** (read the anonymised story in the Knowledge Hub at [pan-biotech.com/knowledge-hub](https://pan-biotech.com/knowledge-hub)). That work is externally recognised: PAN-Biotech was named among **Pharma Tech Outlook's "Top 10 Contract Manufacturing Organizations in Europe" (2024)**. For a CDMO whose own reputation rests on never missing a client delivery, that is the second-source security and speed you can underwrite – and because it is the same GMP-grade material from early development through to commercial supply, you can take a client's programme the whole way on one consistent, filed material set.

## In one arc

38 years of upstream expertise → an EU Annex 1 GMP capability with the workhorses held on stock → water engineered beyond the monograph → DMF-backed regulatory confidence → a complete 31-product downstream foundation for four applications. Upstream to downstream, bench to commercial fill on one GMP-grade material set – from a single partner whose

reason for building all of this is to take risk and time out of *your* path to the clinic.

## Working with PAN

There are two ways in. **Develop with us:** build your process on the GMP-grade material you will scale and file with – the same liquid from bench to commercial fill, with a research-grade (RUO) build available on request. Or **switch to us:** qualify one audited GMP source across your downstream train and retire a fragmented supplier base. Commercial terms and price lists, samples, product specifications 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** – GMP-grade material for development and scale, research-grade (RUO) builds on request, samples and product specifications.

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

**Procurement** – price lists and framework/supply-agreement terms, lead-time and stock commitments, and a TCO comparison for your current downstream basket.

**Quality Assurance** – specifications and CoA samples, audit access and a quality agreement, and change-notification terms.

**Regulatory Affairs** – DMF numbers and Letters of Authorization, regulatory documentation, impurity and change-notification terms, and custom-DMF scoping.

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

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

## APPENDIX

### The 31-product downstream foundation – catalogue reference

The Open Downstream range in full: exact product name, GMP article number (**CT-**), the research-grade number (**P-**) where one is published, and the single stocked fill size. **Larger formats – 1000 ml bottles and single-use, pre-sterilised bags from 1 L to 1000 L – are available on request**, with the article number created on order, and a **WFI Beyond** version of every buffer is available on request.

| Product                                                  | GMP art. no.     | RUO grade | Stocked fill size          |
|----------------------------------------------------------|------------------|-----------|----------------------------|
| <b>1 • FOUNDATION – WATER &amp; ISOTONIC BASES</b>       |                  |           |                            |
| WFI-quality Water (+ WFI Beyond opt-in)                  | <b>CT-991500</b> | –         | 500 ml                     |
| DPBS w/o Ca & Mg                                         | <b>CT-36500</b>  | P04-36500 | 500 ml                     |
| DPBS 10× w/o Ca & Mg                                     | <b>CT-53500</b>  | P04-53500 | 500 ml                     |
| <b>2 • SALTS &amp; IONIC-STRENGTH STOCKS</b>             |                  |           |                            |
| NaCl 5 M, Stock Solution                                 | <b>CT-77055</b>  | –         | 500 ml                     |
| Ammonium Sulfate 1 M                                     | <b>CT-67500</b>  | –         | 500 ml                     |
| Ammonium Sulfate 3 M                                     | <b>CT-68500</b>  | –         | 500 ml                     |
| Magnesium Chloride 1 M solution                          | <b>CT-75100</b>  | –         | 100 ml                     |
| <b>3 • PH / BUFFERING STOCKS</b>                         |                  |           |                            |
| Tris Buffer 1 M, pH 8.4                                  | <b>CT-05500</b>  | –         | 500 ml                     |
| Phosphate Buffer 100 mM                                  | <b>CT-18810</b>  | –         | 100 ml & 500 ml            |
| Sodium Acetate 100 mM, pH 4.5                            | <b>CT-76451</b>  | –         | 500 ml                     |
| Citrate Buffer 100 mM, pH 3.0                            | <b>CT-62500</b>  | –         | 500 ml                     |
| Glycine 100 mM Buffer, pH 3.0                            | <b>CT-69500</b>  | –         | 500 ml                     |
| Histidine 100 mM                                         | <b>CT-69510</b>  | –         | 100 ml                     |
| HEPES Buffer 1 M                                         | <b>CT-01100</b>  | –         | per catalogue <sup>†</sup> |
| Sodium citrate, neutral (~pH 6.5)                        | <b>CT-62310</b>  | –         | 100 ml                     |
| <b>4 • CHELATION, LYSIS &amp; NUCLEIC-ACID CLEARANCE</b> |                  |           |                            |
| EDTA 0.5 M, pH 8.0                                       | <b>CT-10500</b>  | –         | 500 ml                     |
| PANclear Octoxynol 10% Solution                          | <b>CT-01001</b>  | –         | 100 ml                     |
| Potassium acetate 3 M, pH 5.5                            | <b>CT-76500</b>  | –         | 500 ml                     |
| SDS 10%                                                  | <b>CT-06500</b>  | –         | 500 ml                     |
| PANclear APG 10% Solution                                | <b>CT-01101</b>  | –         | 100 ml                     |
| <b>5 • CIP, SANITISATION &amp; STORAGE</b>               |                  |           |                            |
| NaOH 1 M, Stock Solution                                 | <b>CT-55105</b>  | –         | 500 ml                     |
| Ethanol 20%                                              | <b>CT-89500</b>  | –         | 500 ml                     |
| <b>6 • STABILISERS &amp; FORMULATION EXCIPIENTS</b>      |                  |           |                            |
| Sucrose 30% Stock Solution                               | <b>CT-00131</b>  | –         | 100 ml                     |

| Product                                | GMP art. no.    | RUO grade | Stocked fill size |
|----------------------------------------|-----------------|-----------|-------------------|
| Trehalose 30% Stock Solution           | <b>CT-00231</b> | –         | 100 ml            |
| Polysorbate 20 (PS20) 1%               | <b>CT-00211</b> | –         | 100 ml            |
| Polysorbate 80 (PS80) 1%               | <b>CT-00311</b> | –         | 100 ml            |
| Glucose 20% Stock Solution             | <b>CT-00331</b> | –         | 100 ml            |
| L-Arginine 1 M, pH 7.0                 | <b>CT-69520</b> | –         | 100 ml            |
| Mannitol 10% (w/v)                     | <b>CT-00401</b> | –         | 100 ml            |
| Recombinant human serum albumin (rHSA) | <b>CT-27500</b> | –         | 100 ml            |
| Glycerol 20% (v/v)                     | <b>CT-00901</b> | –         | 100 ml            |

**31 catalogue products in six functional families.** Article numbers are PAN-Celltech GMP catalogue references (CT-); the catalogue is **GMP**, and a **research-grade (RUO) version** can be produced as a custom build on request, carrying its own **P-** catalogue number where a research grade is already published (shown here for the DPBS family). Every buffer is additionally available in a **beyond-compendial (WFI Beyond)** version, and any product can be supplied as a fully custom GMP formulation, on request. † HEPES Buffer 1 M stocked size per current catalogue – confirm with your PAN contact.

## The water portfolio

Water is the base of every buffer, medium and final formulation, so the same range underpins the whole downstream train across grades. **WFI Beyond is opt-in**, ordered where a molecule earns it; larger formats and custom fills are available on request.

| Product                        | Grade                   | Article no.                  | Pack / fill size                                                                                             | Regulatory                                    |
|--------------------------------|-------------------------|------------------------------|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Sterile Water for Cell Culture | Research (RUO)          | <b>P04-991500</b>            | 500 ml; other sizes on request                                                                               | Research use                                  |
| WFI Quality Water              | GMP · WFI (EP/USP)      | <b>CT-991500 · CT-991000</b> | 500 ml / 1000 ml; fill range 10 ml–1000 L on request                                                         | CoA per lot                                   |
| WFI Beyond                     | GMP · beyond-compendial | <b>CT-98 series</b>          | 500 mL & 1000 mL bottles; single-use gamma-irradiated bags 1–1000 L; custom fills from 1 mL tubes on request | Filed FDA Type IV DMF (MF044505); CoA per lot |

The research grade (P-series) and GMP grades (CT-series) share a matched continuum. The full water story – WFI Beyond’s beyond-compendial specification and its filed FDA Type IV (excipient) Drug Master File – is told in **In-Depth · Industry Edition D02 · Water**.

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