

One Foundation for Cell & Gene Therapy

One qualified, serum-free and xeno-free toolkit for the whole process – a shared upstream, then the cell-therapy, viral-vector and plasmid-DNA tracks – from research grade to custom GMP on the identical products.

Cell & gene therapy inverts the economics of a biologic. Batches are small and often autologous, a batch can be a single patient's dose, and the product is living cells or a vector that goes **into the patient** – so whatever the inputs carry goes in with it and **cannot be purified or depyrogenated out afterward**. That makes the quality of the media, buffers and water a direct **patient-safety** question, not a procurement one. This briefing shows how one coherent, serum-free range covers the entire process, and how the water underneath it – **WFI Beyond**, nuclease-free and ultra-low in endotoxin – is the single input where the stakes are highest. A process built this way carries the mark **Built on WFI Beyond**.

[Download the PDF](#)

[The cell & gene therapy toolkit](#)

[Read Edition D02 – Water](#)

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

In-Depth · Industry Edition A03 · Rev 1.0 · 3 Oct 2026 · Author: Jens Hartmann, CEO, PAN-Biotech & PAN-Celltech · a briefing for pharma, biotech & CDMO teams.

Key takeaways

- Cell & gene therapy inverts the usual economics: **tiny, often autologous, patient-specific batches** where a batch can be one patient's dose – so a failed input is not a lost batch, it can be a patient who misses a therapy.

- The product is **living cells or a vector that goes into the patient**. There is no terminal purification of a cell therapy, so **whatever the inputs carry goes into the final product** – input quality is patient safety, directly.
- The process is **one shared upstream** (cell bank & thaw, collection/isolation, expansion/activation, vector production/transfection) that **branches into three tracks**: cell therapy (the cells are the product), viral vector / gene therapy (full AAV/LV downstream) and plasmid DNA.
- PAN covers it with **one serum-free, xeno-free range** – media for immune, stem, mesenchymal and neural cells, cytokines and growth factors, HEK293 vector-production media, and the buffers and stock solutions for the downstream – **research grade today, the identical products custom GMP on request with no reformulation**.
- **Water is the sharpest input**. WFI Beyond is **nuclease-free** (RNase and DNase not detected) so it cannot degrade a plasmid, RNA or vector genome; **endotoxin more than 50x below the limit** (spec < 0.005 EU/mL) so no pyrogen is carried into the cell product; sterile, animal-component-free, with all **24 ICH Q3D elemental impurities measured by ICP-MS** on every lot.
- **DPBS and WFI Beyond are backed by filed FDA Type IV (excipient) DMFs** (MF044371, MF044505), referenceable through a Letter of Authorization – months off the filing critical path.
- Delivered by a GMP operation proven at commercial scale – up to ~1.8M L/year capacity, ~150,000 L over ~2 years with zero rejections – and recognised among Pharma Tech Outlook's Top 10 CMOs in Europe (2024). A process built this way is **Built on WFI Beyond**.

READ BY FUNCTION

A shared story, then a section written for your role: **Developers & Researchers** · **Production** · **Procurement** · **Quality Assurance** · **Regulatory Affairs** · **Decision-makers & BD** · **CDMOs & CMOs**

ONE TOOLKIT, THE WHOLE THERAPY

The cell & gene therapy process, on one foundation

One shared upstream, three modality tracks, one serum-free range – qualify once and carry it from the patient's cells to the final, cryopreserved dose.

1 upstream · 3 tracks

Shared cell bank, isolation and expansion, then the cell-therapy, viral-vector and plasmid-DNA routes – all from one range.

serum-free · xeno-free

Defined serum replacements and xeno-free supplements across immune, stem, mesenchymal and neural cells – research to GMP.

nuclease-free water

WFI Beyond carries no RNase or DNase, so it cannot degrade the plasmid, RNA or vector genome that is the therapy.

2 filed FDA DMFs

DPBS (MF044371) and WFI Beyond (MF044505) – Type IV (excipient), referenceable by Letter of Authorization.

SECTION 1

Where the cost and the risk sit in a cell & gene therapy

In antibody manufacturing the cost and the risk have moved downstream, into a long purification train. Cell & gene therapy is different in kind. Here the batch is **small and often autologous** – made from one patient's own cells, for that one patient – so there is no large lot to average a deviation across, and a failed batch is not simply remade: it can mean a **patient who misses a treatment window**. The value and the risk are concentrated not in a step, but in the **irreplaceability of the material**.

And the product is unlike a molecule. A cell therapy **is living cells**; a gene therapy is a **vector or a plasmid** that will be introduced into cells. Either way, the therapeutic goes into the patient, and there is **no terminal sterilisation and no final purification** that can strip out what the process put in. Whatever an input carries – an endotoxin, a trace of a nuclease, a contaminant – **travels with the product into the patient**. That reframes every media bottle,

every buffer and above all the water: in cell & gene therapy, **input quality is patient safety, measured directly.**

There is no step at the end that rescues a bad input. In cell & gene therapy, the quality you buy is the quality the patient receives.

SECTION 2

One shared upstream, then three tracks

The process can be written as **thirteen steps**. The first four are a **shared upstream** common to every modality; the process then **branches into three tracks**. In **cell therapy** the cells are the product, so after modification the route is harvest and wash, formulate, fill and cryopreserve – there is no lysis, no nuclease digestion and no chromatography, because there is no molecule to purify out of the cells. In **viral-vector / gene therapy** (AAV, lentivirus) and **plasmid DNA**, the product is released from the cells and runs a full downstream – lysis, nuclease treatment, clarification, capture, polishing, concentration and formulation. PAN supplies the process liquids for every step of all three.

Step	Stage	What happens
SHARED UPSTREAM (USP) · EVERY MODALITY		
S1	Cell bank & thaw	Thaw of MCB/WCB, DMSO handling, washing and viability check.
S2	Cell collection / isolation	Density-gradient separation and washing of primary cells (PBMC, MNC).
S3	Cell expansion / activation	Expansion and activation of immune, stem and mesenchymal cells on serum-free media with cytokines.
S4	Vector production / transfection	HEK293 transfection for AAV / lentiviral vector production; plasmid (pDNA) supply.
DOWNSTREAM (DSP) · VIRAL VECTOR / GENE THERAPY & PLASMID DNA · (CELL THERAPY BRANCHES - SEE NOTE)		
S5	Harvest & lysis	Cell harvest; lysis to release the vector or plasmid (alkaline lysis for pDNA). Cell therapy: harvest & wash, no lysis.
S6	Nuclease treatment	

Step	Stage	What happens
		Broad-range endonuclease digests host-cell and residual DNA. Not used in cell therapy.
S7	Clarification	Depth filtration → 0.2 µm; clarified vector or plasmid stream.
S8	Capture / affinity	AAV/LV affinity or ion-exchange capture; plasmid capture.
S9	Polishing / IEX	Charge/size polishing; full/empty capsid separation for viral vectors.
S10	UF/DF	Concentration and buffer exchange into the formulation buffer.
S11	Formulation	Final formulation; cryoprotectants and stabilisers (glycerol, sucrose, trehalose, rHSA, poloxamer).
S12	Fill & cryopreservation	Fill – down to custom 1 mL vials – and cryopreservation (Cryopan II / III).
ACROSS ALL TRACKS		
S13	QC & stability	Endotoxin, sterility, residual nuclease, identity and potency; ICH Q1A stability; DMF-backed support.

Reading the branch. Cell therapy runs the shared upstream (S1–S4), then genetic modification / transduction, harvest and wash, formulation (S11), fill and cryopreservation (S12), and QC (S13) – it skips the lysis, nuclease and chromatography steps (S5–S10), because the cells are the product and nothing is being purified out of them. Viral-vector / gene therapy and plasmid DNA run the full downstream.

SECTION 3

One serum-free foundation – a handful of recurring stocks

Beneath the three tracks is a single, coherent range. Its upstream half is built on **serum-free and xeno-free media** – defined serum replacements (Panexin CD / basic / NTA), human platelet lysate instead of foetal serum, and dedicated media for immune cells (Panserin, Pancell T, Lymphopan), stem and mesenchymal cells (PowerStem MSC1, Mesenpan, Endopan), neural cells (Neuropan) and haematopoietic cells (Marrowpan, ErythroPlus), with recombinant human cytokines and growth factors (IL-2, IL-15, FGF-2, SCF, TGF-β1, EGF, LIF, HGF). Its downstream half is built, exactly as the antibody and

downstream editions describe, from a **small set of concentrated stock solutions that recur again and again**.

The recurrence is the economy. Across the thirteen steps, **WFI-quality water is the base of ten of them** and **DPBS recurs in eight**, from cell washing through to downstream buffers; Tris, NaCl 5 M, histidine, glycerol and the cryo/stabiliser excipients each serve several steps. Qualify a handful of stocks once, and they carry across the whole process – fewer SKUs to qualify, full flexibility to prepare working buffers, and one consistent chemistry from the bench to the clinic.

THE VALUE, STATED PLAINLY

Serum-free, xeno-free – from research to GMP

Every upstream medium in the range is offered **research-grade today**, and the **identical product** is available **custom GMP on request, with no reformulation**. So the media a team screens, selects and optimises its cells on is the media it scales and files with – no serum to remove, no xenogeneic components to justify to a regulator, and **no comparability gap** opening up when a programme crosses from research into GMP. Research today, GMP tomorrow, on the same defined chemistry.

SECTION 4

Delivered as process bundles – one box per step

PAN delivers the range the way the process runs it – as **step-specific process bundles**, one box per step, each holding the exact set of liquids that step needs, every bottle labelled with its name, article number, lot, volume, storage and production date. A team orders the **bundle for its process step** – the *Cell Expansion Bundle*, the *Vector Production Bundle*, the *Nuclease & Clarification Bundle*, the *Formulation & Fill Bundle* – rather than assembling a catalogue list and reconciling it on receipt. The shared upstream bundles are **research-grade today, custom GMP on request**; the downstream buffer bundles are **GMP grade**, and any buffer in them can be produced on the **WFI Beyond** water base as an added safety standard (Section 7). Full component-and-article-number listings are in Appendix A.

SECTION 5

Upstream: from the patient's cells to an activated culture

The shared upstream takes cells from the bank or the patient into an expanded, activated culture. **Cell bank & thaw (S1)** runs on WFI-quality water and DPBS with **Cryopan II / III** for cryopreservation (DMSO and DMSO-free).

Collection / isolation (S2) separates primary mononuclear cells on **Pancoll** density-gradient medium with HBSS/EBSS balanced-salt washes.

Expansion / activation (S3) is where the serum-free range does its work: **Panserin 701 and Pancell T** for immune and T cells, **PowerStem MSC1 and Mesenpan** for mesenchymal cells, **Neuropan** for neural cells, the **Panexin** serum replacements and **human platelet lysate** in place of foetal serum, and the recombinant cytokines (IL-2, IL-15, FGF-2 and the rest) that drive proliferation and activation – with Accutase for gentle dissociation and the stocks that buffer and protect the culture.

Vector production (S4) adds the HEK293 route for gene therapy:

Panserin 293A / 293S serum-free media for adherent and suspension HEK293, with glutamine and poloxamer shear protection, for AAV and lentiviral vector production and plasmid supply. Underneath all of it run the two universal utilities – **WFI-quality water** for every preparation and **DPBS** for washing and resuspension – so the upstream already shares its foundation with the downstream that follows.

SECTION 6

Downstream: releasing and purifying a vector or plasmid

For viral vector and plasmid programmes, the downstream begins where cell therapy stops. **Harvest & lysis (S5)** releases the vector or plasmid from the cells – alkaline lysis (NaOH, SDS, potassium acetate) for plasmid DNA.

Nuclease treatment (S6) then digests host-cell and residual DNA with a broad-range endonuclease and its magnesium cofactor – a step whose job is precisely to remove nucleic-acid contaminants, which is why the water it runs on must itself be nuclease-free. **Clarification (S7)** filters the stream; **capture (S8)** takes the vector or plasmid onto an affinity or ion-exchange resin on a Tris/NaCl base; **polishing (S9)** separates on phosphate/acetate bases – for viral vectors, the all-important **full/empty capsid separation**; **UF/DF (S10)** concentrates and exchanges into the formulation buffer.

Formulation (S11) stabilises the product for storage with the excipients cell & gene therapies rely on – **glycerol, sucrose, trehalose, recombinant human albumin, poloxamer** – and **fill & cryopreservation (S12)** fills to dose, down to **custom 1 mL vials** sized to a single manufacturing run, and cryopreserves. One qualified set of stocks carries the whole downstream, and every buffer in it can be built on WFI Beyond.

SECTION 7

Water, and why it matters most here

Water is the base of every medium, buffer and final formulation, so it sets the quality ceiling for the whole process. In cell & gene therapy that ceiling is not an abstraction: because there is no terminal purification, the water's quality **is carried into the patient**. And the pharmacopoeial Water for Injection monograph (Ph. Eur. 0169, its core dating to 1969) was never written for this – it limits conductivity, organic carbon and endotoxin, and is **silent on the two attributes that decide a gene-therapy input: nuclease activity and trace metals**. 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:

- **Nuclease-free** – RNase and DNase **not detected**. This is the attribute that matters most in gene therapy: a residual nuclease in the water would attack the very plasmid, RNA or vector genome that is the therapy. The monograph does not test for it.
- **Endotoxin more than 50x below the compendial limit** (spec < 0.005 EU/mL) – because endotoxin carried into a cell product cannot be removed afterward, and ex vivo cell culture leaves no margin.
- **Sterile** (0.1 µm filtered, filled into gamma-irradiated single-use containers) and **animal-component-free**, with a signed BSE/TSE and ICH Q3 declaration.
- **All 24 ICH Q3D elemental impurities specified and measured by ICP-MS** on every lot – a first for a water, since the monograph tests none of them.
- **DMF-backed** – a filed FDA Type IV (excipient) Drug Master File (MF044505), referenceable in an IND/BLA through a Letter of Authorization.

Why it matters for a cell or gene therapy. The two inputs most capable of silently harming an advanced therapy are a **residual nuclease** – which

degrades the nucleic-acid payload – and **endotoxin**, which travels into the patient with a product that cannot be depyrogenated. WFI Beyond is engineered against exactly those two. Controlling the water controls them at the source, upgrading every medium and buffer built on it. (*The full water story is In-Depth · Industry Edition D02 · Water: The WFI Beyond Standard.*)

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

A SAFETY STANDARD FOR A PRODUCT THAT REACHES THE PATIENT

Built on WFI Beyond

Because every medium and buffer in the range is built on a water base, the same upgrade is open to all of them. On request, the buffers for any step – or the whole process – can be produced on the **WFI Beyond** water base instead of standard WFI-quality water, giving the finished liquids the same nuclease-free, ultra-low-endotoxin, metal-controlled foundation. For a clinical cell or gene therapy, this is the **recommended safety standard**: it removes the two inputs most likely to harm the product, at the layer where it is cheapest to control.

How to get it. The WFI Beyond upgrade is **opt-in and made to order** – produced through PAN-Celltech's Custom Solutions / custom GMP program, with a Certificate of Analysis per lot and DMF-backed regulatory support, in formats from **custom 1 mL vials** up to 1000 L. Ask your PAN contact to build any step, or the whole process, 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 what these materials are in a finished cell or gene therapy, 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 – and a cell & gene therapy case

The GMP liquids are filled by the PAN-Celltech GMP 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):

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 CoA on every lot.

A representative case: a CAR-T developer needed the highest-quality water to dilute a plasmid before electroporating human T cells – and PAN-Celltech supplied **WFI Beyond custom-filled into 1 mL vials**, one vial per manufacturing run, for an early-phase programme – read the anonymised story, [WFI Beyond in 1 mL vials for clinical CAR-T manufacturing](#), in the Knowledge Hub. Track-record figures are anonymised; capacity figures are stated as "up to".

AUTHOR'S INSIGHT

The input that reaches the patient unfiltered

Across the interviews behind this series, one fear is specific to advanced therapies: that a developer does everything right in the clinic and is undone by **something the process carried in** – because here, uniquely, there is no purification at the end to catch it. A trace of a nuclease that quietly nicks a plasmid and drops a batch's potency; an endotoxin that a molecule could have been polished away from, but a living cell product cannot; a contaminant that in an antibody train would never have survived to the vial.

That is why, for a cell or gene therapy, the **media and the water are not commodities to be bought on price**. They are the parts of the process that reach the patient least changed. Controlling them up front – serum-free and xeno-free media that scale to GMP without a comparability gap, and water that is nuclease-free and ultra-low in endotoxin before it ever touches a cell – is among the **cheapest insurance an advanced-therapy programme can buy** against its most expensive kind of failure.

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

SECTION 10 • READ BY FUNCTION

What the one-foundation 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 therapy on one serum-free foundation

A cell or gene therapy process touches isolation media, a dozen serum-free expansion media and supplements, cytokines, vector-production media and – for vector and plasmid work – a full set of downstream buffers. Assembled from a scattered supplier base, each carries its own qualification and its own xenogeneic-component justification. PAN lets you build the whole thing on **one coherent, serum-free and xeno-free range**, and – because every upstream medium scales to the identical GMP product with no reformulation – the material you optimise your cells on is the material you file with. No serum to remove late, no comparability gap to close.

The chemistry is built for how advanced therapies behave – **defined serum replacements and human platelet lysate** instead of foetal serum, dedicated media for immune, stem, mesenchymal and neural cells, recombinant cytokines for activation, and a downstream of recurring stocks for vector and plasmid work – and every buffer can be built on **WFI Beyond** where a fragile payload earns it. (See the [cell & gene therapy toolkit](#) in the Knowledge Hub.)

B · PRODUCTION & MANUFACTURING

Ready-made media and buffers – fewer open events in a sterile suite

On the floor of a cell & gene therapy suite, every manual preparation is an **open event in an aseptic process** – and the batch is irreplaceable. Ordering the media, supplements and buffers **ready-to-use, in GMP grade with a CoA per lot**, in one packaging standard from a single qualified source, takes weighing, mixing and QC-checking off the floor and removes contamination entry points at the stage where contamination cannot be filtered out later. And you can order them **by the process step** – as a bundle, one labelled box carrying exactly what that step needs – instead of picking each item off a catalogue line.

It also fits how advanced therapies are dosed. Custom fills **down to 1 mL vials** mean one ready-to-use unit per manufacturing run – no opening a large container for a fraction of a millilitre, no carry-over between patients – and on-stock dispatch keeps a patient-scheduled campaign from waiting on a custom-manufacturing slot.

C · PROCUREMENT

Qualify one serum-free range, not a fragmented basket

Because a **handful of universal stocks** and a single serum-free media range cover the whole process, you qualify and carry far fewer SKUs than a product-by-product basket implies – fewer vendors, fewer audits, one documentation and packaging standard. The right lens is **total cost of ownership**, where for an advanced therapy the hidden tail is dominated by the cost of a **lost, irreplaceable batch** and the qualification burden of xenogeneic materials – both of which a single serum-free, GMP-grade, DMF-supported source collapses.

Held stock is insurance against a patient-driven schedule you cannot forecast. The reliability is proven: 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, and the attributes advanced therapies are judged on

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

The attributes that matter here are built in and documented: a **serum-free, xeno-free** position with a signed BSE/TSE declaration answering the adventitious-agent question up front; **nuclease-free, ultra-low-endotoxin water** on the Certificate of Analysis; and the modern impurity classes (ICH Q3D elemental impurities, residual solvents, nitrosamines) documented ahead of the questions. Stability support is available on request.

E · REGULATORY AFFAIRS

Reference our filings; answer the advanced-therapy questions once

The two universal utilities most likely to sit in a cell or gene therapy 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 product, without rebuilding a dossier or re-proving the material – months off the critical path.

Because one serum-free range carries the process from research to GMP on the identical chemistry, the material named in your control strategy is **consistent from the patient's cells to the final dose**, and the beyond-compendial dossier – serum-free / xeno-free with a signed BSE/TSE declaration, plus ICH Q3D, Q3C and nitrosamine assessment – answers the questions an advanced-therapy filing draws 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 timeline; de-risk an irreplaceable batch

For the fastest-growing, highest-value modality in the industry, **time to clinic and batch reliability are the asset**. One qualified, serum-free range across the whole process – research grade today, the identical GMP material tomorrow – plus DMF-backed references takes weeks-to-months out of qualification and filing and removes the serum-to-GMP comparability work that quietly slows an advanced-therapy programme.

The larger prize is **de-risking a batch that cannot be remade**. Removing the avoidable failure modes a fragmented, under-documented, serum-containing supply invites – an adventitious-agent finding, a nuclease or endotoxin surprise, a supply gap against a patient's schedule – is exactly the CMC and supply-chain diligence investors and partners look for in cell & gene therapy. It reframes PAN from a vendor of liquids into a partner that takes time and risk out of the path to the patient, backed by external recognition (Pharma Tech Outlook's "Top 10 CMOs in Europe", 2024) and a proven continuity record.

G · CDMOS & CMOS

A serum-free toolkit you can run – and offer to your clients

For a contract manufacturer running many advanced-therapy programmes, one qualified, serum-free range – media and supplements upstream, buffers and stocks downstream, all with a CoA per lot – lets you **standardise incoming materials across every client** rather than re-qualifying a different media and buffer set, with its own xenogeneic-component file, 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 custom single-use fill **from 1 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. The same serum-free GMP material serves a client's programme from early development through to commercial supply.

In one arc

One shared upstream, then three tracks – cell therapy, viral vector, plasmid DNA → a serum-free, xeno-free media range for immune, stem, mesenchymal and neural cells → the downstream stocks for vector and plasmid work → research grade today, the identical products custom GMP with no reformulation → water engineered beyond the monograph, nuclease-free and ultra-low in endotoxin → DMF-backed regulatory confidence. One foundation for the whole therapy, from a single partner whose reason for building it is to take risk and time out of *your* path to the patient.

DOCUMENTS – SELF-SERVICE

What to ask your PAN contact for

The cell & gene therapy toolkit specification, a representative Certificate of Analysis, a DMF Letter of Authorization, and the water story behind the safety standard.

TOOLKIT

The CGT process toolkit

Products by step, article numbers and process notes.

ON REQUEST

Certificate of Analysis

A representative production-lot CoA; a lot-specific CoA is issued with every delivery.

ON REQUEST

DMF Letter of Authorization

Reference our filed FDA Type IV DMFs – WFI Beyond (MF044505), DPBS (MF044371).

IN-DEPTH D02

The WFI Beyond Standard

The full water story behind the safety standard.

Downstream buffer bundles are GMP grade, manufactured by PAN-Celltech; the shared upstream media are research-grade today, the same products custom GMP on request with no reformulation. Human platelet lysate and recombinant cytokines are supplied research-grade (no GMP). Manufactured to GMP in an EU Annex 1 facility (a capability, not a certification). WFI Beyond is opt-in, for further manufacturing / as an excipient.

APPENDIX A · CATALOGUE REFERENCE

The cell & gene therapy toolkit – by process step

Key products by step, with article numbers. The **shared upstream (S1–S4)** media are **research-grade (P- numbers)** unless shown as GMP – the same products available custom GMP on request with no reformulation; the **downstream buffers (S5–S12)** are **GMP (CT- numbers)**. Every buffer is available **beyond-compendial**, produced with **WFI Beyond** (CT-981500) instead of standard WFI, on request. Pack sizes and article numbers are verified against PAN datasheets, Catalogue 03/2026 and the webshop.

Step	Key product	Article no.
SHARED UPSTREAM (USP) · S1–S4 · SERUM-FREE / XENO-FREE, RESEARCH GRADE (CUSTOM GMP ON REQUEST)		
S1 · Cell bank & thaw	WFI Quality Water (GMP)	CT-991500
	DPBS w/o Ca & Mg (GMP)	CT-36500
	Cryopan II, with DMSO (GMP)	CT-94100
	Cryopan III, DMSO-free (GMP)	CT-96100
	Penicillin-Streptomycin (GMP)	CT-07110

Step	Key product	Article no.
S2 · Cell collection / isolation	L-Glutamine 200 mM (GMP)	CT-80100
	RNase/DNase Neutralizer	P10-61500
	Pancoll Human 1.077 g/ml	P04-60500
	HBSS w: Ca & Mg	P04-32500
	EBSS w/o Ca & Mg	P04-31500
	DPBS w/o Ca & Mg (GMP)	CT-36500
	WFI Quality Water (GMP)	CT-991500
S3 · Cell expansion / activation	Panserin 701 (immune cells)	P04-710701
	Pancell T Kit (T cells)	P04-710414K
	Panserin 413 (lymphocytes)	P04-71413
	Lymphopan	P04-70700
	ErythroPlus (erythroid)	P04-20251K
	PowerStem MSC1 Kit (MSC)	P04-77355K
	Endopan 3 Kit (endothelial)	P04-0010K
	Mesenpan Kit (MSC, xeno-free)	P08-50400K
	Neuropan (neural)	P04-00900
	Marrowpan (bone marrow)	P04-70250
	DMEM w: stable Gln (GMP)	CT-04500
	RPMI 1640 w: stable Gln (GMP)	CT-18500
	DMEM/F-12	P04-41150
	IMDM	P04-20150
	Panexin CD (serum replacement)	P04-93100
	Panexin basic (serum replacement)	P04-96900
	Panexin NTA (serum replacement)	P04-95700

Step	Key product	Article no.
	hPL def b (human platelet lysate)	P40-28050
	ITS Solution I	P07-03100
	Stable Glutamine 200 mM	P04-82100
	IL-2 human rec.	CB-2130203
	IL-15 human rec.	CB-2131500
	FGF-2 human rec. (bFGF)	CB-1102024
	SCF human rec.	CB-1110000
	TGF- β 1 human rec.	CB-1111131
	EGF human rec.	CB-1101001
	LIF human rec.	CB-1106001
	HGF human rec.	CB-1108002
	Accutase (dissociation)	P10-21500
	Trypsin 0.05 % / EDTA 0.02 % in DPBS	P10-029100
	Gentamicin Sulfate 10 mg/ml	P06-03050
	Amphotericin B 250 μ g/ml	P06-01050
	Pluronic F-68 10 %	P08-02100
	Sodium Bicarbonate 7.5 %	P04-44100
	HEPES Buffer 1 M (GMP)	CT-01100
S4 · Vector production / transfection	Panserin 293A (adherent HEK293)	P04-710608
	Panserin 293S (suspension HEK293)	P04-710609
	L-Glutamine 200 mM (GMP)	CT-80100
	Pluronic F-68 10 %	P08-02100
	WFI Quality Water (GMP)	CT-991500
	Transfection reagent (PEI)	coming soon

Step	Key product	Article no.
DOWNSTREAM (DSP) · S5-S12 · GMP BUFFERS & STOCK SOLUTIONS (VIRAL VECTOR / PLASMID; CELL THERAPY USES S11-S12 ONLY)		
S5 · Harvest & lysis	NaOH 1 M Stock	CT-55105
	SDS 10 %	CT-06500
	Potassium acetate 3 M	CT-76500
	Tris Buffer 1 M	CT-05500
	WFI Quality Water	CT-991500
S6 · Nuclease treatment	Broad-range endonuclease (article under revision)	on request
	Magnesium Chloride 1 M (cofactor)	CT-75100
	Tris Buffer 1 M	CT-05500
	WFI Quality Water	CT-991500
S7 · Clarification	DPBS w/o Ca & Mg	CT-36500
	NaCl 5 M Stock	CT-77055
	WFI Quality Water	CT-991500
S8 · Capture / affinity	Tris Buffer 1 M	CT-05500
	NaCl 5 M Stock	CT-77055
	Phosphate Buffer 100 mM	CT-18810
	Sodium acetate 100 mM	CT-76451
	WFI Quality Water	CT-991500
S9 · Polishing / IEX	Phosphate Buffer 100 mM	CT-18810
	NaCl 5 M Stock	CT-77055
	Ammonium Sulfate 1 M	CT-67500
	Ammonium Sulfate 3 M	CT-68500
	Citrate Buffer 100 mM	CT-62500
	Glycine 100 mM	CT-69500

Step	Key product	Article no.
S10 · UF/DF	WFI Quality Water	CT-991500
	Histidine 100 mM	CT-69510
	Phosphate Buffer 100 mM	CT-18810
	NaCl 5 M Stock	CT-77055
	Sodium citrate neutral 100 mM	CT-62310
	DPBS w/o Ca & Mg	CT-36500
S11 · Formulation	WFI Quality Water	CT-991500
	Glycerol 20 %	CT-00901
	Sucrose 30 %	CT-00131
	Trehalose 30 %	CT-00231
	rHSA 20 %	CT-27500
	Mannitol 10 %	CT-00401
	L-Arginine 1 M	CT-69520
	Histidine 100 mM	CT-69510
	EDTA 0.5 M	CT-10500
	Poloxamer (Pluronic F-68 10 %)	P08-02100
	WFI Quality Water	CT-991500
	Cryopan II, with DMSO	CT-94100
S12 · Fill & cryopreservation	Cryopan III, DMSO-free	CT-96100
	Glycerol 20 %	CT-00901
	rHSA 20 %	CT-27500
	Custom 1 mL fill	on request
	WFI Quality Water / WFI Beyond	CT-991500 / CT-981500

Step	Key product	Article no.
S13 · QC & stability · service	Release testing: CoA per lot, endotoxin (LAL), residual nuclease, bioburden & sterility, ICH Q1A stability, DMF / LoA	-

Universal utilities. WFI Quality Water (CT-991500) recurs across ten steps and DPBS (CT-36500) across eight; Tris, NaCl 5 M and the cryo/stabiliser excipients serve several each. **WFI Beyond** (CT-981500) is Water for Injection engineered beyond Ph. Eur. monograph 0169 – nuclease-free (RNase & DNase not detected), endotoxin < 0.005 EU/mL (>50x below limit), all 24 ICH Q3D elements by ICP-MS – and, with DPBS, is backed by a filed FDA Type IV (excipient) DMF (MF044505, MF044371). The shared upstream media (S1-S4) are serum-free / xeno-free, research grade today and custom GMP on request with no reformulation; human platelet lysate and recombinant cytokines are research grade (no GMP). Full specifications and current article numbers on request.

FREQUENTLY ASKED QUESTIONS

The cell & gene therapy toolkit, answered

Why is input quality a patient-safety question in cell & gene therapy? +

Because the product is living cells or a vector that goes into the patient, and there is no terminal sterilisation or final purification to strip out what the process put in. Whatever an input carries – endotoxin, a residual nuclease, a contaminant – travels with the product into the patient. So the quality of the media, buffers and water is carried through to the patient directly.

How does one toolkit cover three different modalities? +

The process shares one upstream – cell bank & thaw, collection/isolation, expansion/activation and vector production/transfection – and then branches. Cell therapy (the cells are the product) runs the upstream plus modification, harvest, formulation and fill, skipping lysis, nuclease and

chromatography. Viral vector / gene therapy and plasmid DNA run the full downstream. One serum-free media range and one set of recurring downstream stocks serve all three.

What does "serum-free, xeno-free – from research to GMP" mean in practice? +

Every upstream medium is offered research-grade today, and the identical product is available custom GMP on request with no reformulation. There is no serum to remove and no xenogeneic component to justify to a regulator, and no comparability gap when a programme crosses from research into GMP, because the chemistry does not change.

Why does nuclease-free water matter most in gene therapy? +

Because the therapeutic payload is a nucleic acid – a plasmid, an RNA or a vector genome – and a residual nuclease in the water would degrade exactly that. The pharmacopoeial Water-for-Injection monograph does not test for nuclease activity. WFI Beyond is nuclease-free: RNase and DNase are not detected, so the water cannot attack the payload.

What does "Built on WFI Beyond" mean for a cell or gene therapy? +

Every medium and buffer is built on a water base, so any step – or the whole process – can be produced on the beyond-compendial WFI Beyond water base instead of standard WFI. That removes the two inputs most likely to harm an advanced therapy – residual nuclease and endotoxin – at the cheapest layer to control. It is opt-in and made to order, with a CoA per lot and DMF-backed support, in formats from custom 1 mL vials up to 1000 L.

Can I reference the Drug Master File in my submission? +

Yes. DPBS and WFI Beyond are backed by filed FDA Type IV (excipient) DMFs (MF044371, MF044505). You cross-reference them in your IND/BLA through a Letter of Authorization, so the material is referenceable as exactly what it is in the product without rebuilding a dossier.

Can I develop in research grade and move to GMP later?



Yes. The shared upstream media are research-grade today; the identical products ship custom GMP on request with no reformulation, across immune, stem, mesenchymal and neural cells and the HEK293 vector-production media. So the material you optimise your cells on is the material you scale and file with.

GO FURTHER

Related reading

IN-DEPTH D02

The WFI Beyond Standard

The full water story behind the safety standard.

CASE STUDY

WFI Beyond in CAR-T

Beyond-compendial water in 1 mL vials for clinical CAR-T manufacturing.

TOOLKIT

The CGT process toolkit

Products by step, with article numbers.

KNOWLEDGE HUB

Case studies & tech papers

The anonymised proof stories, in full.

Build your cell & gene therapy process on one foundation

Develop with us from research grade to the identical GMP material with no reformulation, or switch to us and qualify one audited, serum-free, DMF-backed range across your whole process. Request the specification, a Certificate of Analysis, a DMF Letter of Authorization, or a custom GMP quote – and put **Built on WFI Beyond** beneath your therapy.

[Start a Custom & GMP Project Enquiry](#)

info@pan-celltech.com

PAN-Biotech GmbH · PAN-Celltech GmbH (GMP arm / manufacturer of record). Made in Germany. GMP-compliant, audit-proven; EU Annex 1 is a capability, not a certification. WFI Beyond is opt-in and is an excipient for further manufacturing, not for direct human use.