

One Foundation for the Whole Vaccine Process

One qualified GMP supply base for the widest process in biomanufacturing – from cell-line-specific viral culture media, through harvest, nuclease treatment and purification, to excipient-grade formulation – that carries a vaccine from the substrate cell line to the final injectable.

A vaccine programme spans more of the process than almost any other modality: it starts with a **substrate cell line** and ends with a **formulated injectable**, and the two halves need completely different chemistry. Very few suppliers make both the **cell-line-specific viral culture media** and the downstream buffers, nuclease reagents and excipients – PAN-Biotech, **38 years deep in cell-culture upstream**, makes them under one roof. Every vaccine shares one upstream – expand a substrate, then infect or transfect it – and the downstream then branches by modality, but the buffer, nuclease and stabiliser chemistry is largely shared. This briefing shows how one coherent, qualified PAN range covers that whole span, and how the water underneath it – **WFI Beyond** – sets the quality floor for an injectable. A process built this way carries the mark **Built on WFI Beyond**.

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[The vaccine process toolkit](#)

[Read Edition D02 – Water](#)

BUILT ON WFI BEYOND

the mark for the water beneath a molecule that earns it.

Key takeaways

- Vaccines span the **widest process of any modality** – from a substrate cell line to a formulated injectable – and PAN is one of very few suppliers that makes **both the cell-line-specific viral culture media and the downstream chemistry**, under one roof.
- The shape is **one shared upstream, a modality-specific downstream**: every vaccine expands a substrate and infects or transfects it; the downstream then branches by modality (live/inactivated viral, recombinant subunit, viral-vector) – but the buffer, nuclease and stabiliser chemistry is **largely shared**.
- PAN's core expertise is **cell-line-specific viral culture media** – Vero, MDCK, BHK21, Sf9/Sf21 and Drosophila S2 – the substrates behind viral, subunit and vector vaccines, built on **nearly four decades of cell-culture upstream** and proven from research to GMP.
- A **small set of qualified PAN stocks recurs across the whole process**: WFI-quality water is the base of them all; Tris, NaCl 5 M, sucrose and DPBS recur again and again – fewer SKUs to qualify, one consistent chemistry.
- **Host-cell DNA clearance is a regulated release attribute** for cell-derived vaccines, so nuclease treatment (broad-range endonuclease, DNase I, magnesium cofactor) is a built-in step, not an afterthought.
- The final product is an **injectable**, so the **excipient-grade formulation set** – polysorbates, sucrose, trehalose, mannitol, glycerol, rHSA – and the **water underneath** set the quality floor. The final formulation can be built on **WFI Beyond**: ultra-low endotoxin (spec < 0.005 EU/mL, >50x below limit), sterile, animal-component-free, all 24 ICH Q3D elements by ICP-MS.
- Built for **speed against emerging pathogens**: rapid development and scale-up, proven at **~50,000 L of GMP supply delivered in under five weeks** (quote in 3 days).
- **DPBS and WFI Beyond are backed by filed FDA Type IV (excipient) DMFs** (MF044371, MF044505); research grade to GMP with no reformulation; delivered by a GMP operation in an EU Annex 1 facility, recognised among Pharma Tech Outlook's Top 10 CMOs in Europe (2024).

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 SUPPLY BASE, THE WHOLE PROCESS

The vaccine process, on one foundation

From the substrate cell line to the final injectable, built from a handful of recurring stocks on a WFI-quality water base – one qualified supplier from research to GMP.

substrate to vial

Cell-line-specific viral culture media, harvest, nuclease treatment, purification and excipient-grade formulation – one coherent range.

one upstream, a branching downstream

The same substrate expansion and infection feed every modality; the downstream chemistry is largely shared.

~50,000 L in < 5 weeks

Rapid GMP supply for emerging-pathogen timelines – quote in 3 days, delivered in under five weeks.

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 vaccine programme

Of all the modalities in this series, vaccines have the **widest process span**. A vaccine programme begins where a cell-therapy or antibody programme does – a **substrate cell line** that has to be grown, often to very large scale – and ends where an mRNA programme does – a **formulated, filled injectable**. Between those two points sit two quite different disciplines: the **biology of growing virus or antigen in a cell substrate**, and the **chemistry of clarifying, clearing, purifying and formulating** what comes out. Most suppliers are strong at one end or the other. The programme's cost, its timeline and much of its risk sit in **stitching the two halves together** from a fragmented supplier base – and in doing it fast, because vaccines are the one modality routinely built against an **emerging-pathogen clock**.

The upstream carries a particular dependency. A viral vaccine is only as good as the **cell substrate and the medium that grows it**: Vero, MDCK, BHK21, insect cells and others each need media tuned to the line, and switching medium mid-programme can change yield, glycosylation and the downstream clearance burden. The downstream carries a particular obligation: because the product is grown in cells, **residual host-cell DNA and host-cell protein are regulated impurities** with hard release limits, so nuclease treatment and purification are not polish steps but compliance steps. Sourcing the media, buffers, nuclease reagents and excipients that run all of this from many vendors is exactly what slows qualification and scale-up on a modality whose point is often to be ready first.

A vaccine starts as biology in a cell and ends as chemistry in a vial. The supplier who makes both the culture medium and the formulation buffer can carry the whole span – and carry it fast.

SECTION 2

One shared upstream, then a modality-specific downstream

Every vaccine starts the same way – expand a substrate cell line, then infect or transfect it – and PAN covers that shared upstream almost end to end, including the cell-line-specific viral culture media that define the platform. The downstream then branches by modality, but the buffer, nuclease and stabiliser chemistry is largely shared, so a small set of qualified stocks recurs across the whole process.

Step	Stage	What happens
SHARED UPSTREAM (USP) · SUBSTRATE, EXPANSION & INFECTION		
V1	Cell line development & maintenance	Master/working cell bank, cryopreservation, decontamination control – on a WFI-quality water base.
V2	Cell expansion	Substrate grown on cell-line-specific viral culture media (Vero, MDCK, BHK21, Sf9/Sf21, S2) with supplements.
V3	Virus infection / transfection	Infect the substrate with seed virus, or transfect for virus rescue, viral-vector and recombinant-antigen routes.

Step	Stage	What happens
MODALITY-SPECIFIC DOWNSTREAM (DSP) - HARVEST, CLEARANCE, PURIFICATION & FORMULATION		
V4	Viral harvesting & clarification	Harvest and clarify the virus or antigen; wash and dilution buffers on a WFI-quality base.
V5	Cell lysis (non-enveloped / lysis-based)	Solubilise or lyse to release intracellular virus or antigen (PANclear APG, SDS, EDTA).
V6	Nuclease treatment	Broad-range endonuclease and DNase I (magnesium cofactor) clear host-cell DNA/RNA to the regulated limit.
V7	Purification / chromatography	Capture and polish - IEX, density-gradient and buffer stocks (NaCl, Tris, phosphate, acetate, sucrose).
V8	Concentration / buffer exchange (UF-DF)	Concentrate and diafilter into the formulation buffer by tangential-flow filtration.
V9	Formulation (excipient grade)	Final injectable - tonicity, stabilisers, surfactants and diluent, on a WFI-quality / WFI Beyond base.
ACROSS THE CHAIN		
V10	QC & stability	Endotoxin, sterility, residual host-cell DNA, identity and potency; ICH Q1A stability; DMF-backed support.

Which downstream steps apply depends on the modality: enveloped live/inactivated viral vaccines are harvested, clarified, nuclease-treated and purified; non-enveloped or vector vaccines add a lysis step; recombinant subunit vaccines follow a capture-and-polish route. The shared buffer and stabiliser stocks recur across all of them.

SECTION 3

One foundation – a handful of stocks, reused across the process

Look across the steps and the same pattern appears as in every PAN process edition: the dozens of working media and buffers are built from a **small set of concentrated stock solutions that recur again and again. WFI-quality water is the base of every step. DPBS** runs through cell handling, infection and harvest; **Tris 1 M, NaCl 5 M** and **phosphate** recur across nuclease treatment, purification, exchange and formulation; the **magnesium cofactor** serves the nuclease step; and the formulation excipients – **sucrose**,

trehalose, mannitol, glycerol, polysorbate 20/80, rHSA – carry from stabilisation into the final injectable. Qualify a handful of stocks once, and they serve the whole process – fewer SKUs to qualify, one consistent chemistry from research to GMP.

THE VALUE, STATED PLAINLY

Media, buffer and excipient chemistry – from research to GMP

Every medium and stock in the range is offered **research-grade today**, and the **identical product** is available **GMP grade on request, with no reformulation**. The viral culture medium a team develops its substrate on, and the buffers it purifies with, are the materials it scales and files with – so there is **no comparability gap** opening up when a vaccine programme crosses from research into GMP, on the modality where being ready first can be the entire point.

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 media and 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 step** – the *Cell Expansion Bundle*, the *Nuclease Treatment Bundle*, the *Purification Bundle*, the *Formulation Bundle* – rather than assembling a catalogue list and reconciling it on receipt. The stocks are **research grade today, GMP on request**, and the downstream buffers 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

The substrate and the culture – where vaccine expertise lives

The upstream is where a vaccine programme is won or lost, and it is where PAN's deepest expertise sits. This is no recent extension: PAN-Biotech has spent **38 years on the cell-culture upstream** – the media, sera and supplements that keep cells productive and consistent – with a catalogue of

around **1,800 products** built over that time, and it is the house that developed **Panexin**, described as the **world's first serum-replacement product**. The cell-line-specific viral culture media sit squarely on that heritage. **Cell line development & maintenance (V1)** establishes and banks the substrate – master and working cell banks, cryopreserved in chemically defined, protein-free or DMSO-free freezing media, with antibiotics and glutamine for maintenance, all on a WFI-quality water base. **Cell expansion (V2)** is the heart of it: PAN makes **cell-line-specific viral culture media** for the substrates the industry actually uses – **Panserin ProVero for Vero** (polio, rabies, influenza), a **serum-free medium for MDCK** (influenza), **EMEM Fibroblast and Panserin 401 for BHK21**, **Spodopan for Sf9/Sf21 insect cells** (baculovirus, subunit and VLP) and **Schneider's Drosophila Medium for S2** – with the base media, supplements, dissociation reagents and shear protectant that round out a bioreactor process.

Virus infection / transfection (V3) then starts production: the substrate is infected with seed virus, or transfected for virus rescue, viral-vector vaccines and recombinant-antigen expression, on WFI-quality water and DPBS. Running this on **serum-free and protein-free media** is not just a safety-and-supply choice; it lowers lot-to-lot variability and cuts the **downstream clearance burden** – fewer undefined proteins to remove later. Because the identical media are available GMP on request with no reformulation, the substrate a programme develops on is the substrate it manufactures on.

SECTION 6

Harvest, host-cell DNA clearance, purification and formulation

The downstream turns a cell culture into a purified, formulated injectable. **Viral harvesting & clarification (V4)** recovers the virus or antigen on WFI-quality water and DPBS wash buffers; for non-enveloped or lysis-based products, **cell lysis (V5)** releases the intracellular product with PANclear APG, SDS and EDTA. **Nuclease treatment (V6)** is the step a cell-derived vaccine cannot skip: a **broad-range endonuclease** and **DNase I**, with a **magnesium cofactor**, digest host-cell DNA and RNA down to the regulated residual limit – a release attribute for any cell-substrate vaccine, not an optional polish.

Purification / chromatography (V7) captures and polishes the product on ion-exchange, density-gradient and buffer stocks (NaCl 5 M, Tris, phosphate,

sodium acetate, NaOH, sucrose), and **concentration / buffer exchange (V8)** concentrates and diafilters into the formulation buffer by tangential-flow filtration. **Formulation (V9)** is the excipient-grade set that turns bulk into an injectable – tonicity (NaCl, sodium chloride 0.9 %), stabilisers and cryoprotectants (**sucrose, trehalose, mannitol, glycerol**), surfactants (**polysorbate 20 and 80**) and an animal-free stabiliser (**rHSA**) – with the **final formulation built on WFI Beyond**. One qualified set of stocks carries the whole downstream, and every buffer in it can be built on WFI Beyond. (Adjuvants and preservatives are specialised formulation actives outside the PAN range and are sourced separately.)

SECTION 7

Water, and why it sets the floor for an injectable

Water is the base of every medium, every buffer and the final formulation, so it sets the quality ceiling for the whole process. For a vaccine the decisive moment is the end: the product is an **injectable**, and the water in the final formulation goes into a human being. The pharmacopoeial Water for Injection monograph (Ph. Eur. 0169, its core dating to 1969) sets the floor; WFI Beyond starts where the monograph stops.

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:

- **Endotoxin more than 50x below the compendial limit** (spec < 0.005 EU/mL) – the attribute that matters most for an injectable, because endotoxin in a final vaccine formulation cannot be removed downstream and drives the product's pyrogen risk.
- **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 – a clean fit for a sterile injectable on a serum-free process.
- **Nuclease-free** – RNase and DNase **not detected** – useful wherever a vaccine route handles nucleic-acid-sensitive intermediates or a nucleic-acid-based product.
- **All 24 ICH Q3D elemental impurities specified and measured by ICP-MS** on every lot – a first for a water – so the elemental-impurity question is answered at the water layer rather than argued downstream.

- **DMF-backed** – a filed FDA Type IV (excipient) Drug Master File (MF044505), referenceable in an IND/BLA through a Letter of Authorization.

(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 molecule that earns it.

A SAFETY STANDARD FOR AN INJECTABLE GROWN IN CELLS

Built on WFI Beyond

Because every medium, buffer and the final formulation 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 ultra-low-endotoxin, sterile, metal-controlled and nuclease-free foundation. For an injectable vaccine, this is the **recommended safety standard** for the final formulation and the buffers closest to it: it controls the contaminant classes – endotoxin above all – that cannot be removed from the product once it is filled.

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 small 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 vaccine, 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. And PAN goes one step further: on a

customer's request, PAN-Celltech will file the products they rely on with the FDA as well, extending the same regulatory shortcut to the materials that matter most to their programme. (DMF and stability support are optional, on-request services.)

SECTION 9

The proof – rapid GMP supply at scale

Vaccines are the modality where **speed is most often the point**, and PAN's record is built on exactly that. The GMP liquids are made 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):

~150,000 L · zero rejections

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

up to

Comb

Track-record figures are anonymised; capacity figures are stated as "up to". Read the anonymised vaccine-supply story – [~50,000 L of GMP supply in under five weeks](#) – in the Knowledge Hub.

AUTHOR'S INSIGHT

The modality that asks for everything at once

Vaccines are the hardest supply challenge in this series precisely because they refuse to specialise. A vaccine programme needs a partner who understands **cell biology** – the quirks of a Vero or an MDCK or an Sf9 line, and the medium that coaxes yield out of it – and, in the same breath, a partner who understands **the chemistry of an injectable** – endotoxin control, host-cell DNA clearance, a stabiliser set that survives a cold chain. Those are usually two different vendors, and the seam between them is where programmes lose time.

What I have come to believe, from the interviews behind this series, is that the real value of making both ends ourselves is not the catalogue breadth – it is the **speed that breadth unlocks when a pathogen does not wait**. When the medium, the buffers and the formulation water all come qualified from one house, a developer can compress the part of the timeline that is pure logistics and spend its urgency on the science. That is the promise a vaccine supply base should make, and it is the one we built ours to keep.

– 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 substrate and downstream on one qualified base

A vaccine process touches a substrate cell line, a viral culture medium, infection or transfection, harvest, lysis, nuclease treatment, purification and a formulation – two different disciplines usually assembled from a scattered supplier base. PAN lets you build it on **one coherent range**: cell-line-specific viral culture media (Vero, MDCK, BHK21, Sf9/Sf21, S2), base media and supplements, dissociation reagents, nuclease reagents, purification and diafiltration stocks and the excipient-grade formulation set. Because the media and stocks scale to the identical GMP product with no reformulation, the substrate and chemistry you develop on are the ones you file with – no comparability gap on a modality where being first matters.

The range is built for how vaccines behave – serum-free and protein-free media that lower variability and downstream clearance burden, a nuclease step sized for host-cell DNA limits, and a stabiliser set built for a cold chain – and every buffer can be built on **WFI Beyond** where the product earns it. (See the [vaccine process toolkit](#) in the Knowledge Hub.)

B · PRODUCTION & MANUFACTURING

Ready-made media and buffers off the shelf – at vaccine volume

A vaccine campaign burns through culture-media, buffer and excipient volume across expansion, infection, harvest, nuclease treatment, purification and formulation, and every litre made in-house is weighing, mixing and QC-checking that isn't making product. Ordering the media and ready-to-use buffers **from stock, in GMP grade with a CoA per lot**, on a WFI-quality water base, takes that off the floor. And you can order them **by the process step** – as a bundle, one labelled box – instead of picking each off a catalogue line.

It also keeps a time-critical modality fast. **On-stock dispatch** replaces custom-manufacturing slots and multi-week lead times – PAN has delivered **~50,000 L in under five weeks** – and the range scales from a development prep to full process volumes without re-qualifying the supply.

C · PROCUREMENT

Qualify one supply base, not two disciplines

A vaccine's supply challenge is that it needs both a media house and a downstream-chemistry house, usually sourced separately, which multiplies qualification, audits, documentation and packaging standards and slows scale-up. Because PAN makes **both the cell-line-specific viral culture media and the downstream chemistry**, and a **handful of universal stocks** cover the whole workflow on one water base, you qualify and carry far fewer SKUs – fewer vendors, fewer audits, one standard. The right lens is **total cost of ownership**, where the hidden tail – qualification labour, incoming QC, and the cost of a delayed campaign – dwarfs the unit price, and a single on-stock, GMP-grade, DMF-supported source collapses most of it.

Held stock is insurance against the demand an emerging-pathogen modality cannot forecast. The reliability is proven: ~50,000 L delivered in under five weeks on one programme, and 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 a vaccine is actually judged on

Consolidating media, buffers, nuclease reagents and excipients to **one audited GMP source** collapses the QA load a fragmented vaccine 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 for a cell-derived injectable are built in and documented: **ultra-low endotoxin on the CoA**, sterility, a documented low elemental-impurity profile, nuclease-free water, and a signed BSE/TSE declaration – with the modern impurity classes (ICH Q3D, residual solvents, nitrosamines) answered ahead of the questions. Residual host-cell DNA clearance is supported by a defined nuclease step. Stability support is available on request.

E • REGULATORY AFFAIRS

Reference our filings; document the vaccine dossier once

The two utilities most likely to sit in a vaccine 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 aqueous 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 qualified range carries the process from research to GMP on the identical chemistry, the material named in your control strategy is **consistent from substrate to drug product**, 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

Be ready first; de-risk the campaign

A vaccine's competitive advantage is often simply **being ready first** – and a fragmented, two-discipline supply base is precisely what erodes it. One

qualified supply base across the whole process, from the cell-line-specific viral culture medium to the formulation water, research grade to GMP with no reformulation, plus DMF-backed references, takes weeks-to-months out of qualification and filing. The proof is on the record: **~50,000 L of GMP supply in under five weeks.**

The larger prize is **de-risking a campaign against an emerging pathogen.** Removing the failure modes a fragmented supply invites – a medium change that shifts yield, an endotoxin excursion in an injectable, a supply gap against a pandemic schedule – is exactly the CMC and supply-chain diligence that governments, investors and partners look for in vaccines. It reframes PAN from a vendor of liquids into a partner that takes time and risk out of the path to supply, backed by external recognition (Pharma Tech Outlook's "Top 10 CMOs in Europe", 2024) and a proven continuity record.

G · CDMOS & CMOS

A standard vaccine supply base you can run – and offer to your clients

For a contract manufacturer running vaccine programmes, one qualified range – cell-line-specific viral culture media, buffers, nuclease reagents, purification stocks and the excipient-grade formulation set, all with a CoA per lot – lets you **standardise incoming materials across every client and modality** rather than re-qualifying a different media-and-chemistry chain 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 **up 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 GMP chemistry serves a client's programme from early development through to commercial supply.

In one arc

The widest process in biomanufacturing → one shared upstream of substrate expansion and infection, then a modality-specific downstream → cell-line-specific viral culture media and the downstream chemistry, made under one roof → a handful of qualified stocks recurring across

every step → all on a WFI-quality water base → research grade today, the identical products GMP on request with no reformulation → a final injectable built on water engineered beyond the monograph, ultra-low in endotoxin → DMF-backed regulatory confidence → proven fast when a pathogen does not wait. One foundation for the whole vaccine process, from a single partner whose reason for building it is to take risk and time out of *your* path to supply.

DOCUMENTS - SELF-SERVICE

What to ask your PAN contact for

The vaccine process toolkit specification, a representative Certificate of Analysis, a DMF Letter of Authorization, and the water story behind the safety standard.

TOOLKIT

The vaccine 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.

Most cell culture media are RUO catalogue products with a GMP grade available on request; buffers, salts and formulation excipients are available as GMP (CT-) grades. The recombinant cytokines and growth factors are research grade (RUO). 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. Adjuvants and preservatives are sourced externally.

APPENDIX A · CATALOGUE REFERENCE

The vaccine toolkit – by process step

Key products by step, with article numbers, across the vaccine process V1–V9 plus QC (V10). Media are RUO catalogue products with **GMP grade on request** unless a **CT-** number is shown; buffers, salts and excipients are available as GMP (**CT-**) grades; cytokines and growth factors are research grade (RUO). Every buffer is available **beyond-compendial**, produced with **WFI Beyond** (CT-981500) instead of standard WFI, on request. Article numbers are taken from the PAN vaccine-production product pages.

Step	Key product	Article no.
SHARED UPSTREAM (USP) · V1–V3 · SUBSTRATE, EXPANSION & INFECTION		
V1 · Cell line development & maintenance	WFI Quality Water (nuclease-free base)	CT-991500
	DPBS w/o Ca & Mg	P04-36500 · GMP CT-36500
	Cryopan II, chemically defined, protein-free freezing medium	P07-93100 · GMP CT-94100
	Cryopan III, DMSO-free freezing medium	P07-96100 · GMP CT-96100
	Penicillin–Streptomycin (10,000 U/ml / 10 mg/ml)	P06-07100 · GMP CT-07110
	L-Glutamine 200 mM	P04-80100 · GMP CT-80100
V2 · Cell expansion — cell-line-specific viral culture media	Panserin ProVero (Vero cells)	P04-710613 · GMP on req.
	Serum-free Medium for MDCK	P04-71105 · GMP on req.
	EMEM Fibroblast (BHK21)	P04-08049 · GMP on req.
	Panserin 401 (BHK21, serum-free allround)	P04-710401 · GMP on req.
	Spodopan (Sf9/Sf21 insect cells)	P04-850500 · GMP on req.

Step	Key product	Article no.
	Schneider's Drosophila Medium (S2)	P04-90500 · GMP on req.
	M199 w/ EBSS, w/ L-Glutamine, w/ 2.2 g/L NaHCO ₃	P04-07050 · CT-07050
	MEM Eagle w/ EBSS, w/ L-Glutamine, w/ 2.2 g/L NaHCO ₃	P04-08500 · CT-08500
	CMRL-1066 (w/o L-Glutamine, w/o Phenol red)	P04-84600 · CT-84600
V2 · Cell expansion — base media	DMEM/F-12	P04-41150 · GMP on req.
	RPMI 1640, w/ stable Glutamine, w/ 2.0 g/L NaHCO ₃ (GMP)	CT-18500
V2 · Cell expansion — dissociation	Accutase Cell Detachment Solution (w/ 0.5 mM EDTA)	P10-21500
	Trypsin/EDTA 0.05/0.02 % in DPBS	P10-023100 · GMP on req.
V2 · Cell expansion — antibiotics / antifungals	Gentamicin sulfate 10 mg/ml	P06-03050 · GMP on req.
	Amphotericin B 250 µg/ml	P06-01050
V2 · Cell expansion — growth factors & cytokines (RUO)	FGF-2 human rec. (bFGF)	CB-1102024
	IL-2 human rec.	CB-2130203
	IL-15 human rec.	CB-2131500
	EGF human rec.	CB-1101001
V2 · Cell expansion — media supplements	ITS solution I (100x)	P07-03100 · CT-03110
	Insulin human rec., 10 mg/ml solution	P07-04300 · GMP on req.
	Stable Glutamine 200 mM (100x)	P04-82100 · CT-82100
	Glucose 20 % stock solution	CT-00331

Step	Key product	Article no.
	Pluronic F-68 10 % (shear protection)	P08-02100 · CT-02110
	Sodium bicarbonate 7.5 %	P04-44100 · GMP on req.
	Sodium pyruvate 100 mM	P04-43100 · CT-43100
	MEM NEAA, Non-Essential Amino Acids (100x)	P08-32100 · CT-32100
	HEPES Buffer 1 M	CT-01100
V3 · Virus infection / transfection	WFI Quality Water	CT-991500
	DPBS w/o Ca & Mg	P04-36500 · GMP CT-36500
	Transfection reagent	in preparation
MODALITY-SPECIFIC DOWNSTREAM (DSP) · V4-V9 · HARVEST, CLEARANCE, PURIFICATION & FORMULATION		
V4 · Viral harvesting & clarification	WFI Quality Water	CT-991500
	DPBS w/o Ca & Mg (GMP)	CT-36500
V5 · Cell lysis (non-enveloped / lysis-based)	PANclear APG 10% Solution	CT-01101
	SDS 10 %	CT-06500
	EDTA 0.5 M, pH 8.0	CT-10500
V6 · Nuclease treatment (host-cell DNA clearance)	Broad-range endonuclease	article under revision · on request
	Magnesium Chloride 1 M (cofactor)	CT-75100
	DNase I	P60-37780100
V7 · Purification / chromatography	NaCl 5 M, stock solution	CT-77055
	Tris Buffer 1 M, pH 8.4	CT-05500

Step	Key product	Article no.
	Phosphate Buffer 100 mM	CT-18810
	Sodium acetate 100 mM, pH 4.5	CT-76451
	NaOH 1 M, stock solution	CT-55105
	Sucrose 30 % stock solution (density gradient)	CT-00131
V8 · Concentration / buffer exchange (UF-DF)	WFI Quality Water	CT-991500
	Tris Buffer 1 M, pH 8.4	CT-05500
	NaCl 5 M, stock solution	CT-77055
V9 · Vaccine formulation (excipient grade)	WFI Quality Water (diluent base)	CT-991500
	Recombinant human serum albumin (rHSA)	CT-27500
	Sucrose 30 % stock solution	CT-00131
	Trehalose 30 % stock solution	CT-00231
	Mannitol 10 % (w/v)	CT-00401
	Glycerol 20 % (v/v)	CT-00901
	Polysorbate 20 (PS20) 1 %	CT-00211
	Polysorbate 80 (PS80) 1 %	CT-00311
	Tris Buffer 1 M, pH 8.4	CT-05500
	NaCl 5 M, stock solution	CT-77055
	Sodium chloride solution 0.9 % (GMP; RUO P05-39500)	CT-39500
	WFI Beyond, Water for Injection (final formulation)	CT-981500
SERVICE · V10		
V10 · QC & stability · service	Release testing: CoA per lot, endotoxin (LAL), residual host-cell DNA, bioburden &	-

Step	Key product	Article no.
	sterility, identity & potency, ICH Q1A stability, DMF / LoA	
Universal utility. WFI-quality water (CT-991500) is the base of every step. WFI Beyond (CT-981500) is Water for Injection engineered beyond Ph. Eur. monograph 0169 – endotoxin < 0.005 EU/mL (>50x below limit), sterile, animal-component-free, nuclease-free (RNase & DNase not detected), all 24 ICH Q3D elements by ICP-MS – and, with DPBS, is backed by a filed FDA Type IV (excipient) DMF (MF044505, MF044371). The broad-range endonuclease article number is under revision; it is available on request. Full specifications and current article numbers on request.		

FREQUENTLY ASKED QUESTIONS

The vaccine toolkit, answered

Which medium should I use for my cell substrate?



PAN offers cell-line-specific viral culture media: Panserin ProVero for Vero cells, a serum-free medium for MDCK cells, EMEM Fibroblast and Panserin 401 for BHK21, and Spodopan and Schneider's Drosophila Medium for insect cells (Sf9/Sf21, S2) – plus base media, supplements and dissociation reagents. Most are RUO catalogue products with a GMP grade available on request.

How does one supply base cover the whole vaccine process?



Every vaccine shares one upstream – expand a substrate cell line, then infect or transfect it – and the downstream branches by modality but shares most of its buffer, nuclease and stabiliser chemistry. PAN makes both the cell-line-specific viral culture media and the downstream buffers, nuclease reagents and excipients, built from a small set of recurring stocks on a WFI-quality water base, so one qualified supplier carries the process from research to GMP.

Which downstream steps apply to my vaccine?



It depends on the modality: enveloped live/inactivated viral vaccines are harvested, clarified, nuclease-treated and purified; non-enveloped or viral-vector vaccines add a lysis step; recombinant subunit vaccines follow a capture-and-polish route. The shared buffer and stabiliser stocks recur across all of them.

How do you handle host-cell DNA clearance?



Residual host-cell DNA is a regulated release attribute for cell-derived vaccines, so nuclease treatment is a defined step (V6): a broad-range endonuclease and DNase I, with a magnesium chloride cofactor, digest host-cell DNA and RNA down to the regulated residual limit. The broad-range endonuclease article number is currently under revision and is available on request.

Can I run a serum-based or a serum-free process?



Both. PAN offers serum-free and protein-free cell-line-specific media as well as a full range of sera (FBS) for serum-based processes, plus the common supplements – Pluronic F-68 for suspension culture, sodium bicarbonate, sodium pyruvate, non-essential amino acids and HEPES. Serum-free lowers lot-to-lot variability and the downstream clearance burden.

Can you support rapid vaccine supply against an emerging pathogen?



Yes. PAN offers rapid development and scale-up and works with developers to optimise yield and consistency. On one vaccine programme, PAN quoted in 3 days and delivered ~50,000 L of GMP supply in under five weeks from first production.

GO FURTHER

Related reading

IN-DEPTH D02

The WFI Beyond Standard

The full water story behind the safety standard.

CASE STUDY

~50,000 L in under five weeks

Rapid GMP vaccine media supply against the clock.

TOOLKIT

The vaccine process toolkit

Products by step, with article numbers.

KNOWLEDGE HUB

Case studies & tech papers

The anonymised proof stories, in full.

Build your vaccine 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, DMF-backed supply base across your whole process – from the cell-line-specific viral culture medium to the formulation water. 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 vaccine.

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

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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. Adjuvants and preservatives are sourced externally.