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TECHNICAL PAPER

DOWNSTREAM WHITEPAPER

THE OPEN DOWNSTREAM

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For antibody, mRNA, cell & gene and vaccine downstream processing

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THE OPEN DOWNSTREAM

The complete GMP downstream (DSP) system for monoclonal antibody, mRNA, cell & gene and vaccine processes: standard buffers, reagents and Water for Injection at every step – flexible, scalable to 1,000 L, fully customizable, with quality control, documentation and FDA Drug Master File (DMF) support from a single partner.

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Key takeaways

- Downstream processing accounts for well over half of a biologic's production cost – and it is where a single mistake is most expensive to unwind.
- PAN offers a qualified GMP product for every downstream step: buffers, stock solutions, reagents and WFI-quality water, in stock and dispatched worldwide within 24 hours.
- Qualify once and scale without re-qualifying – one stocked size per product, 1000 ml bottles and single-use bags to 1,000 L on request, matched RUO to GMP.
- WFI Beyond adds a beyond-compendial quality ceiling on request; a fully customized GMP formulation is available at any step without switching supplier.
- One partner, manufactured to GMP in an EU Annex 1 facility; DPBS and WFI Beyond are backed by filed FDA Drug Master Files.

In brief

Downstream is where the value of a biologic concentrates – and where a mistake is most expensive. Yet the materials that run through it are still treated as commodities. This paper reframes them: a complete GMP downstream range with a qualified product for every step, in stock and ready to use, to build your own formulations from, and to scale from a 500 ml bottle to a 1,000-litre single-use bag – with WFI Beyond quality where a molecule needs it, and a fully customized GMP formulation at any step, without changing supplier. The point is not the cost you avoid, but the opportunity you own.

1. The weight of downstream

It is tempting to treat downstream raw materials as commodities – a buffer is a buffer, water is water. The economics say otherwise. Downstream processing – capture, viral inactivation, chromatographic polishing, ultrafiltration and diafiltration, final formulation – accounts for well over half of the total production cost of a modern biologic. It is where the molecule is most valuable, where the process is most fragile, and where a single deviation is most expensive to unwind.

The materials that flow through those steps are not a line item to be squeezed. They are the foundation the whole project stands on – and, because the water and the buffers touch nearly every step, their quality is multiplied through everything downstream of them. The most ordinary-looking input carries the least ordinary risk.

2. What a downstream mistake costs

Consider what one wrong move downstream actually costs – not the material, the project. A buffer that varies batch to batch; a supplier changed after the process is fixed; a documentation gap found during a filing. None of these is a purchasing problem. Each is a project problem. At the bench it is an inconvenience; at clinical or commercial scale it is comparability work, re-validation, a slipped filing, or a failed lot.

WHERE IT GOES WRONG	WHAT IT TRIGGERS	THE COST TO THE PROJECT
Variable / off-spec raw material	Comparability, investigation, batch loss	Quality risk multiplied across every batch
Supplier changed mid-programme	Re-validation, re-filing, re-qualification	Months lost; regulatory risk re-opened
In-house buffer inconsistency	QC/release burden, deviations	Capacity and documentation drain
A failed / interrupted lot at scale	Lost batch, schedule slip	One lot can dwarf years of unit-price savings
A documentation / DMF gap	Filing delay, authority questions	Time-to-clinic lost when it matters most
An impurity / animal-origin question	Added testing and justification	A filing risk that should have been closed early

> At the bench, the wrong raw material is an inconvenience. At scale, it is a project risk.

3. From cost to opportunity

So the raw-material question is not really about price. Given what downstream can cost you, the smart move is not to minimise the unit price – it is to own the options that take the risk off the table. Standard or custom, small-scale or 1,000-litre, compendial or premium: held as options, a downstream range stops being a cost to squeeze and becomes an opportunity to own.

> Total cost of ownership asks what a material costs you. The open downstream asks what it lets you do.

4. A product for every step – the open portfolio

Map a downstream process end to end and every step draws on the same short list of building blocks: salts, buffering agents, a chelator, a detergent, stabilisers, and the water beneath them all. We built that list into a complete GMP portfolio – a qualified, documented product for every step, from DPBS and Water for Injection to the chromatography and formulation stocks.

Use them ready-made, or buy the concentrates and build your own formulations – the choice is yours at every step. And because they are standard, they are on the shelf: all standard RUO and GMP items in stock, dispatched worldwide within 24 hours.

YOUR OPTIONS – AT EVERY STEP	WHAT YOU GET	THE OPPORTUNITY IT UNLOCKS
Standard GMP product	A qualified, documented buffer or reagent for every step – in stock	Start now – no development wait
Build-your-own	Buy the concentrates and mix your own formulations	Flexibility without the in-house QC burden
Scale path	500 / 1000 ml bottles → single-use bags to 1,000 L; matched RUO → GMP	Grow in volume and grade without re-qualifying
WFI Beyond	A premium quality ceiling, opt-in across the range	Raise quality exactly where the molecule needs it
Custom GMP	Bespoke formulation to your own recipe, at any step	Go custom without switching supplier
One roof	GMP manufacture, QC, documentation, audit, DMF support	Own the whole chain through one partner

Note. The newest additions to the range are in preparation and on stock shortly; the 24-hour dispatch applies to the standard items already stocked.

5. Two ways in – the scale-up and the new project

The open downstream has two on-ramps. The first is the scale-up: a developer that started at the bench and grew, carrying the same qualified material up the grades as its programme matured. The second is the new project – including inside a large organisation. A global pharma or biotech launching a new molecule does not have to build its downstream supply in-house; it can adopt qualified, documented, audit-ready materials from day one, clear its own QA and procurement bar with a partner already audited by NASDAQ- and DAX-listed pharma, and keep its own lines and people free for its core product.

> The best raw-material decision is the one you make at the very start – whether you are a founder at the bench or a programme lead inside a global pharma.

6. Qualify once – and the re-validation trap

A programme does not stay at the bench, and the open downstream scales with it: the same qualified product from 500 ml and 1,000 ml bottles to single-use bags of 1 to 1,000 litres, and from a P- research grade to the mirrored CT- GMP grade. You qualify a material once and climb in volume and in grade without changing it.

That matters because of the re-validation trap. Early in a programme a raw material is a purchasing decision; once the process is fixed and the filing is built around it, changing a medium, a buffer or a reagent is no longer a line-item swap – it is a re-validation event, with comparability, revalidation, lost time and regulatory risk, exactly when a programme can least afford any of them. The way out is not to negotiate the switch better later; it is never to need it.

> The most expensive raw-material decision is the one you make early and revisit late. Never change a winning team – so we built a downstream you never have to revisit.

7. The three continuities

„One partner" is not a slogan; it is three specific continuities, and each one takes cost and risk off the table:

- **Formulation continuity** – the same recipe across grades; no silent composition drift between research and GMP, so the process you validated is the process you run.
- **Documentation continuity** – Certificates of Analysis, and DMF support where available, that carry your filing rather than burden your QA team.
- **Relationship continuity** – a manufacturer who has followed your programme from the bench and understands what changing anything would cost you.

8. Make or buy – not „can", but „should"

Many teams make their own buffers, and at bench scale that is the obvious choice: small volumes, total control. At GMP scale it quietly turns from a convenience into a constraint – the QC and release burden on every batch, the documentation that has become the real deliverable, batch-to-batch consistency at volume, and a supply that rests on one or two people.

The question is no longer whether the team can make the buffer. It is whether it should. Buying it from a qualified partner turns a fixed internal burden into a variable, documented, de-risked supply – and frees your lines, your capacity and your QA to do the one thing only you can do: advance your molecule.

9. The foundation – the water beneath every buffer

Water for Injection is the most underestimated raw material in the whole process: it is the base of nearly every buffer and the vehicle for the final formulation, so its quality cascades into everything downstream of it. That is why WFI-quality water is the base of every standard product we supply – released to compendial requirements, batch after batch. Get the water right and the foundation is right; every buffer, every polishing step and every final formulation stands on it.

> Everything downstream stands on the water – so we start every standard product there.

10. Quality on top – exactly where you need it

The compendial floor is right for most of the range. But some molecules – mRNA, cell and gene therapies – need more. WFI Beyond is that ceiling, on demand: endotoxin roughly fifty times below the compendial limit, nuclease-free, animal-component-free, and backed by a filed FDA Drug Master File. It is opt-in – orderable across the portfolio exactly where your molecule earns it, never imposed and never implied as already inside every product. The opportunity is precision: raise the quality ceiling only where it matters, and pay for premium only where it counts.

11. Custom at any stage – without switching

Standard gets you moving; it does not box you in. At any step, a standard product can become a fully customized GMP formulation, manufactured by PAN-CellTech to your own recipe – the same partner, the same quality system, the same documentation. You are never forced to choose between the speed of a catalogue and the fit of a bespoke process: start standard, and go custom exactly where your process demands it, without switching supplier or restarting qualification.

> **Open where it helps you, proprietary where it protects you.** Open to test, mix, scale and customize at every step – proprietary in the method, the documentation and the quality that de-risk your filing.

12. The audit burden, removed

There is one cost in GMP sourcing that every quality lead feels personally: the audit. Before a new supplier can feed a regulated process, it has to be qualified – audited, documented and stood behind. That takes time, travel and, most of all, experience on both sides of the table. A supplier that turns qualification into a project is one that costs you before it ships a single litre.

PAN-CellTech is built to take that burden off the table, not add to it. The GMP arm has been audited successfully by customers across the spectrum – from NASDAQ- and DAX-listed pharmaceutical and biotechnology companies to small, single-programme biotechs – and passed. It rests on an ISO 9001 quality system with filed FDA Drug Master Files as its documentary backbone – which is also why the honest phrase is audit-proven and GMP-compliant, manufactured to GMP in an EU Annex 1 facility, never „GMP-certified". There is no government GMP certificate for this class of product; a demonstrated audit history, backed by ISO 9001 and DMFs, is what stands in its place.

> Audits can be run remotely, in full or in part – cutting the travel, the days and the cost of qualification without cutting the rigour. One more option you own: qualify us faster, and keep your QA free for your molecule.

13. All under one roof

Everything above comes from one partner. PAN-CellTech, the GMP arm of a group built on bioprocess materials since 1988, manufactures the GMP and clinical-grade supply in an EU Annex 1 facility within an ISO 9001 quality system – with quality control in-house (sterility, endotoxin, mycoplasma, RNase/DNase and more), documentation that carries your filing rather than burdens it, an audit track record from NASDAQ- and DAX-listed pharma down to small biotech (remote or hybrid audits available), and FDA Drug Master File support where a product genuinely needs it. It is the three continuities in practice, from bench to patient.

> **Proven under pressure.** Roughly 50,000 litres of GMP supply delivered in under five weeks for a vaccine manufacturer; and about 150,000 litres – some 300,000 bottles – over nearly two years with no rejections recorded, bridging a manufacturer through an FDA-driven shutdown, all tested, labelled, packed and shipped under one roof.

14. The opportunity of ownership

Add it up and the picture inverts. A downstream range judged on unit price looks like a cost to be squeezed. The open downstream – complete, in stock, scalable, customizable, quality-assured, one roof – is something else entirely: a set of options you own. The freedom to start today. To build your own or take ours. To scale without re-qualifying. To raise quality where it matters. To go custom without switching.

That optionality is the real total of ownership – not the cost you carry, but the opportunity you hold. Open where it helps you, proprietary where it protects you, from bench to patient, on your terms.

> Test it. Mix it. Scale it. Perfect it. Never switch supplier.

FAQ 1

What is the Open Downstream range?

It is PAN-Biotech's complete GMP downstream (DSP) system: a qualified buffer, stock solution or reagent for every purification step – capture, viral inactivation, chromatographic polishing, ultrafiltration/diafiltration and final formulation – manufactured by PAN-CellTech. One partner, bench to patient.

FAQ 2

Why is downstream where cost and risk concentrate?

Downstream processing accounts for well over half of total production cost, it is where the molecule is most valuable and the process most fragile, and a single deviation – a variable buffer, a mid-programme supplier change, a documentation gap – triggers comparability work, re-validation or a lost lot at commercial scale.

FAQ 3

What pack sizes and scale are available?

Each standard product is stocked in one defined size with its own article number (500 ml or 100 ml). 1000 ml bottles and single-use bags from 1 L to 1000 L are available on request, with the article number created on order. Grades are matched RUO to GMP, so you qualify once.

FAQ 4

What is WFI Beyond?

WFI Beyond is Water for Injection engineered beyond the Ph. Eur./USP monograph – endotoxin roughly fifty times below the compendial limit, nuclease-free, animal-component-free, backed by a filed FDA Drug Master File. It is opt-in and orderable across the range exactly where a molecule needs it.

FAQ 5

Can I get a custom GMP formulation?

Yes. At any step a standard product can become a fully customized GMP formulation manufactured by PAN-CellTech to your own recipe – the same partner, quality system and documentation – without switching supplier or restarting qualification.

FAQ 6

Are the products GMP grade and documented?

The core range is catalogue GMP, manufactured to GMP in an EU Annex 1 facility within an ISO 9001 quality system, with a Certificate of Analysis on every lot. DPBS (CT-36500) and WFI Beyond are additionally backed by filed FDA Type IV Drug Master Files.

Open the downstream for your programme

To request a product, a Certificate of Analysis, a WFI Beyond specification or a custom GMP quote – for antibody, mRNA, cell & gene or vaccine processes – get in touch.

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PAN-Biotech GmbH · PAN-CellTech GmbH (GMP arm / manufacturer of record) · Manufactured to GMP in an EU Annex 1 facility within an ISO 9001 quality system. WFI Beyond is an opt-in, beyond-compendial grade available on request.