

# Scaling up WFI for a GMP clean room – the bag stays outside, only the line goes in

As a cell and gene therapy manufacturer scaled up its process, its demand for Water for Injection in the GMP clean room grew well beyond small containers. At that scale, WFI is typically sold in drums – which would have meant substantial investment and bringing large volumes of water into the clean room again and again. PAN-Celltech offered a safer and more cost-efficient route: **WFI Beyond** in a single-use bag set-up that **stays outside the clean room**, with only the tubing line introduced **aseptically through a wall connector**. And because the customer's application depends on ultra-pure raw materials, WFI Beyond added a safety margin that compendial WFI alone does not provide: **every lot tested for elemental impurities**.

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## At a glance

- **The bag stays outside** · only the line enters the clean room
- **Aseptic transfer** · closed tubing line through a wall connector
- **No clean room crane** · no investment in handling equipment
- **200 / 500 / 1000 L** · single-use bag in a reusable pallet-format container
- **Beyond Ph. Eur./USP** · all 24 ICH Q3D elements + iron, every lot
- **Endotoxin >50× below the limit** · DMF-backed (MF044505)
- **Bag format in the DMF** · referenceable FDA Type IV DMF

This story is published with the customer **anonymised**. It describes a real PAN-Celltech engagement; the customer's name is withheld.

## THE CONTEXT

# When the process grows, the water becomes a clean-room question

In GMP cell and gene therapy, WFI is used in quantity – for buffers, media, dilutions and rinses – and it is needed inside the clean room. At small scale that is easy. But as a process moves towards larger-scale GMP production, the demand climbs from a few litres to tens or hundreds of litres.

At those volumes, WFI is commonly supplied in drums. The real question, however, is not the container – it is how large volumes of sterile water get into a classified clean room safely, efficiently and without a major infrastructure project.

## THE CHALLENGE

# More water in the clean room – without new cost and new risk

When the customer scaled up its process, its water demand outgrew the containers it had used so far, and the supply options at that volume pointed to drums. Integrating them into the production environment and the manufacturing process would have had two major consequences:

- **High investment.** Bringing large volumes into the clean room requires dedicated equipment – such as a clean room crane – plus facility adaptation and qualification, adding up to a significant up-front cost before a single litre is used.
- **Contamination risk.** Every time large volumes of WFI have to be brought into the clean room, the transfer across the clean-room boundary is a contamination-control event – a risk that is easy to underestimate and that recurs with every delivery.

On top of that, the customer works in a highly sensitive application in which the finished product depends on ultra-pure raw materials. Any residue the water brings into the process is a potential risk to the product.

**The question was not only how to get more water into the clean room – but how to do it without adding cost and risk.**

## THE SOLUTION

# The bag stays outside – only the line goes in

PAN-Celltech proposed supplying WFI Beyond in a **sterile, gamma-irradiated single-use bag set-up** that makes it possible to leave the bag **outside the clean room**. Only the bag's tubing line is introduced **aseptically into the clean room through a wall connector**. The water reaches the point of use in a closed system – the container itself never crosses the clean-room boundary.

### THE CONVENTIONAL ROUTE

#### Bring the water into the clean room

Large containers have to cross the clean-room boundary with every delivery – requiring equipment such as a clean room crane and creating a recurring contamination-control event.



### WHAT PAN PROPOSED

#### Only the line enters the clean room

The single-use bag stays outside; its tubing line is introduced aseptically through a wall connector. No crane, no container in the clean room, no open transfer.

## Large volumes: single-use bag in a pallet-format container

For large volumes – **200 L, 500 L and 1000 L** – the WFI is filled into a single-use bag that sits in a **reusable plastic container in pallet format**, placed outside the clean room:

- **Secure during transport and storage.** The bag is held and protected inside a rigid container instead of travelling and standing unsupported.
- **No daylight on the bag.** The closed container shields the bag and its contents from light.
- **Moves like a pallet.** The pallet footprint means the unit is transported, stored and positioned with standard pallet handling.
- **Simple withdrawal from the base.** The outlet at the bottom of the container gives direct access to the bag's tubing line, which runs to the wall connector.

The same format is not limited to WFI: buffers or any other sterile liquid can be supplied and transferred into the clean room in exactly the same way.

## Aseptic transfer through the tubing line

The water leaves the bag only through its pre-attached, gamma-sterilised tubing – via the outlet at the base of the container and through the wall connector into the clean room. There is no open transfer step: from the bag to the point of use, the water stays inside a closed system and is not exposed to the environment. Getting water into the clean room becomes part of a controlled, closed process rather than a recurring intervention – adding safety to the process instead of risk.

### BEYOND THE MONOGRAPH

## Purity that protects a sensitive product

WFI according to the Ph. Eur. and USP monographs is controlled for parameters such as conductivity, TOC, microbial quality and endotoxin. For most uses that is entirely sufficient. But it is not released against an element-by-element quantification of elemental impurities – and for an application that depends on ultra-pure raw materials, a residual element in the water is a risk to the finished product.

#### WFI PER PH. EUR. / USP

##### Compendial parameters

Conductivity, TOC, microbial quality and endotoxin within the monograph limits.  
Elemental impurities are not quantified element by element at release.



#### WFI BEYOND

##### Compendial – plus measured purity

All 24 ICH Q3D elements quantified by ICP-MS on every lot, iron in an oxidation-metals addendum, endotoxin more than 50× below the compendial limit – documented per lot.

For this customer, that made the difference between assuming the water is clean and knowing it. Because the exceptionally high purity of every lot is tested and documented, the risk of elemental impurity residues compromising the finished product is reduced further – and the data feed directly into the customer's own ICH Q3D risk assessment.

## WHY IT TRAVELS

# The same move works for far more than one clean room

This was one customer's clean room – but the situation is common. Any GMP operation whose water demand grows faces the same question of how to get large volumes across a classified boundary. Keeping the bag outside and introducing only a closed line through a wall connector is a general answer: the format grows with the process up to 1000 L, the closed transfer stays the same – and it works just as well for buffers or any other sterile liquid as for WFI.

It is also the thread that runs through PAN's Custom Solutions work: listening to the actual requirement – more water in the clean room, safely and without a large infrastructure project – rather than simply supplying the format that is usually sold at that volume. The right product follows the process, not a catalogue.

## THE RESULT

# A safe, cost-efficient alternative to a major investment

The customer did not have to invest in a clean room crane or in bringing large containers into the clean room. The WFI Beyond bag stays outside, and the water enters the clean room aseptically through a closed line and a wall connector – compared with the investment the conventional route would have required, a markedly more cost-efficient and safer solution. As demand grows further, the same set-up is available in 200 L, 500 L and 1000 L bags, each held in a reusable pallet-format container.

The water itself carries the same **WFI Beyond** specification in every format in which WFI Beyond is supplied, from the 1 mL vial to the 1000 L bag – sterile, animal-component-free, endotoxin more than 50× below the compendial limit, all 24 ICH Q3D elements quantified by ICP-MS on every lot with iron in an oxidation-metals addendum, and backed by a filed FDA Type IV (excipient) Drug Master File (MF044505).

There is one more advantage that is specific to the bag. Because a single-use bag is a primary container – part of the product, not just transport – it matters that the bag format is **covered by the FDA Type IV (excipient) Drug Master File (MF044505)**. Customers can reference the DMF in their own regulatory documentation instead of building that documentation from scratch.

## Why it works

1

### The bag stays outside

Only the tubing line enters the clean room through a wall connector – no container crosses the boundary.

2

### No major investment

No clean room crane, no facility adaptation – a fraction of the cost of the conventional route.

3

### Purity beyond Ph. Eur./USP

All 24 ICH Q3D elements plus iron tested on every lot – less risk of elemental residues in the finished product.

4

### Single-use and documented

Gamma-irradiated, no cleaning or carry-over; specification, CoA and DMF in one package.

## FAQ

# Frequently asked questions

### Does the bag have to be brought into the clean room?

No. The WFI Beyond bag set-up is designed so that the bag stays outside the clean room. Only the tubing line is introduced aseptically into the clean room through a wall connector, so the water reaches the point of use in a closed system while its container never crosses the clean-room boundary. That removes the need for equipment such as a clean room crane and the contamination-control event of bringing large volumes into the clean room.

### How is the water withdrawn from the bag? —

Through the bag's pre-attached, gamma-sterilised tubing line. For the large-volume formats the line leaves the container through the outlet at its base, runs to the wall connector and is introduced aseptically into the clean room. There is no open transfer step, so the water is not exposed to the environment on its way to the point of use.

### How are large volumes such as 200 L, 500 L or 1000 L supplied? —

Large volumes are filled into single-use bags that sit in a reusable plastic container in pallet format. The container keeps the bag secure during transport and storage and protects it from daylight, and the pallet footprint means the unit can be moved with standard pallet handling. The outlet at the base of the container allows WFI – or a buffer or any other sterile liquid supplied in this format – to be withdrawn simply and aseptically.

### How does WFI Beyond differ from WFI according to Ph. Eur. or USP? —

WFI according to the Ph. Eur. and USP monographs is controlled for parameters such as conductivity, TOC, microbial quality and endotoxin; it is not released against an element-by-element quantification of elemental impurities. WFI Beyond meets the compendial requirements and goes further: all 24 ICH Q3D elements are quantified by ICP-MS on every lot, with iron reported in an oxidation-metals addendum, and endotoxin is more than 50x below the compendial limit. For applications that depend on ultra-pure raw materials, this reduces the risk of residual elements reaching the finished product and supports the customer's own ICH Q3D risk assessment.

### Does the water quality or documentation change between WFI Beyond formats? —

No. Whether WFI Beyond is supplied in a 1 mL vial, a bottle or a single-use bag of up to 1000 L, the water is the same WFI Beyond specification, released against the same Certificate of Analysis per lot, and backed by the same filed FDA Type IV (excipient) Drug Master File (MF044505).

### Is the single-use bag format covered by the Drug Master File? —

Yes. WFI Beyond in the single-use bag is covered by the filed FDA Type IV (excipient) Drug Master File (MF044505). Because the bag is the primary container – part of the product, not just transport – this matters: customers can reference the DMF in their own regulatory documentation instead of building that documentation from scratch.

## RELATED

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## Water that scales with your process

Tell us how much water your clean room needs and how it gets there. We will scope a WFI Beyond format – from a 1 mL vial to a 1000 L single-use bag – around the way you actually work.

**Start a Custom & GMP Project Enquiry**

**[info@pan-celltech.com](mailto:info@pan-celltech.com)**

WFI Beyond is supplied as an excipient / for further manufacturing – for compounding buffers and media and as process water in the manufacture of medicinal products. It is not Sterile Water for Injection for direct human use. Manufactured to GMP in an EU Annex 1 facility within an ISO 9001 quality system (a capability, not a certification). Customer anonymised. PAN-Celltech GmbH is the GMP arm and manufacturer of record.