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Written By Miguel Ángel Ortega Sánchez

Water for Injection:

Strategic Utility and the Case for Outsourcing

Miguel Ángel Ortega Sánchez is Corporate Industrial Director at ROIS, with over 30 years of experience in pharmaceutical manufacturing and supply chain. Holding an ESADE MBA in Operations and a Chemistry degree from the University of Barcelona, he has spent more than a decade at ROIS overseeing industrial operations across sites and strategic projects delivery, with a focus on quality, efficiency and scalable solutions for high value injectable manufacturing.

Strategic Utility and the Case for Outsourcing

Water for injection (WFI) sits at the heart of injectable drug manufacturing.

This ultra-pure, sterile water is used as a solvent and diluent for parenteral drug products and in the manufacturing of lyophilised drug products. In short, it's essential for any medicine that must be sterile and safe for injection. Compliance with WFI quality standards isn't optional: it's a regulatory requirement and paramount for patient safety. Errors and delays in WFI production can stall projects, trigger costly investigations or – in the worst-case scenario – compromise patient safety.

Let's examine why WFI represents a strategic utility for pharma and biotech, why many organisations choose to outsource its production and management, and the key considerations when deciding whether to build or buy WFI capability.

What WFI is – and how it's made

Just like all drug manufacturing processes, WFI production must comply with stringent microbiological, endotoxin and chemical purity limits. While the conventional route is distillation, non-distillation approaches are now permitted when validated and properly controlled. This added flexibility has changed the cost calculations involved in WFI systems.

There are two key technical considerations to bear in mind in this regard. Firstly, WFI is subject to strict GMP and validation regimes. Secondly, the choice of production technology affects capital cost, footprint, energy use and ongoing operational risk.

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The strategic importance of WFI

Several industry trends have combined to elevate WFI from a background utility to a strategic operational focus. For one, the recent surge in biologics, vaccines and high-dose injectables is fuelling WFI demand across clinical and commercial manufacturing.

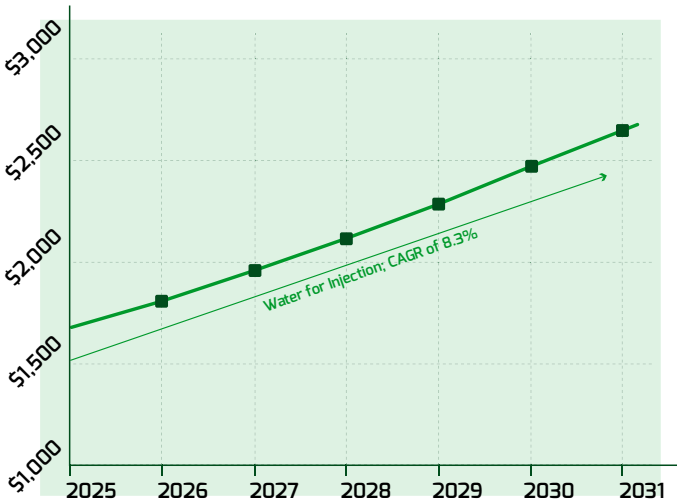
Moreover, regulators – such as the FDA and EMA – expect flawless WFI generation, seamless distribution and robust continuous monitoring as part of GMP. Consequently, building and validating a WFI facility is a major financial and time investment and calls for specialist operational expertise.

In short, WFI is not a simple utility that companies can simply tack onto their existing operations: it is a specialist, regulated manufacturing service subject to stringent regulation and significant resource requirements.

The value of outsourcing WFI production and management

Besides avoiding significant capital investment, there are a host of reasons why pharmaceutical companies often outsource WFI production to CDMOs:

- **Speed:** Designing, installing and qualifying a compliant WFI system can take months, if not years. Outsourcing provides immediate access to validated WFI.
- **Lower total cost of ownership:** For many small and mid-sized biotechs, capital, energy and ongoing OpEx (plus validation and lab staffing) make internal WFI less economical than buying in WFI or contracting a specialist.
- **Operational expertise:** Specialists run continuous monitoring and scheduled sanitisation cycles, responding swiftly when deviations occur.



WFI Projected Market Growth (USD Millions)

Sources: Sterile Water for Injection market forecasts. Annual values derived from reported CAGR.

- **Regulatory confidence:** Partnering with a provider that can demonstrate multi-authority approvals reduces risks – especially for pharma companies with distribution across jurisdictions.

For many small and medium-sized companies, this decision is a pragmatic one. Leaving WFI to the specialists allows them to focus their capital and scientific effort on drug development.

Common pitfalls of trying to go it alone

Biotech teams often discover WFI complexity late in development. Typical missteps include:

- **Underestimating timescales:** Commissioning, sanitisation cycles and microbial trending are required for systems to stabilise and become operational.
- **Misjudging the required investment:** For some markets, obtaining approval means producing several validation batches and completing a minimum of one year of stability studies.
- **Undervaluing staff and testing requirements:** WFI demands the same lab capacity and capabilities as any other drug product.
- **Selecting inappropriate technology**: It is essential to factor in downstream polishing and maintain a laser focus on regulatory acceptance.

These are just a handful of the reasons many organisations opt to partner with a CDMO rather than internalise WFI production prematurely.

ROIS: Scalable, WFI-ready, sterile manufacturing

ROIS (formerly ROVI Pharma Industrial Services) is a forward-looking CDMO that has integrated WFI into its sterile manufacturing. Consequently, it offers rapid supply at scale in full compliance with Ph. Eur. and USP requirements.

Headquartered in Madrid with five facilities across Europe and the US, the injectables specialist embeds WFI considerations early in the tech transfer and line design stages. That means validated water generation, closed distribution loops, routine TOC and endotoxin monitoring, and trained operational teams – all operating under harmonised GMP systems. ROIS has an impressive inspection history and multi-authority approvals, demonstrating proactive management of WFI production.

In practice, this translates to far lower risk and shorter lead times for WFI than developing in-house WFI dossiers from scratch. ROIS offers immediate access to validated WFI and sterile utilities, integrated process design and the operational bandwidth to support both clinical and commercial volumes.

ROIS: An innovative approach to WFI formats

Another vital consideration regarding WFI is the delivery format.

In healthcare settings and in laboratories, the standard choices include multidose bags and vials of various sizes. But, when it comes to high-value drug products, such as biosimilar injectables, market demand centres on ultra-safe unidose WFI delivery – adding a further layer of complexity to filling and finishing workflows.

Drawing on its expert industry insights, ROIS took the decision to invest in filling capacity for PFS with Luer lock adapters. This approach maintains WFI sterility through to the point of use and has been approved by the FDA and EMA. ROIS offers this format in a modular bracketing approach to facilitate PFS fill levels ranging from 1.25 ml to 10 ml for an optimised time-to-market – with FDA and EMA approvals.

So, while some biotechs consider building their own WFI production and filling facilities, ROIS already offers flexible and scalable WFI supply. With its proven expertise, modular systems and track record of compliance, the Spanish CDMO represents an ideal outsourcing partner for those moving swiftly into clinical and commercial stages.

Build or buy?

The essential checklist

If you're debating whether to build WFI capability, it's important to fully understand the potential opportunities and ramifications.

Consider these six key aspects:

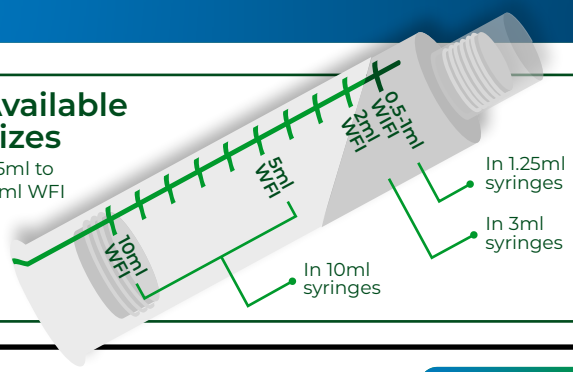
- ☐ **Projected WFI demand**
  Are you looking for clinical or commercial volumes? Do you anticipate pronounced seasonal peaks?
- ☐ **Timeline**
  Do you need production to start immediately? Can you afford to wait for in-house facilities to secure the requisite qualifications?
- ☐ **CapEx & OpEx**
  Do you have the budget available for the necessary equipment, energy costs, validation, lab testing and specialist staff?
- ☐ **Risk appetite**
  Are you comfortable taking on the regulatory risks?
- ☐ **Flexibility**
  Do you need modular, rapidly expandable capacity?

ROIS WFI Capabilities at a Glance

- ✓ **Ph. Eur. & USP**
  Compliant WFI
- ✓ **DMF & CTD**
  Module 3 available
- ✓ **Aseptic Fill**
  & Terminal sterilisation
- ✓ **4-Year**
  Shelf life (Up to)

Available Sizes

0.5ml to 10ml WFI



> **WFI is not a simple utility that companies can simply tack onto their existing operations.**

Conclusion: WFI is a strategic utility, not an afterthought

As the injectable market grows, driven by biologics, vaccines and high-value therapies, WFI has shifted from a background utility to a strategic operating decision. With various trends fuelling demand for WFI, there are arguments in favour of bringing production in house.

Yet, for many companies, particularly smaller biotechs and sponsors under tight timelines, outsourcing WFI to a CDMO offers faster compliance, lower total cost and the operational muscle to support scale-up.

ROIS is a prime example of a partner that combines scale, regulatory approvals and operational capability to deliver WFI-backed sterile manufacturing quickly, reliably and at scale. With multi-authority approvals, validated data and integrated water systems, a partner like ROIS can remove a major point of friction for sponsors – ensuring WFI is not an afterthought but a seamless part of the supply chain.

Selected sources & further reading

- EMA – Guideline on the quality of water for pharmaceutical use (EMA)
- FDA – Guidance on Water for Pharmaceutical Use / High Purity Water System
- Manufacturing Chemist – Beyond WFI generation: safe and efficient distribution of WFI (April 2025)
- Biospace – Global Pharmaceutical Water Market reports and industry analysis

ROIS

ROIS is a top three Global CDMO for sterile injectable manufacturing capacity. With proven expertise, global capacity, and personalized partnerships, ROIS partners with science leaders to deliver complex injectable medicines to patients worldwide. With approvals from leading regulators – including the FDA, EMA, PMDA, KFDA, ANVISA, and MHRA – ROIS offers end-to-end support across multiple formats, including syringes, cartridges, and vials.

info@roiscdmo.com

roiscdmo.com