BioPhorum

A case for shifting to water stewardship in the biopharma sector

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About BioPhorum

BioPhorum's mission is to create environments where the global biopharmaceutical and device industry can collaborate and accelerate its rate of progress, for the benefit of all.

Since its inception in 2004, BioPhorum has become the open and trusted environment where senior leaders of the biopharmaceutical industry come together to openly share and discuss the emerging trends and challenges facing their industry.

Growing from an end-user group in 2008, BioPhorum's membership now comprises top leaders and subject matter experts from global biopharmaceutical manufacturers and suppliers, working in both long-established and new Phorums. They articulate the industry's technology roadmap, define the supply partner practices of the future, and develop and adopt best practices in drug substance, fill finish, process development and manufacturing IT.

In each of these Phorums, BioPhorum facilitators bring leaders together to create future visions, mobilize teams of experts on the opportunities, create partnerships that enable change and provide the quickest route to implementation, so that the industry shares, learns and builds the best solutions together.

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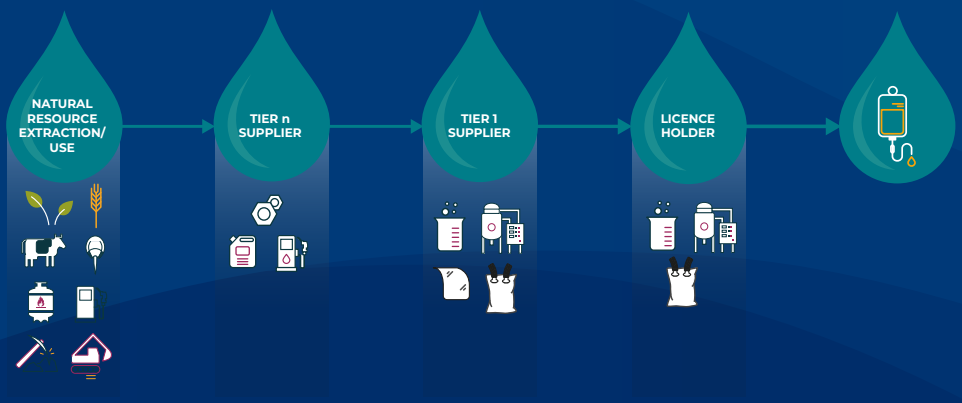
1.0

Business case for water stewardship

Reliable access to clean water is critical for the Biopharmaceuticals sector, especially to make monoclonal antibody (mAb) drugs and vaccines produced around the world. Water is used across the supply chain and throughout the production process, from manufacture of filters, manifolds, and sterile bags to the cleaning of equipment and the preparation of media and buffer solutions needed for production.



There is no alternative raw material for the many uses of water in manufacturing, either for traditional large-batch facilities or the continuous, 'next generation' processing that many companies have in development. The industry's dependence on high quality water from basins around the world is only growing as more patients are reached. Many of these basins are under pressure from the impacts of climate change, pollution, and increasing demand from growing populations and business. Therefore, it is an imperative that the industry takes action on two fronts:

- Continue to innovate and drive efficiencies in water use and design out pollution throughout the process to avoid further contributing to these pressures.
- Broaden the understanding of connections to local water supply by considering the impacts and dependencies that each facility has on freshwater as a shared resource in the basins where their medicines are manufactured.

There are several factors that are understood to be barriers to wider action within the industry, including:

The cost of water

Globally, it is agreed that water is undervalued, which is a significant barrier to investment[1]. Within the Biophorum Sustainability Water workstream, it is a shared challenge to secure funding for water efficiency projects since traditional return on investment (ROI) calculations are typically far less than energy projects competing for the same resources.

Navigating perceived tradeoffs and regulatory hurdles

As a highly regulated industry with a critical need for clean, controlled processes, there are challenges and risks associated with limiting water demand in manufacturing and cleaning processes that must be carefully managed. Any changes to these processes once filed with regulatory bodies are time consuming and resource intensive to gain approvals for implementation.

Lack of appropriate risk management and assumed security of wider infrastructure and supply chain

As a sector, we are highly dependent on infrastructure such as municipal supply or wastewater treatment, as well as the availability of raw materials, that are beyond each site or company's direct control. Without transparency and close relationships with these critical partners, emerging risks to business continuity may be difficult to identify. Considering how critical water is across our sector, the resilience of the wider industry is at risk without a stronger awareness and strategic connection to this need for maintained access.

In a benchmarking exercise of Biophorum member companies' targets and commitments, it was found that of those with public facing targets and commitments, the vast majority were focused on efficiency within site boundaries, often with global targets to reduce water use in their own operations. In addition, it is assumed that compliance with permits for water quality is additional action that companies are taking, perhaps in certain cases going beyond local requirements, but seemingly without a strong understanding of the impact to the broader basin. For example, a site may be well within permit limits for all emissions to the local wastewater treatment plant, but those limits may not be sufficient, unknowingly resulting in adverse impacts to local biodiversity and the community.

While these efforts are important and laudable, they result in minimal reduction of individual company or site exposure to broader water risks, such as water scarcity, flooding, or poor quality that could impact a company's resilience, along with the associated reputational and regulatory risks. Focusing only within your own operations also limits the opportunity to increase awareness of local conditions and strategically connect this wider knowledge into the company's strategy and risk management processes.

The variety of water risks that our industry has already begun to face are a strong indication that it is time to rethink the Biopharma industry's approach to water in order to maintain business continuity and avoid impacting access to the medicines that patients rely on. Shifting from 'water management' with a focus within your own operations to 'water stewardship' requires significant change management, and support from senior leaders is essential. This paper aims to:

- Educate on what water stewardship is
- Share resources available for our industry
- Encourage sufficient resourcing and budgeting across the industry to support our wider contribution to shared water challenges as a sector.

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What is water stewardship

The Alliance for Water Stewardship defines Water Stewardship as the use of water that is socially and culturally equitable, environmentally sustainable and economically beneficial, achieved through a stakeholder-inclusive process that includes both site- and catchment-based actions[2]. This definition has been widely adopted, including by the United Nations[3].

Consider the analogy of a fish in a pond. You can be the 'cleanest fish' in the pond, taking actions to improve water efficiency and manage the discharge from your own operations, but if you disregard the fact that the pond you are in is getting dirtier, you are unlikely to survive. Any site or critical node across the broader supply chain located in a 'dirty pond' with any associated water risk could impact business continuity across our industry. Water stewardship helps to shift the understanding of water beyond site boundaries, effectively putting a site's water use into the context of the local water basin by providing the set of practices to address the challenges we face around sustainable and equitable water management.

Water risks can be found across the value chain, even if a company doesn't seem to have a large direct reliance on water, including from disruptions in commodity production and distribution channels, and damage to capital infrastructure[4]. Within this context, it has become imperative for organizations to not only be sustainable, but water resilience needs to be incorporated into business practices to prepare for, recover from, and adapt to these water-based risks. Companies can manage water and climate risks by building resilience in their supply chains, the communities where they operate, and the natural systems they rely upon.

An appropriate context-based water resiliency strategy can be developed by approaching water management through the lens of Water Stewardship. Guidance for how to approach this has been well described by experts in the water stewardship community, including **WWF's Putting Water Strategy into Context**.

For companies, this often starts by considering how water is used within direct operations (i.e. at owned and operated facilities), how its water use impacts the local watershed, and how the conditions of the watershed impact its operations. Water challenges are diverse and their corresponding risks to businesses are hyperlocal[5].

External risk evaluation

Water is not fungible, and location is critical to proper water stewardship. If you are an organization with multiple locations, each one has a unique risk profile as it relates to water use. From cost to risk exposure to local regulations and infrastructure, each facility across a company's supply chain will have different local 'context'.

As such, water stewardship efforts typically start with a risk evaluation. Water-related risks are varied and include physical, regulatory, and reputational risks, both from a wider basin and more specific operational perspective. An initial risk analysis generally leverages tools such as the World Wildlife Fund (WWF) Water Risk Filter[6] or the World Resources Institute (WRI) Aqueduct Risk Atlas[7], which give a general overview of potential water-based risks based on the watershed of a particular location. These tools are designed for companies to use as a screening and prioritization tool to identify 'hotspots' of risks, including measures for availability or 'quantity' (such as stress, scarcity, or flooding), as well as quality and the commonly associated reputational and regulatory risks, across a global network of sites. They are not intended to be used to assess specific conditions at site-level[8], but they are highly useful to begin to understand how the risks that exist in the wider area may affect the operational requirements of a facility.

A basin level risk assessment has been performed for the pharmaceutical sector[9]. While the list of facilities was only using publicly available locations for facilities and is by no means holistic, it outlined that water quality was highly relevant to the sector as a whole and it illustrates how the high-level data from these risk screenings can be applied more widely to support prioritization of efforts.

Following the high-level risk assessment at the site level, a deeper dive is needed to better assess each site's water risk, narrowing beyond a basin or watershed level to give an accurate risk profile. For example, a given site may be located in an identified flood zone, but if the facility is at the top of the hill, the risk impact is likely minimized when evaluating for the actual building. However, thinking more widely, if the local treatment plant that the facility depends on is not able to operate in that flooding event, then business continuity is still impacted.

Evaluation of water quality in context with operational requirements and local water source quality is also imperative. For example, common water quality factors such as hardness and conductivity can directly affect operations from cooling towers to filtration requirements, and will vary across water sources, varying gradually from season to season or abruptly when municipalities change water sources throughout the year.

Moreover, each site will have its own reputational and regulatory risks based on the culture of the surrounding communities and the relevant existing and emerging relevant regulatory frameworks, such as EU's Corporate Sustainability Reporting Directive[10], Water Framework Directive[11], and Urban Wastewater Treatment Directive[12], along with various PFAS[13] regulations or the discharge of priority substances.

The analysis of these site-level risks can then be assessed at an enterprise level, leading to risk prioritization and actions at the highest risk sites, and will naturally progress beyond risk evaluation to context-based water targets.

Progressing beyond risk evaluation

Water Stewardship is often referred to as a 'journey', which the WWF's water stewardship ladder articulates as a shift starting with general awareness and deepening understanding of where the most significant water challenges exist across the value chain. From there, a company can confidently decide where to further act and move up the ladder to the point that they are involved in collective action, loosely defined as working together to solve shared water challenges[14]. This typically involves partnering and engaging broadly with stakeholders, including with regulators and governments who provide the critical infrastructure needed to support their business, often with companies financially supporting at least a portion of the project costs[15, 16]. By moving up the ladder and focusing efforts far beyond one's own operational control to address these challenges is what is known as shifting from water management, often involving more 'inside site boundary thinking', to water stewardship.

While WWF's ladder describes the maturity level each firm exhibits as it increases the rigor of its water action, other approaches such as the AWS standard are complementary to this approach as a tool to help companies assure they are credibly addressing water risks at individual sites. For example, a company that is just beginning to adopt water stewardship practices may not see a full picture of water risks and opportunities, but as they deepen understanding, the business case to engage and invest in specific basins where they are most exposed to water risks often becomes much more clear.

Image by WWF[16]

Because of our critical dependence on water as a shared resource, we are open to risks far beyond site boundaries, both upstream and downstream. These types of risks can be daunting for any one facility to even scope out, let alone begin to address. This is why the conventional wisdom in the water stewardship community is to work together, or 'collectively' to address shared water challenges and opportunities[17, 18].

It is widely recognized that engaging with stakeholders in the wider community and investing in projects outside of a company's operational control requires a significant change in approach for a typical business. According to the CEO Water Mandate's Guide to Water Related Collective Action, "effective collective action requires establishing nonconventional relationships with nontraditional partners" and "requires the development of new skills and knowledge, such as a more in-depth understanding of community needs and values"[19].

Hence, in order to be successful in these efforts toward enhancing water security for their business, senior level commitment is needed to drive meaningful target-setting, investments, and resourcing to support broader engagement outside of site boundaries. It is important to remember that collective action is not philanthropy or a one-off event, but is a step change in how a company thinks about its connection to risk in the wider watershed.

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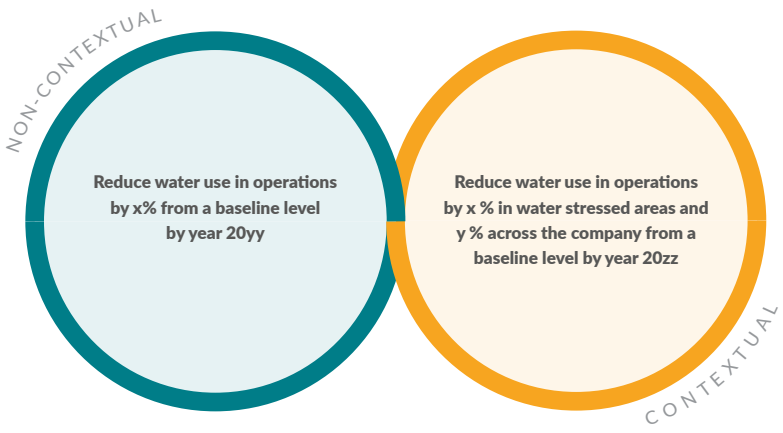
Resources and guidance for taking action

Targets

Once local risks are better characterized and an understanding of where to prioritize is built, another challenge emerges for large companies—with water risks and opportunities understood to be so local, what is the best approach to connect this highly local way of thinking into a global company-wide strategy? Action in companies are often driven by target setting, which is no different for water stewardship.

As described in **WWF's Putting Water Strategy into Context**, strategic goals set at a corporate level will ideally meaningfully connect to the specific local conditions, or 'context' of each location. Furthermore, 'science-based' freshwater targets are also emerging, which are better informed by local hydrological data[20]. Ultimately, the aim is to use the existing resources and emerging wider access to data to better inform water targets that are strategically relevant, meaningful, and connected to local context, focusing efforts where they will make the most impact.

There are various ways that targets and corporate level programs can mobilize efforts where companies have the most control, which is typically within their own sites. Efforts that may be relevant to drive to varying degrees in our sector include those for water efficiency or enhanced measurement of a full water balance (taking both withdrawals and discharge into account), along with those that drive actions to limit impacts on water quality beyond local permit requirements.



Investment in water infrastructure

Although the cost of water may lessen the return on investment for water projects within facilities, when viewed more widely, they often provide opportunities far beyond just saving water. When monitored properly, the co-benefits often include energy savings and a reduced carbon footprint—especially when considering not only the charges to withdraw and discharge water, but additional costs such as pumping, treating and heating expense, as well as the value of chemicals and raw materials discharged in wastewater streams[21].

Certifications

There are also certifications that focus on water use and water stewardship at a facility or enterprise level, that can support company efforts to limit impacts from their facilities on the basins where they operate, while also demonstrating evidence of their commitment externally. These include:

- The Alliance for Water Stewardship Standard certification[22]
- The Water Council WAVE Water Stewardship Verified[23]

Collective action beyond operational control

Several resources are available to connect companies who have prioritized locations to engage with others to address the water challenges that are most strategically relevant to them. These include:

- The CEO Water Mandate's Water Resilience Coalition[24]
- The Water Action Hub and 100 Priority Basins with highest level of opportunity for collective action[25]
- The Alliance for Water Stewardship Impact Accelerator program[26]

4.0

Conclusion

Regardless of a company's specific approach on water—from how they set targets or what organizations or guidance they choose to engage with, the key for building a resilient business is through adoption of water stewardship. The work starts with deepening understanding of where to prioritize efforts, driven by a robust assessment of wider water risks. These risks are quite broad—from worsening quality caused by pollution, physical climate change related risks like flooding and scarcity, to regulatory and reputational risks that are likely to increase as local conditions worsen. It is not possible to assess or prioritize which present-day or future water risks tied to each given location in a company's value chain are most likely to have significant impact without connecting local data and stakeholder knowledge to global risk management processes. From there, a case for meaningful engagement that clearly defines the challenges, followed by local partnerships and projects that address them becomes clear.

Considering the Biopharma sector's dependence on clean freshwater as a vital input across the supply chain, right-sized efforts and investments that positively impact the basins most in need of the support is imperative to strategically manage risks and improve business continuity. This will only become more true as the climate continues to change, resulting in more intense wet and dry weather patterns, likely driving increased focus from the public and regulators on how water is used.

Now is the time for our sector to engage more meaningfully on water, both within and beyond our operations, to maintain our supply to patients—they are depending on us.

Appendix

Case studies

These case studies from the biopharma sector show action within site boundaries that considers local context:

Case study 1—AstraZeneca

AstraZeneca's Operations site in Canóvanas, Puerto Rico is located on 65 acres in a tropical area prone to localised flooding. The area has also historically faced challenges with supplying and treating water, especially during past hurricane activity, which has led to disparities in water services and communities recovering at different rates. By taking a water stewardship approach, the site recognized an opportunity to take action and contribute to solutions for these shared water challenges.

The installation of a pond at the low point of the grounds with capacity up to 2 million gallons helped mitigate the flooding risk not only for the site, but also for an adjacent road that is one of the critical access points for the wider area that was frequently inaccessible before the pond was in place. As part of the global climate and water risk assessment program that brings together site-based experts with data on the projected physical risks resulting from climate change, it was identified that the benefits from the pond will continue as maximum daily rainfall is likely to further increase. Retaining the stormwater runoff within the site's pond also helps to relieve pressures on the local wastewater treatment plant.

Further benefits were realized when the pond became an additional source of water for the facility, treated on site and used in the cooling towers needed for the site utilities. This reduced the site's water demand on the municipal water supply by an average of 29.5%, equating to over 11 million gallons annually that can serve the wider community and support continued growth in the area.

Pond in upper right corner

Case study 2

Water stress assessment (using WRI aqueduct tool) has been performed at all our facilities.

Based on results, water stewardship initiatives have been implemented to minimize the risk.

For example, one of our production sites

- installed water conserving faucet heads to reduce the consumption of freshwater. The initiative resulted in conserving approximately 130K liters/year
- started to reuse treated water in non-technical areas to minimize freshwater usage in flush tank. This resulted in conserving approximately 4,500K liters/year
- installed a wastewater discharge meter to eliminate the need for estimating discharges and refine estimates of water consumption.

These initiatives have supported a reduction of 24.5% of freshwater consumption (2022 vs 2021)

Opportunities to engage

As a sector, opportunities to engage more broadly beyond facility boundaries may include:

- Working with water providers to identify opportunities to support and diversify the local water supply where scarcity risk is high. This could include repairing leaks or creating 'purple pipes' to reuse water elsewhere in the area.
- Identify locations within a given company network where they are dependent on infrastructure, such as water treatment facilities, that are at risk of exceeding capacity or of being unable to serve the wider community. If projects within site boundaries do not sufficiently resolve the shared water challenge, take action in partnership with the water authority and providers to plan for an appropriate solution, which could include expanding the capacity of the existing systems or building a new treatment facility for the region.
- Biotechnology manufacturing has been identified as having a high materiality rating for water pollutants[27]. Identifying hotspots of locations where many different companies are emitting to the same wastewater treatment plant and collectively engaging with them to understand how the varied discharge from the various manufacturing processes impede their ability to effectively treat it. Using a risk-based approach, find ways to work together to avoid adverse impacts on water quality from the concentration of biologics production.
- As healthcare companies, deepen understanding of how Water Access and Sanitation issues (WASH) are connected to preventing disease and partner with NGOs to best address areas in need that are strategically relevant to our mission and purpose.

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