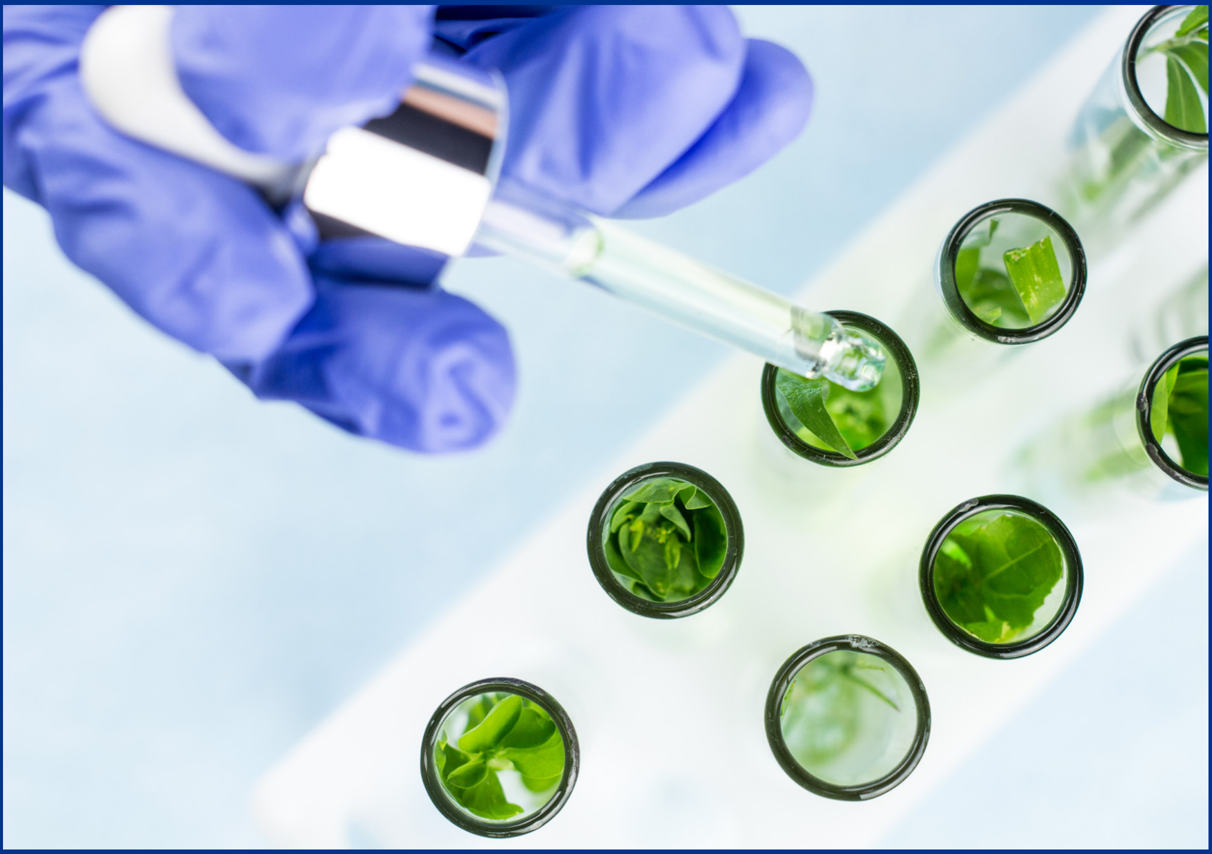
KPMG

Navigating CSRD Reporting in Life Sciences

The implications and challenges of the EU's new Corporate Sustainability Reporting Directive (CSRD) and how Life Sciences companies are preparing for it.



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Background

The recent IPCC climate change 2023 report[1] has made one thing very clear. When it comes to protecting the environment, everyone must do more. And do it now.

This isn't hyperbole. As the report stated, it is 'likely that global temperature rise will exceed 1.5°C during the 21st century and make it harder to limit global warming to below 2°C'.

That may not sound like much, but, as the report further noted:

"Risks and projected adverse impacts and related losses and damages from climate change escalate with every increment of global warming (very high confidence). Climatic and non-climatic risks will increasingly interact, creating compound and cascading risks that are more complex and difficult to manage (high confidence)."

Even a rise of half a degree will see substantial increases in heatwave duration and intensity, water scarcity, rising sea levels, coral reef loss, and reductions in crop yields – as was reported in a European Geosciences Union study published in their journal, Earth System Dynamics[2].

Climate change is expected to have **significant direct and indirect impacts on human health and biodiversity**, including extreme weather events, air pollution, heat-related illnesses, vector-borne and waterborne diseases, mental health issues (such as stress and anxiety), loss of habitats and a rise in extinctions, food and water security, displacement, and disruption in the supply chain. Some of these impacts are already being felt today, and the list is constantly growing.

Governments around the world are implementing a range of regulations, laws, frameworks, and guidelines to address and mitigate the impacts of climate change.

One of the great achievements in recent years has been the establishment of Environmental, Social, and Governance (ESG) goals to ensure long-term sustainable business practices and responsible corporate citizenship.

And, most recently, a major ESG regulation came into force in January 2023, the mandatory EU Corporate Sustainability Reporting Directive (CSRD). Set to ensure that ESG becomes part of the annual reporting process (via a combination of financial data, sustainability information, and assurance), its implementation poses several implications, and challenges, to the Life Sciences industry.

But getting it right will be transformative for the industry. In a nutshell, CSRD will be a catalyst on how Life Sciences enterprises are run – from profit-only to purpose-driven where communities matter, the environment is protected, and diversity is celebrated – and help create both business value and a competitive edge.

We discussed these challenges in a recent KPMG webcast on CSRD reporting with Dr Klaus Kunz, Head of ESG External Engagement and Performance Reporting at Bayer in Germany, Maria Schaad, Head of Performance and Reporting, Group Corporate Sustainability at Merck in Germany, and Véronique Toully, Global Head of Sustainability, Corporate Affairs and Enterprise Risk Management at UCB in Belgium.

Notes:
(1) IPCC, 2023: Climate Change 2023: Synthesis Report. A Report of the Intergovernmental Panel on Climate Change. Contribution of Working Groups I, II and III to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change [Core Writing Team, H. Lee and J. Romero (eds.)]. IPCC, Geneva, Switzerland, (in press).
(2) Schleussner, C.-F., Lissner, T. K., Fischer, E. M., Wohland, J., Perrette, M., Golly, A., Rogelj, J., Childers, K., Schewe, J., Frieler, K., Mengel, M., Hare, W., and Schaeffer, M.: Differential climate impacts for policy-relevant limits to global warming: the case of 1.5 °C and 2 °C, Earth Syst. Dynam., 7, 327–351, https://doi.org/10.5194/esd-7-327-2016, 2016.

What exactly is the CSRD and who does it impact?

The directive aims to encourage companies to adopt sustainable practices, improve transparency, and provide investors with more reliable and comparable sustainability information.

Replacing the EU's non-financial reporting directive (NFRD), the CSRD requires all large, EU-listed business entities and global businesses that have operations in Europe (with a net turnover of €40 million or more, a balance sheet total of €20 million, and 250+ employees on average over the financial year), as the European Commission notes: "…to publish regular reports on the social and environmental risks they face, and on how their activities impact people and the environment."

Non-financial information, in particular, must be reported in far greater detail than before.

Set to initially involve over 50,000 companies, it will soon expand to cover small and medium enterprises (SMEs) as well. If you're reporting in line with NFRD, the first reports will be from January 1, 2024, and for large companies not currently subject to NFRD, from January 1, 2025. Listed SMEs follow in 2026.

An exemption rule is applicable for subsidiaries that are included in the CSRD-compliant report of their parent company.

Reporting areas will include 'strategy & governance', where companies must report on the sustainability aspects of their strategy and business model, their process of material assessment, management responsibilities, and the processes and reporting procedures used to address and monitor sustainability issues. Additionally, companies must report how their strategy is put into action and provide metrics and targets to show how the process is going.

For Life Sciences, this will require a focus on resource management, supply chains, access to healthcare, technology & data, compliance with regulations, and the development of certifications and guidelines.

CSRD and Life Sciences: The implications

Because Life Sciences encompasses many activities related to the development of products and services intended to improve health and well-being, the industry is subject to a large range of environmental and social considerations that are relevant to CSRD (and ESG overall).

Some of the most important implications for CSRD include:

Increased reporting requirements

Detailed information must be provided on sustainability performance, including ESG metrics.

Greater transparency

CSRD requires the disclosure of more detailed and standardised information to increase transparency and help investors and other stakeholders to be able to make informed decisions about the sustainability of the companies they invest in or work with.

Bigger focus on sustainability

Increased reporting requirements and greater transparency will better enable companies in the Life Sciences industry to improve their sustainability performance. This may involve implementing more sustainable practices, such as reducing greenhouse gas emissions, minimising waste, and improving access to medicine and

Enhanced reputation and stakeholder engagement

Compliance with the CSRD is likely to enhance business reputation and build trust with stakeholders, which will lead to increased customer loyalty, improved employee morale, and a better relationship with regulators and other stakeholders. Importantly, it will also promote a more collaborative approach to sustainability, which can lead to greater innovation and more effective solutions to sustainability challenges.

Competitive advantage

Companies that demonstrate strong ESG performance and who transparently disclose this information to stakeholders will gain a competitive advantage: Investors and customers want more sustainable products and services. By implementing sustainable practices and disclosing information on ESG performance, companies can improve their reputation and attract new customers and investors.

CSRD and Life Sciences: The challenges

Owing to the industry's complexity, its highly regulated nature, and the large number of stakeholders involved, implementing CSRD comes with numerous challenges, including the need to:

1. Collect relevant sustainability data from a wide variety of sources, including third parties.

2. Develop a standardised reporting process that considers various reporting requirements and different data sets. Reporting must also comply with the European Sustainability Reporting Standards[3].

3. Find additional resources when implementing the CSRD to ensure that reporting requirements are aligned with existing regulatory frameworks.

4. Determine what constitutes a material sustainability topic for the business, and how to quantify it. For example, is it a risk to operations or potentially negative to stakeholders and customers? Additionally, what impact does the business have on the environment and society? The 'double materiality' requires that all potentially positive and negative impacts on people and the environment must be identified.

5. Set up an independent assurance of sustainability reports to improve the quality and reliability of the reported information.

6. Define, develop, and manage a robust sustainability risk management strategy that includes areas such as product safety, data privacy, and environmental impact.

For most companies, solving these challenges will not be easy.

Obtaining relevant sustainability data can be challenging for many players in the industry due to their lack of experience in where, how, and when to source meaningful data (or to even how to define what is meaningful and impactful). Technical systems are simply not ready, and the short time frame to prepare it can be a significant problem.

(3) KPMG in the Netherlands: Get ready for European Sustainability Reporting Standards – Understanding the first set of draft ESRSs, 30 November 2022.

Even for these industry leaders, who are well along their non-financial reporting and ESG journeys, there are still many questions to ask and challenges to solve, especially around data.

As Dr Klaus Kunz mentioned, “The key challenge that we all have is that the maturity of the full breadth of ESG is completely different. There are some areas such as biodiversity, where we struggle how to measure this, and there are some areas, like carbon, where we know how to measure this. The carbon framework is very developed, but nothing of this is as developed as the financial and accounting frameworks. And when it comes to collecting data for the reports, we can do this for some areas, and for others we have a hard time collecting this as of today.”

Time and resources must be invested into ensuring that non-financial data is as robust as financial data. The problem, however, as he continued, is that CSRD will require a LOT of data but “which of this data is actually meaningful? What’s the message? What’s the real learning that you have from collecting all of thousands of data points? Is it really impactful? Is it helping investors to make decisions in a different way than in the past?”

Another significant challenge is collecting the ESG data. Especially if it is located in countries outside of the EU with different ideas on what to collect and how it is stored and reported. The reporting standards between (for example) the United States and the EU can vary significantly.

For Véronique Toully, in addition to the data challenge, it was that (reasonable) assurance presents itself as “a completely new ball game” with the acknowledgement that a lot of work still has to be done to go from limited assurance as provided by UCB already for their key non-financial metrics to reasonable assurance for all their non-financial reporting.

This shouldn’t come as a surprise. Assurance poses multiple challenges, including the complexity of sustainability issues, lack of standardisation, limited data availability, and no universally harmonized standards for sustainability reporting.

From Merck’s perspective, as Maria Schaad noted, one very challenging issue is that: “All these non-financial supporting frameworks are slightly different, making things even more complex.”

Overcoming these challenges will take time. But time is quickly running out.

Getting it right, however, means companies can improve their sustainability performance and enhance their reputation. It can also be a vital catalyst for ESG-driven business transformation by helping to improve the comparability, consistency, and transparency of sustainability reporting.

In this regard, identifying and quantifying the unique, and specific, topics that are relevant to the Life Sciences industry is vital to ensure CSRD reporting is successful and helps fuel overall ESG efforts. As is the need to fully harmonize ESG-reporting frameworks to ensure consistency and comparability, to avoid greenwashing, improve efficiencies by simplifying the reporting process, increase transparency, and standardise ESG reporting across industries and geographies.

Sustainability matters: Key aspects for Life Sciences

Although long-term sustainability has become part of everyone's agenda in recent times, many organisations lack substantial experience in dealing with various sustainability topics.

This is arguably the most significant problem. The reports are mandatory and ESG is becoming a core factor in investor and customer considerations, and government regulations. But many businesses in Life Sciences simply aren't ready and have little understanding of what high-quality, impactful, and meaningful sustainability data they need to collect (especially from third parties).

This is further exacerbated by the unique, and diverse, needs of Life Sciences organisations. Each must approach their ESG goals in a variety of ways, and that means each has different challenges to tackle, and goals to achieve.

Environmental topics

Three ESG leaders and their experiences

As a significant contributor to carbon emissions and waste generation (specifically in the manufacture and distribution of pharmaceuticals and medical devices), the Life Sciences industry has a range of challenges to overcome. But as our speakers discussed, significant efforts are being made to overcome these challenges.

As Véronique Toully mentioned, reducing Scope 3 emissions "has been a strong focus for us (UCB) in the past three years, with different actions taken. First of all, we have a 'green clause' in all our contracts, which signifies to our suppliers that they need to commit to science-based targets. We also interact with our suppliers on a regular basis." Furthermore, CEO-level engagement with their suppliers is paramount.

> "When our CEO takes the time to engage in a dialogue with our strategic suppliers on their GHG emissions targets and explore how we can help them, I can tell you that it has an impact."
>
> **Véronique Toully**
> Global Head of Sustainability, Corporate Affairs and Risks UCB[4]

Merck, as Maria Schaad added, has a goal to be climate-neutral by 2040 throughout the entire value chain but "that's a long time to go, so we also have intermediate 2030 targets. These are to have our Scope 1 and 2 emissions reduced by 50 percent as well as reduce our Scope 3 emissions by 52 percent per Euro of gross profit respectively."

A big lever to achieve their Scope 1 goal is to reduce process-related emissions, for example in the production of special chemicals for the electronics industry, while Scope 2 is to get 80 percent of their energy from renewable sources. With regards to Scope 3 emissions, transparency and extensive data collection are key to achieving the goal.

When asked how their organisations managed water usage, as scarcity and pollution within the R&D and production process is an ongoing problem, Dr Klaus Kunz noted that for Bayer, "As a company working in agriculture, one of our key impacts is downstream, in the farm. The water topic has been relatively minor in the public space, relative to carbon, while of course climate change and water scarcity are completely closely connected topics."

Dr Klaus Kunz also mentioned that measuring the effectiveness of policies and actions regarding water management is not easy, but it is not as complex as addressing biodiversity.

Moving forward, while meeting regulations is important, all actions regarding the environment must be designed around creating a positive impact.

(4) UCB S.A. (2023): Sustainability at the heart of all we do, [online] URL: https://www.ucb.com/our-company/sustainability [Accessed on 30 May 2023].

Social topics

Three ESG leaders and their experiences

Companies in the Life Sciences industry are intricately linked to social issues and the communities in which they do business. For example, ethical considerations around research and the role it plays in developing treatments and therapies, or issues around the broader impact the industry has on society by seeking to address health inequalities and access to medicine and healthcare.

It is no surprise, therefore, that consumers and governments increasingly expect the industry to 'do the right thing' where they operate.

Achieving such universal access requires looking at every place that you operate in, not just low- and middle-income countries (LMICs) but also high-income markets. As Véronique Toully emphasised, UCB "started a "social business approach" with the objective to measure social and financial impacts in LMICs which are outside our direct markets scope. But for our core markets too, we take the access piece very seriously with the objective to improve access to our innovative products, in countries such as the United States, where "you still have a lot of needs in terms of access to innovation for underserved populations."

According to Dr Klaus Kunz, Bayer has also "Set up very ambitious targets four years ago, for access, across all of our divisions. We want to support 100 million small-holder farmers by 2030 from the agriculture division. We want to provide access to nutrition for 100 million people in under-served communities, and we want to provide access for women to contraception in lower-and-middle-income countries. These are very big challenges for us."

While unsure how the divisions would meet these targets when setting them up, Bayer had to redefine their business strategies to make this happen.

> "This is not about charity, this is redesigning business and redirecting business a little bit away from the very high margin areas into some lower margin areas."
>
> **Dr Klaus Kunz**
> Head of ESG External Engagement and Performance Reporting Bayer[5]

This strongly highlights how commitment must come from the top and the business must focus on creating impact, not just meeting regulations.

As Maria Schaad continued, "Access to health is vitally important to Merck." And a significant priority is to "expand access to our healthcare portfolio in lower-and-middle-income countries."

To achieve this, and to tackle other challenges, there is a clear need to boost local engagement and capabilities. Also, a culture needs to be developed that openly welcomes diverse perspectives and encourages diversity (both with regard to the company's employees and their ethnicity and gender representation, and in its business operations – including clinical trials to ensure they represent the groups most affected by a particular disease).

Creating a positive social impact should be part of the company's culture and enable it to become a purpose-driven company.

(5) Bayer AG (2023): Sustainability Report 2022, February 28, 2023.

Governance topics

Three ESG leaders and their experiences

The Life Sciences industry faces a range of governance challenges, including regulatory compliance, IP protection, transparency, board diversity, accountability, and risk management.

Good governance is critical, must be led from the top, and be a part of the entire business strategy. It is also vital when it comes to meeting the various challenges of integrating ESG throughout the business, which was discussed in-depth during the webcast.

For Dr Klaus Kunz, ensuring ESG is trusted was essential. If it wasn't connected to the CEO's and board's reward system, it would make people sceptical of any positive sustainability reporting. Therefore, ESG was best seen as "transforming a sustainability and business strategy into an investible framework which is trustable and that's where you need the 'G'."

That governance agenda should be about disclosure and building trust into the sustainability strategy.

> "The sustainability strategy needs to be part of the business strategy and sustainability needs to be a part of our normal day-to-day business. A second element, she continued, 'is to incorporate it into our processes. So, if our policies and standard procedures do not include sustainability, it will not be deeply integrated into what everybody does every day and how decisions are taken."
>
> **Maria Schaad**
> Head of Performance and Reporting,
> Group Corporate Sustainability Merck[6]

This is a change that must be supported by everyone, and properly aligned. For Merck this also meant setting up an external board to help with their sustainability efforts, to ensure "we are not only in our own realm where we reassure ourselves and think everything is fine and we are progressing well." We want this external panel to challenge us.

A good point is to see that everyone is doing this together. As Véronique Toully mentioned, "We are facing a societal transformation. It's not us on our own that can make this happen. We need investors to align, we need regulators to help, and we need, basically, every citizen to be really convinced that they should favour companies that are doing the right thing."

Everyone contributes, and everyone wins.

The CSRD may be mandatory and will certainly create many challenges but with organisations using it to bolster their ESG efforts, which are integrated into how each business is run, it can become a massive catalyst for positive change.

(6) Merck, Group Corporate Sustainability (2023): Sustainability Report 2022, April 13, 2023.

ESG, CSRD, and Life Sciences: Enabling a purpose-driven company

There are several ways that the CSRD can serve as an incentive to drive change. The CSRD:

01 Requires companies to report a much wider and more detailed range of sustainability factors, which also include environmental and social matters. Having this information available for public scrutiny will ensure more transparency and accountability.

02 Mandates that reports must adhere to European Sustainability Standards, which helps to standardise ESG reporting.

03 Provides a solid framework for companies to integrate ESG considerations into their strategy and decision-making processes, which can help companies to identify and manage ESG risks and opportunities and align their business activities with the UN Sustainable Development Goals.

04 Requires companies to engage with shareholders and investors on ESG issues, which can lead to increased dialogues that result in better-in-formed decision-making and a better understanding of the impact of their operations.

05 Promotes more transparency and better risk management. This can help investors and stakeholders make informed decisions and lead to better governance and sustainability practices.

For those who get their sustainability (and ESG) reporting right, however, the benefits will be substantial. CSRD will improve the quality of your ESG reporting, change how your business is run – from profit-only to purpose-driven where communities matter, the environment is protected, and diversity is celebrated – and help create both business value and a competitive edge.

As we've seen, even for some of the big players in Life Sciences, ensuring that meaningful and high-quality sustainability data is correctly gathered, analysed, and reported won't be easy.

But many are already on the way. The big question is, are you?

Key takeaways

- Consider CSRD as a business enabler to build a purpose-driven enterprise.
- CEO and board-level support is vital to build an impactful business that helps to conserve our planet and contribute to society.
- Effective change management is needed to cascade sustainability throughout the organisation.
- Extensive effort must be made to collect relevant and detailed data on biodiversity and other sustainability topics. This will require close collaboration with Finance/Controlling, whose processes are more established and whose data more mature.
- New skillsets must be developed and/or new roles created to better manage your sustainability transformation (business acumen + ESG + analytics).
- Seamless collaboration is essential to get it right both externally with investors, business partners, regulators, and communities, and internally across all business segments, sustainability, finance, investor relations, and IT.

Scan the QR code to learn more about the impact of the new EU Sustainability Reporting Directive on the Life Sciences industry

Authors

Andrea Sternisko
Partner, Head of ESG Life Sciences Germany
KPMG in Germany
asternisko@kpmg.com

Michael Wagemans
Partner, EMA Head ESG in Life Sciences/Head of ESG, KPMG in Belgium
mwagemans@kpmg.com

Thomas Hillek
Partner, EMA Head of Life Sciences
KPMG in Germany
thillek@kpmg.com

Meino Müller
Partner, Head of Life Sciences & Chemicals Germany
KPMG in Germany
mmueller@kpmg.com

Contacts

KPMG AG Wirtschaftsprüfungsgesellschaft

National Life Sciences Leads

Koen Van Ende
Partner, KPMG in Belgium
kvanende@kpmg.com

David Ikkersheim
Partner, KPMG in the Netherlands
ikkersheim.david@kpmg.nl

Mathieu Schohn
Partner, KPMG in France
mschohn@kpmg.fr

Natasha Vaidanis
Partner, KPMG in South Africa
natasha.vaidanis@kpmg.co.za

Vijay Chawla
Partner, KPMG in India
vschawla@kpmg.com

Luis Buzzi Fagundo
Partner, KPMG in Spain
lbuzzifagundo@kpmg.es

Brian Egan
Partner, KPMG in Ireland
brian.egan@kpmg.ie

Martin Rohrbach
Partner, KPMG in Switzerland
martinrohrbach@kpmg.com

Paolo Mantovano
Partner, KPMG in Italy
pmantovano@kpmg.it

Adrian Griffiths
Partner, KPMG in the UK
adrian.griffiths@kpmg.co.uk

www.kpmg.com

home.kpmg/socialmedia