PwC's Pharma & Life Sciences Regulatory Radar

Increasing regulatory challenges

The pharmaceutical & life sciences industry, a long-standing, innovative and successful industry, needs to function in an increasingly challenging market environment. Regulation is one of the main reasons for this. In an increasingly interconnected world where more and more sophisticated pharmaceutical (e.g. genetically engineered, and biologicals, orphan drugs), Medtech as well as nutrition products are being developed, public scrutiny and ultimately legal frameworks are tightening. Governments and regulators are adopting more regulations in order to meet the requirements of technological advancement and changing social conditions (e.g EU GMP/GDP Annex 21, Annex 6 and 16 for clinical trials and the new Swiss "Arzneimittelverordnung"). Given the vast quantity of regulations, there is an inherent risk of missing out on critical topics or taking the required action too late. Therefore, the pharmaceutical & life sciences sector will have to be vigilant and adapt to the constantly changing regulatory landscape.

Our digital solution to sure you are fully informed

The Regulatory Radar is our response to the regulatory avalanche. With our **Pharma & Life Sciences Regulatory Radar,** you will not miss out on any new **regulations** concerning clinical trials and commercial (e.g. R&D **products and precision medicines or to reimbursement** of medicines through the social security systems. At the same time, you will receive a **tailor-made solution** that **analyses regulatory initiatives** and draws your attention to the need for **potential action.**

Based on our global presence, PwC monitors through its national and international network the publications and updates of the relevant authorities and provides a detailed overview of the latest regulatory developments in various jurisdictions (e.g. US, EU, Switzerland). The Pharma Regulatory Radar measures the impact of regulation on businesses and enables a periodisation in terms of measures. We cover the entire cycle of a regulation, from its legislative formation process, entry into force to its impact on businesses. We thereby not only help you to save money and allocate resources most efficiently, but also provide you with the benefit of our practical experience and knowledge to highlight a way forward.

Your benefits – Our contribution to your business success

- Save costs and resources
- Consolidated supervision
- Tailor-made solution matching your corporate structure
- Clear prioritisation
- Profit from our knowledge and longstanding experience
- Free up time for key strategic issues

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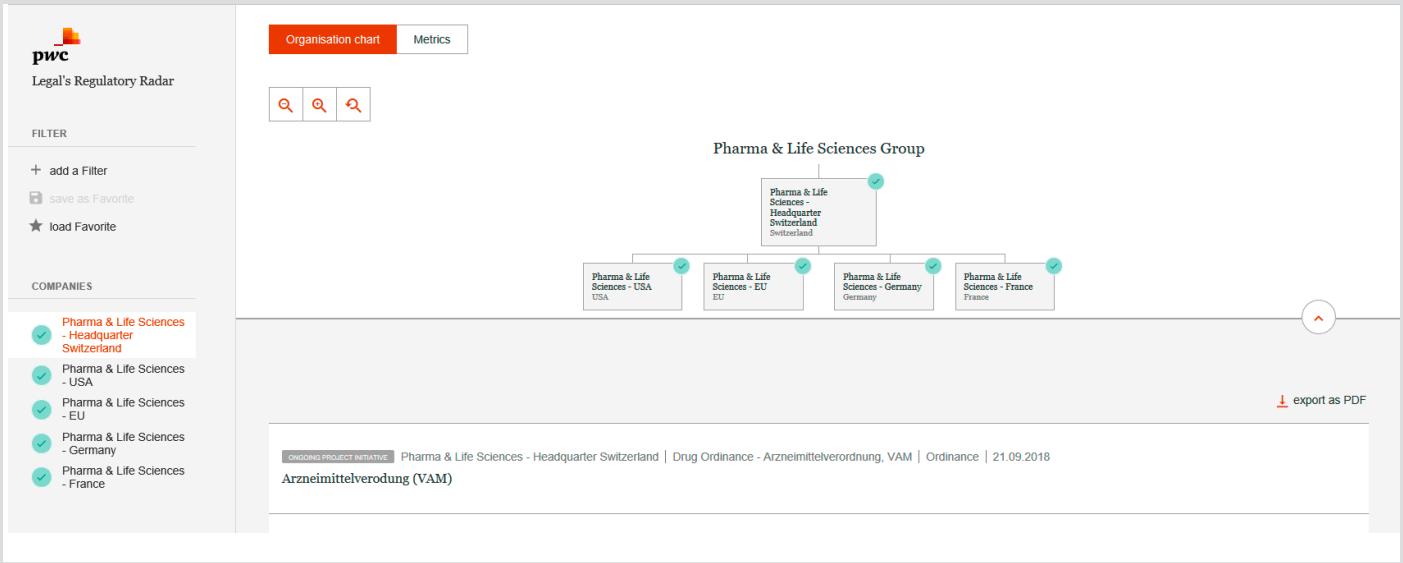
Regulatory Radar – Key features

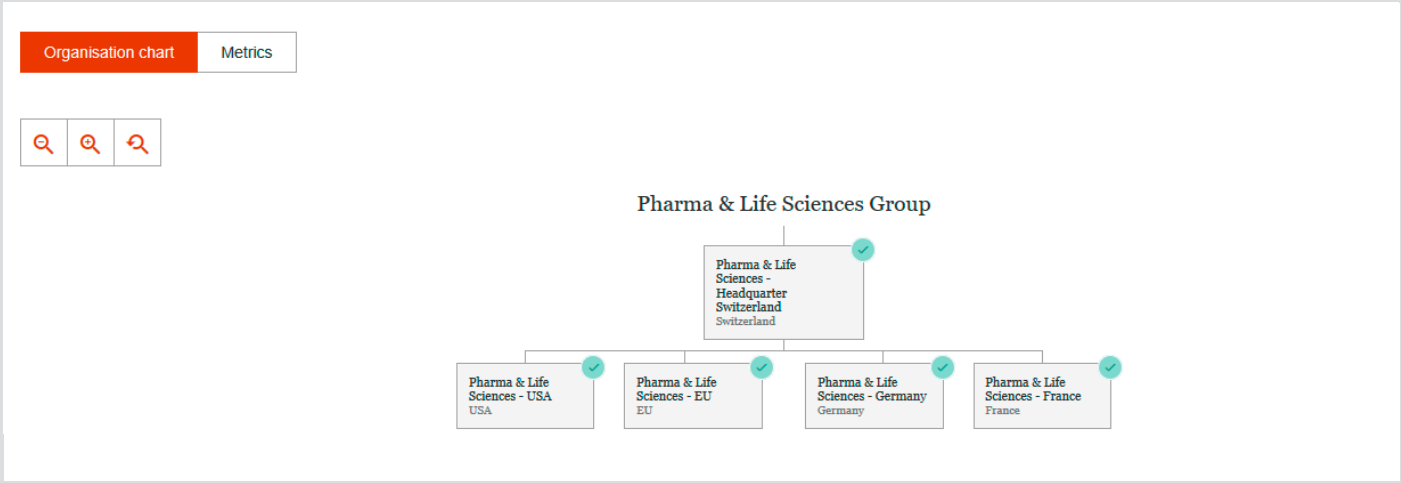
- Regulatory updates
- Early warning system
- Impact analyses, reports and expert advice on corresponding action
- Forward-looking tool
- Easy digital access
- Possibility to customise the tool according to your needs

Screenshots

Group structure and consolidated supervision

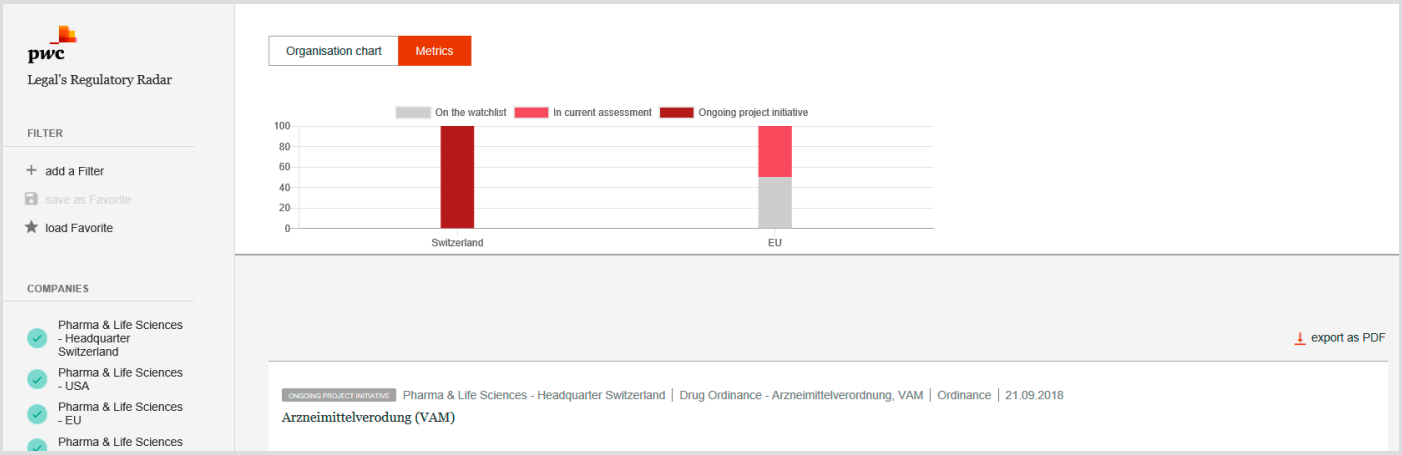
Our tool mirrors your corporate structure, allowing sub-entities to see exactly which regulatory updates apply in their jurisdiction. This guarantees a tailor-made solution with a focus on the essentials. In case you need an overview of all regulations affecting your group, you can easily switch to the group-wide mode to obtain a consolidated view. (Sentence applies to both screenshots on this page)





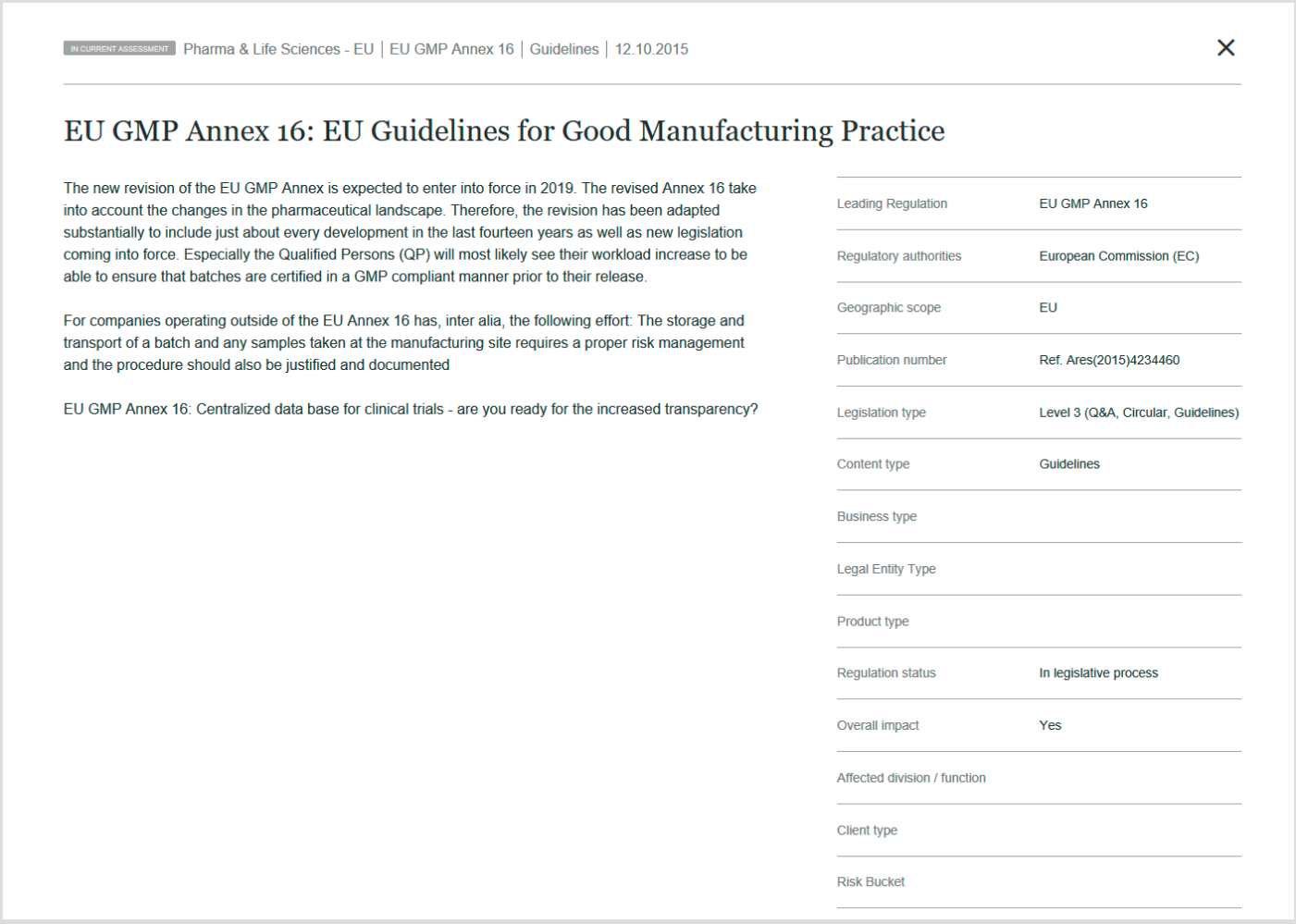
Metrics

The Regulatory Radar monitors regulatory initiatives statistically and allows you to place a special focus on specific regulations. With data gathering and analysis becoming ever more important, we want to provide you with a statistical overview of what matters to your firm.



Regulatory updates

The regulatory updates are exceptional in terms of their granularity. The surface includes various specific parameters, such as a summary of the relevant legal text and an impact description. For a more in-depth analysis, we have created targeted filters to categorise regulations into certain segments. These include, for instance, regulatory authority, legislation type, regulation status and geographic scope.



Tracking the regulatory initiative status

The tool gives you the possibility to track the internal progress of implementing the requirements of a new regulation. Being able to leave notes for colleagues facilitates cross-divisional cooperation during implementation and guarantees efficient working across various teams.

Extract regulatory foresight reports

With the regulatory foresight report function, you can set specific filters in order to receive a corresponding report. This not only provides you with a consolidated overview of the applicable regulations, but also allows for flexible working.