AI Acceleration Program

TLS AI & Data

For Regulatory Functions and Professionals in the Pharma & Life Sciences field







It's time to strategize, bridge the gap, and unleash the true potential of AI

In 2023, a pivotal moment arrived with Gen AI's transformative potential taking Pharma & Life Sciences industries by surprise. Companies, aware of the need for agility, often act impulsively to stay ahead. However, the intricacies of AI continue to baffle many, creating a gap between understanding and practical implementation.

This haste in AI adoption sometimes results in ill-suited solutions that don't align with real-world needs. The absence of a strategic approach leads to AI tools gathering 'digital dust', falling far from their intended potential. From comprehending AI's intricacies to effectively driving organizational change, many companies find themselves ill-prepared for this evolving landscape.

To truly unlock the potential of AI and thrive in this transformative era, it's crucial for Pharma and Life Sciences businesses to **adopt a well-informed**, **strategic approach that bridges the gap between understanding and implementation**.

AI Accelerator PwC

Challenges for Regulatory functions in times of AI

Too many tools, little guidance

One significant challenge for Regulatory functions in the AI era is the overabundance of AI tools and the concurrent lack of understanding regarding how these AI technologies work and their potential applications within the field. Many professionals may not be familiar with AI concepts, making it difficult to harness the technology's full potential.

Use Case Identification

Another challenge is the identification of practical use cases for AI within Regulatory functions. While the potential is vast, departments may struggle to pinpoint specific areas where AI can bring tangible benefits, leading to underutilisation of the technology.

No Common Practices

The absence of a common understanding or standardised framework for implementing AI in Regulatory functions can create confusion and inconsistency within organisations. Without clear guidelines and best practices, different teams or individuals may adopt AI solutions in disjointed ways, hindering efficiency and coherence.

Nurturing AI opportunities in Regulatory functions

In the era of AI integration, there are significant opportunities that promise to reshape the landscapes of Regulatory.

- Education and Training: Develop tailored programs to equip professionals with AI skills which matter to them.
- Use Case Innovation: Encourage systematic exploration of Al-driven use cases to enhance processes.
- Standardised Implementation: Create AI frameworks and best practices for consistent, efficient adoption.





| | Step 1: Al Fundamentals | Step 2: Vision | Step 3: Use Cases | Step 4: Enabling Factors | Step 5: Implementation |
|-------------------|--|--|---|--|---|
| Goal | Fill knowledge gaps about Al. | Define high-level goals for Al application. | Translate vision into use cases. | Prepare a suitable environment to support the implementation of use cases. | Execute use cases. |
| Sample Activities | Educate about Al technologies. Showcase Regulatory Al applications. Address misconceptions, risks, and responsible Al practices. Discuss the Regulatory function's future dynamics. | Evaluate organisational core competencies, value drivers, and AI maturity. Benchmark against AI trends and competitors' strategies. Formulate AI goals that complement organisational objectives. Agree on level of commitment. | Identify Regulatory processes and tasks suitable for AI optimisation. Derive Regulatory use-cases aligned with AI vision. Prioritise use cases based on impact and feasibility. | Assess the readiness for Al use case implementation and scaling in terms of organisation culture expertise data technology partner network Establish governance and change management structures for Al implementation. | Plan the development and operationalisation of AI use cases. Develop minimal viable products. Deploy and integrate AI solutions into business processes. Establish KPIs to track AI efficacy and value addition. |
| Outcomes | A solid foundation in AI to support the definition of a Regulatory AI vision and use cases. | A clear AI vision in alignment with the overall business strategy. | A prioritised portfolio of Regulatory AI use cases. | A gap analysis of necessary strategic enablers. | Operational AI applications generating tangible value. |

What you will get through the Accelerator Tailored to Regulatory professionals in the Pharma and Life Sciences field



Regulatory department with robust knowledge and skills in AI, ensuring they are not only users but also innovators in deploying AI solutions for Regulatory functions. Navigate through the complexity of AI integration in Regulatory functions strategically, ensuring that the department moves from exploration to execution seamlessly and in alignment with organisational objectives.



Minimise the risks related to AI deployment in Regulatory functions and enable the team to make data-driven decisions by precisely understanding and planning AI implementations. 04 Sustained Value and Continuous Improvement

Ensure that the value derived from AI implementations is not transient but is continuously monitored, optimised, and scaled to align with evolving organizational needs and technological advancements.

Your Key Contacts Dedicated Pharma, AI & Next-Gen AI Competence Center for Tax & Legal Services



Dr. Sandra Ragaz

Leader Pharma & Life Science International Indirect Tax & Regulatory

Partner

sandra.ragaz@pwc.ch



Fatih Sahin

Al & Data Leader **Tax & Legal Services**

Director

fatih.sahin@pwc.ch



Jean-Pierre Anzévui

Pharma & Life Science International Indirect Tax & Regulatory, Attorney-at-Law, LL.M.

Director

jean-pierre.anzevui@pwc.ch



Martin Sepiol

Al & Data Senior Manager martin.sepiol@pwc.ch



Dominik Hofstetter

Pharma & Life Science Regulatory, certified pharma sales representative shqa

Senior Associate

dominik.hofstetter@pwc.ch



TLS Switzerland – AI & Data team

Dedicated AI & Next-Gen AI Competence Center for Tax & Legal Services



Fatih Sahin TLS AI & Data Leader Director



Domingo Senise de Gracia Senior Manager



Martin Sepiol Senior Manager



Birgit Arn Manager



Mihael Kresic Manager



Vipin Saroha Manager



Markus Lips Senior Associate



Carla Özen Senior Associate



Luca Rampini Senior Associate



Sascha Liechti Senior Associate



Fran Busquet Senior Associate



Danting Wu

Associate



Roberta Protopapa Associate

