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Date: April 1st, 2025

Subject: Regulatory compliance of service Toxicological Risk Assessment.

To whom it may concern,

Our approach to Toxicological Risk Assessment (TRA) for pharmaceutical products complies, at the best of our knowledge, with internationally recognized regulatory standards. Therefore, our assessments and activities related to service TRA are conducted in full compliance with the state-of-the-art scientific and regulatory standards worldwide.

We pay particular attention to the guidelines and requirements of global regulatory authorities including, but not limited to, the U.S. Food and Drug Administration (US-FDA).

To guarantee the quality and reliability of our services, we operate within a certified quality management system (i.e., ISO 9001 and ISO 13485). This certification attests to our ongoing commitment to maintaining high operational standards and ensuring efficient and traceable processes.

Within our certified quality system, we perform nearly 200 activities every year related to service TRA. These activities are designed and executed with the highest care and scientific rigor and are used to support regulatory submissions globally, with significant experience in those intended for the US-FDA and European Market (European Medicines Agency).

Over the past four years, Eurofins has not received any client complaints regarding its toxicological approach in pharmaceutical context. This figure demonstrates the satisfaction of our clients and the effectiveness of our processes in providing high-quality services that meet their expectations.

Finally, we would like to highlight the presence of 2 European Registered Toxicologists (ERT) within our team. Their expertise and professional registration represent a further guarantee of the scientific competence and rigor of our toxicological assessments, a crucial aspect of regulatory compliance, including US-FDA requirements.

We are confident that this information provides the necessary assurances regarding the regulatory compliance and quality of our approach for service TRA.

We remain at your complete disposal for any further clarifications or details.

Sincerely,

Paolo Pescio, ERT
Managing Director

Eurofins Regulatory & Consultancy Services Italy Srl

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