

Lecture: free communication

## **Regulatory animal testing: factors stimulating or obstructing the adoption of 3R methods in the regulatory process**

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Thirty percent of the animal tests conducted annually in Europe are performed to meet regulatory requirements. Regulatory animal testing is often repetitive in nature and more likely to cause severe suffering due to the procedures used. It proves to be a persistent element in the assessment procedures for registering a substance or product for release onto the market.

Over the last decades the heavy reliance on animal experimentation in this area meets serious objections, both ethical and economical in nature. And even though the number of test-models based on the 3R principle keeps increasing, these new methods are not automatically included in the regulatory decision process. There are several obstacles on the way from test validation to implementation, for example:

- Ongoing scientific discussions about the data coming from the validation studies
- The lengthy process in acceptance of a validated test by regulatory agencies
- Parallel existence of the validated and accepted 3Rs method and the conventional animal test in test regulations

Part of the underlying reasons are scientific of nature. However, there are several political and social reasons that hinder effective test implementation. This overview will offer some insight of the factors and actors influencing the implementation of 3Rs methods in regulatory testing. It aims at being a starting point for further discussion and focused actions to tackle the barriers on the way to regulatory acceptance of 3R methods.

### **References**

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