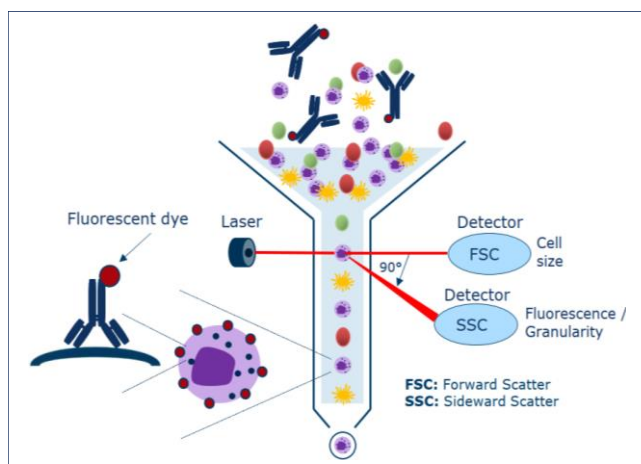


Analytical Method Validation

Development and validation of your analytical method: flow cytometry

Flow cytometry is an advanced analytical technique used for the simultaneous measurement of physical and chemical properties of cells and particles in a liquid. This method is widely used in biomedicine, immunology, hematology and the biopharmaceutical industry. The requirements and standards for the development and validation of analytical methods are defined by ICH guidelines Q2 and Q14, which ensure that the methods are robust, reproducible and suitable for regulatory purposes.

The development and validation of flow cytometric methods is a complex but critical process for the quality and safety of biopharmaceutical products. Compliance with ICH guidelines Q2 and Q14 provides a clear framework for the scientific robustness and regulatory compliance of these methods. Careful planning and execution of validation studies ensure the accuracy and reliability of results by establishing validation parameters and acceptance criteria. This also promotes confidence in analytical methods within the scientific community and regulatory authorities.



Our competences:

- More than 15 years of experience in the development and validation of analytical methods
- Engineers from a wide range of disciplines with technical expertise
- Natural scientists with knowledge of cell biology and process understanding
- Audit-compliant documentation

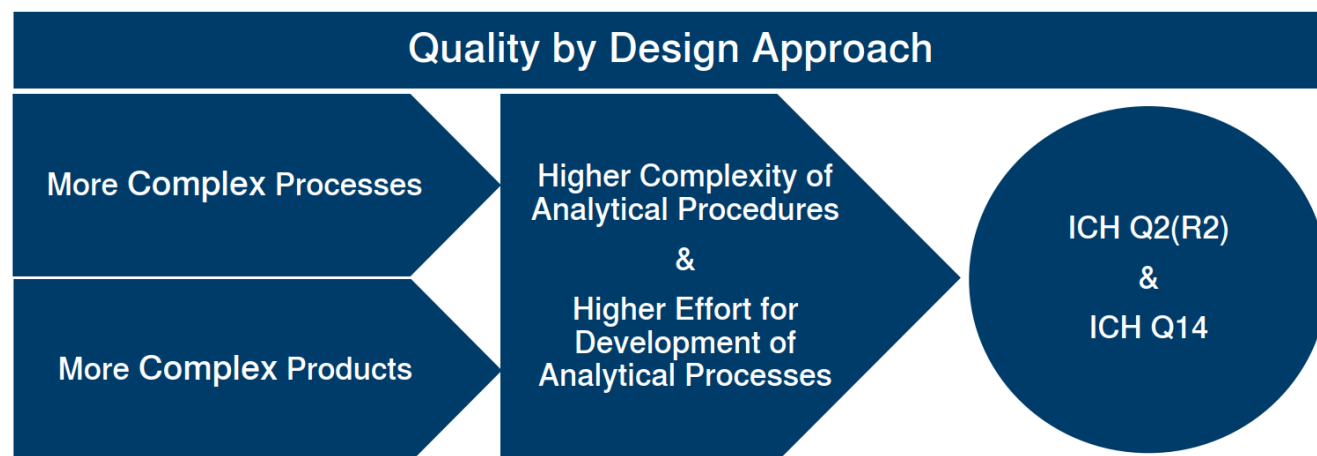
Our services:

- Implementation of the validation concept (from consulting to realization)
- Creation of plans and reports
- Interpretation of ICH Q2 and Q14
- Method transfer
- Verification of pharmacopeial methods

Your advantages:

- Fundamental knowledge of the validation parameters and their applicability
- Reliable resource planning with experienced personnel
- Increased productivity through time and personnel savings

ICH Guidelines Q2 and Q14 for the Development and Validation of your Analytical Method:



Objective: To supplement the ICH guidelines Q8 to Q13

Contact us if you are planning to develop or validate an analytical method. We will be happy to support you!



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