

Flow Cytometry speeds up Drug Development

Flow cytometry technologies are capable of measuring multiple parameters of single cells at a rapid rate. In recent years, flow cytometry applications have gained significant momentum in the drug development process becoming a new and potent tool in drug discovery, target identification, hit to lead generation and lead optimization.

The potential of flow cytometry has been recognized by the regulatory authorities including the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Several International Conference on Harmonisation (ICH) guidelines specifically encourage the use of flow cytometry as suitable tool regarding immunotoxicity studies for human pharmaceuticals prior to entering clinical trials:

According to the **ICH guideline S7A** [Safety Pharmacology Studies for Human Pharmaceuticals], *“the use of new technologies and methodologies in accordance with sound scientific principles is encouraged”* to determine cellular responses of drugs prior to entering clinical trials.

The **ICH Safety guideline S8** [Immunotoxicity Studies for Human Pharmaceuticals] specifically states that “Immunophenotyping” and “Macrophage / Neutrophil Function” *“is usually conducted by flow cytometric analysis”* in immunotoxicity studies.

To adequately address the increasing regulatory burden in pharmaceutical drug development, Pharmacelsus has added several flow cytometry-based assay systems specifically designed to comply with regulations and to speed up drug development.

*Please don't hesitate to contact us for a
customized quotation*

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The Pharmacelsus GmbH *Flow Cytometry Core Facility* has been named

“Immunotoxicology Reference Center”

by Beckman Coulter Germany, a leading manufacturer of biomedical testing instruments, test systems and supplies. Pharmacelsus offers the novel immunotoxicity three-color “iTox®” screening tool to facilitate the required pre-clinical drug discovery studies and immunotoxicology evaluations in animal models. iTox® allows lymphocyte subset immunophenotyping of rat biological samples and has been recognized as a predictive tool for immunological drug effects.

Our Core Facility is equipped with the latest generation of flow cytometers, the **Cytoomics FC 500** with CXP Software, capable of 5-color analysis and post acquisition compensation.

The Electronic Records and Electronic Signatures Rule (21 CFR Part 11) defines the requirements for submitting documentation to the FDA in electronic form and the criteria for using electronic signatures. To satisfy this rule, Pharmacelsus can offer, upon prior request, the 21 CFR Part 11 software tools.



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