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&
22nd International Conference and Exhibition on **Pharmaceutical Formulations**
&
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Biopharmaceutical formulation analysis

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Protagen Protein Services (PPS) is a world leading CRO and recognized expert for protein analytical services in the biopharmaceutical field. With two sites in Germany and since very recently a third site in Boston US we have more than 20 years' experience in supporting customers in the biopharmaceutical, biotech and life science industry. We are partnering them throughout the entire process ranging from candidate selection to development and further to approval and GMP compliant release testing. The integrity of an API is essential for its required efficacy and safety. This integrity depends on the stability, secondary and tertiary structure, aggregation behavior and concentration of the developed molecule, factors which are highly influenced by the formulation of the API. We address such critical quality attributes by applying state of the art analysis techniques:

During formulation studies orthogonal methods are used: To address aspects of higher order structure we apply orthogonal methods like FT-IR analysis in aqueous solution, CD analysis and fluorescence scan. Stability is elucidated by DSC equipped with autosampler, enabling high throughput screening. To assess aggregation behavior, we use highly sensitive DLS and AUC methods as well as SEC-methods equipped with MALLS detection and AF4-MALLS providing a broad range of orthogonal methods for detailed characterization. To precisely determine concentration, we offer AAA or HPLC and photometric techniques. As an expert in all these methods PPS is constantly extending its method portfolio and expertise to steadily improve our support in the formulation field for our sponsors. The poster presentation will illustrate the broad portfolio of methods available at PPS for formulation studies. If you are searching a partner in this field, please contact us. We are delighted to find the right answers to your questions in biopharmaceutical formulation analysis.



Biography

Natalie Perraudeau is an experienced Team Leader within Protagen Protein Services (PPS), a world leading CRO and recognized expert for analytical services in protein science. Ms Perraudeau is an immunologist and applied biology scientist by training and serves as a specialist for protein analysis regarding higher order structure, glycosylation, charge variants and protein stability. Together with her team she offers a broad range of services, from drug discovery and development, to release testing and regulatory compliance applying CD, DSC, Edman, HILIC, IEX analysis methods and ELISA tests.