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**Combining immunoassay and LC/MS to characterize stability of antibody therapeutics *In Vivo***

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As many of therapeutic biologics (including monoclonal antibodies and antibody-drug conjugates) enter the frontline of disease treatment, tracking their stability *in vivo*, is a critical step in development of these therapeutics. Unstable antibody therapeutics (including unstable antibody-drug conjugates) may cause decreased drug activity, fast clearance, increased immunogenicity, and safety issues (toxicities). Non enzyme-mediated deamidation is a common protein degradation that normally occurs on asparagine (and to a lesser extent, glutamine residues), resulting in a conversion to aspartic and isoaspartic acids with a mass shift of +0.984 Da. To monitor the deamidation of therapeutic antibodies dosed *in vivo*, we developed analytical methods with the combination of immunoassay and LC/MS using peptide level MS detection. We further optimized the process and established an automated high throughput method allowing for high fidelity deamidation analysis of human antibodies from *in vivo* study samples. Similarly, we were also able to characterize the stability of antibody-drug conjugates *in vivo*, by using the combination of affinity-capture and intact protein MS analysis. These procedures will help to exclude unstable drug candidates at early development phase, and select stable antibody-based therapeutics for clinical applications.

**Biography**

Jerry Wang received his PhD from the Department of Biochemistry and Molecular Biology at Medical University of Ohio (Toledo, OH). After Post-doctoral studies at University of Michigan Medical Center, he began his industry career as a Pharmacologist. He is currently a Scientist in the Department of Biochemical and Cellular Pharmacology at Genentech. His group supports the therapeutic antibody programs during research and early development phases. His main responsibilities include antibody screening and characterization *in vitro* and *in vivo* studies to select clinical candidates. He has worked in biopharmaceutical industry for more than 15 years including 10 years at Genentech for biotherapeutics R&D.

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