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## ICB PhD public presentations

# STABILITY OF BIOPHARMACEUTICALS DURING MANUFACTURING AND STORAGE


**Ruben Wälchli**
ICB Morbidelli Group
Supervisor: Prof. Dr. Massimo Morbidelli
Co-examiner: Prof. Dr. Paolo Arosio


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**HCI J 4, 14.00 h**


Project Summary: Monoclonal antibodies (mAbs) have become more and more important as pharmaceutical ingredients for the treatment of a remarkable variety of diseases. The chemical and physical stability of these molecules represent a major challenge for their successful development. In this context, aggregation is one of the most problematic possible degradation routes, since aggregates are potentially immunogenic. It is therefore crucial to avoid aggregation during processing and shelf-life. To this aim, mechanistic understanding of mAb aggregation as well as identification of biophysical markers that are able to predict the tendency of a mAb to form aggregates are required. Here, we focus on two aspects of the product life that have particularly high risk to generate aggregates: virus inactivation at low pH and storage at high concentration in liquid formulations for subcutaneous injections. In the first case, we show that neutralization of the solutions triggers the aggregation process and that (partial) decrease of mAb denaturation at low pH can mitigate product loss. In the second case, we identify and discuss the correlation between the phase diagram of mAb and the propensity to aggregate at high concentration over long term during incubation at low temperature.


CV. Ruben Wälchli obtained his BSc and MSc in Chemical and Bioengineering from ETH Zurich. During his Master's studies he spent time at the Massachusetts Institute of Technology to perform his thesis under the supervision of Prof. T. Alan Hatton and Prof. James W. Swan. Currently, he is a PhD student in the group of Prof. Massimo Morbidelli.