International Alliance for Biological Standardization

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Science & Statistics – Elevating CMC through Partnership

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How do theorists and experimentalists interact in a biopharmaceutical company?

Engineers and statisticians are both disciplines involved in drug development who rely heavily on applied mathematics. However the approaches and areas of interest differ greatly between our two areas. Engineering papers are full of carefully controlled experimental data designed to eliminate all sources of variability and to show the nature of the impact of variables of interest on the response. In contrast the statistician begins by looking with the noise in the data to work back to the signal. While in theory these approaches should be highly complementary, in practice they are often siloed and practiced in isolation.

In my lab we work on developing new methods for the next generation of manufacturing processes for biologics and have worked closely with our statistician colleagues. Through a number of case studies we will describe how we approach a new area of interest from an engineering perspective and how and when we think about statistical approaches to model building and data analysis. From searching for signal from soft sensors, to process optimization, to thinking about control strategy in the era of continuous processing, there are many areas where engineering and statistics overlap. There are multiple areas where we have worked well together in the past, and more where we can improve in the future.