

From process understanding to manufacturing process control with PATC. Lautz¹, M. Betschart¹¹F. Hoffmann-La Roche Ltd, CH-4070 Basel - christian.lautz@roche.com

In an early phase of drug substance development, Process Analytical Technology (PAT) tools can help to generate deeper process understanding by real-time insight into chemical processes. With a maturing project and its improved process chemistry, some of the PAT tools applied in laboratory may be used on scale-up and transferred to pilot plant or even full-scale manufacturing.

The requirements and demands for PAT applications grow with the projects, regarding their ruggedness as well as all aspects of technical and GMP compliance.

The presentation will focus on current examples from Roche Small Molecule Development and Manufacturing, covering the range from laboratory PAT experiments for increased process understanding and troubleshooting to fully validated spectroscopic GMP applications substituting classical chromatographic in-process samples.

