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Anton Lofgren

Lund University, Sweden, anton.lofgren@chemeng.lth.se

Niklas Andersson

Lund University, Sweden

Joaquin Gomis Fons

Lund University, Sweden

Anton Sellberg

Lund University, Sweden

Bernt Nilsson

Lund University, Sweden

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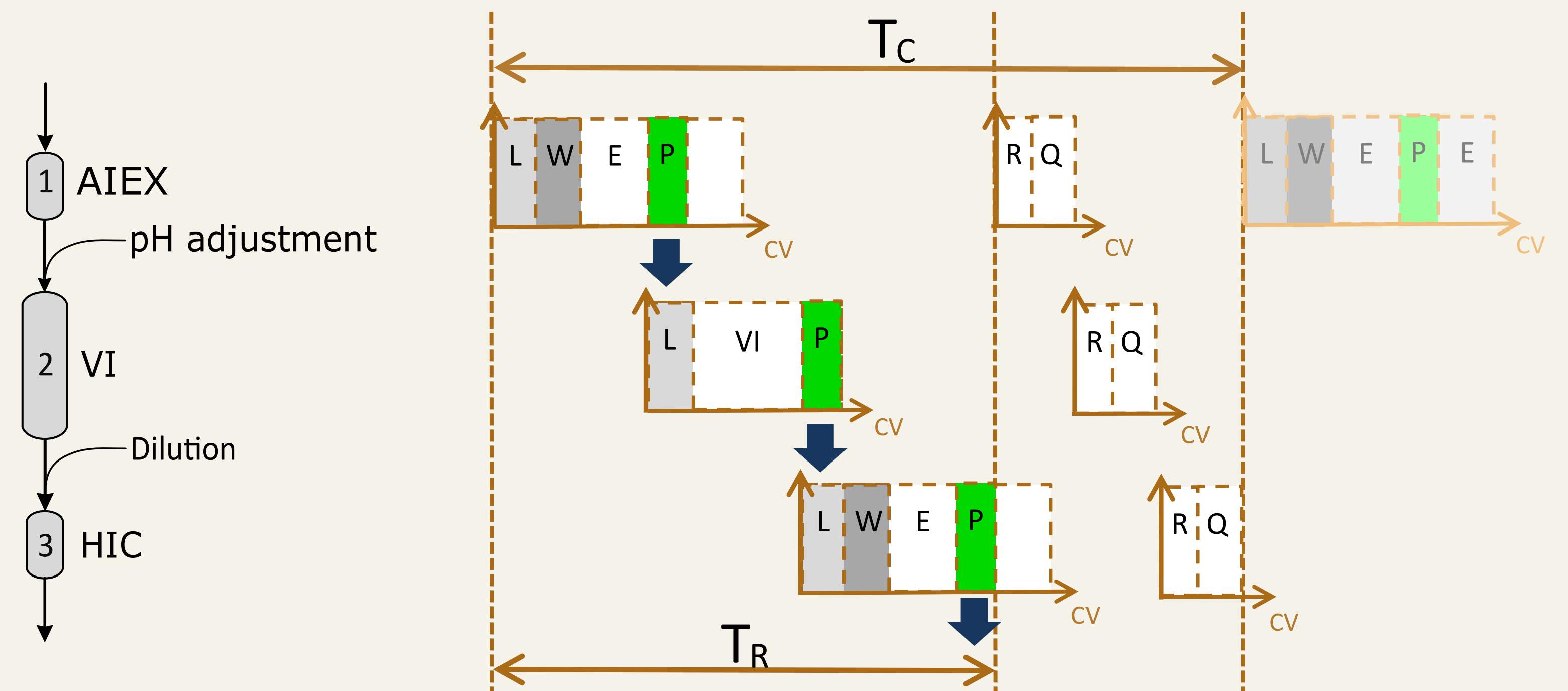
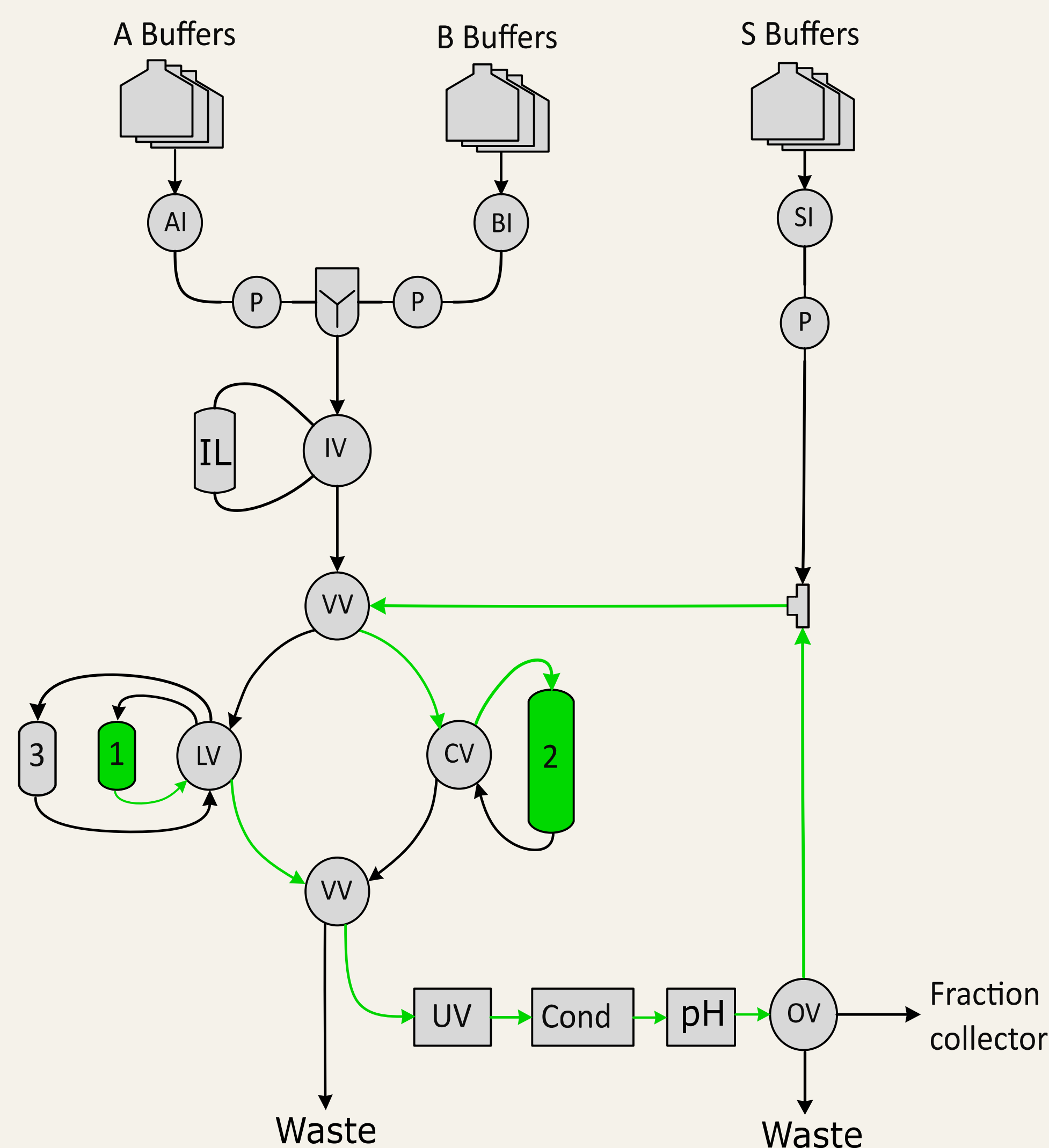
CONVERSION OF AN INDUSTRIAL BATCH SEPARATION PROCESS TO AN AUTONOMOUS INTEGRATED DOWNSTREAM PROCESS – A CASE STUDY

ANTON LÖFGREN¹, NIKLAS ANDERSSON¹, JOAQUIN GOMIS FONS¹, ANTON SELLBERG¹, BERNT NILSSON¹ AND LOTTA BERGHARD²

¹) Dept of Chemical Engineering, Lund University, Lund, Sweden, ²) SOBI, Stockholm, Sweden

Introduction

An industrial case from SOBI AB, Stockholm, Sweden, was integrated in a complete sequence. Part of the downstream process consisted of an anion exchange step, followed by virus inactivation and a hydrophobic interaction step. Integration to single unit minimizes hold-up times, storage tanks and required equipment. The sequence was integrated in an ÄKTA Pure controlled by newly developed research software called Orbit.



Methodology

The load, wash and elute phases are squeezed together over the three steps, leaving the regeneration and CIP phases to be performed after the elution of the final pool. This decreases T_R which is the hold-up time of the protein.

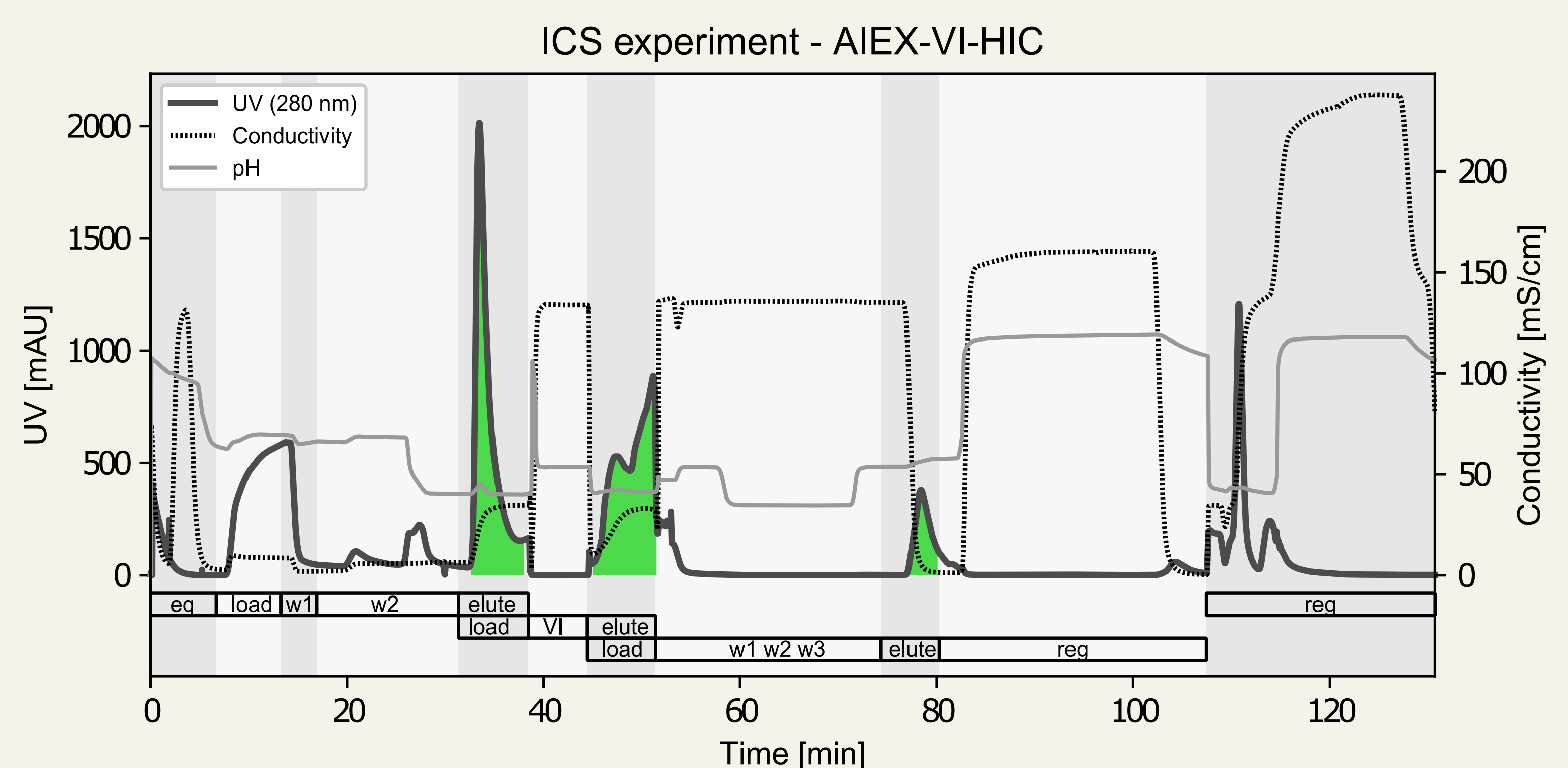
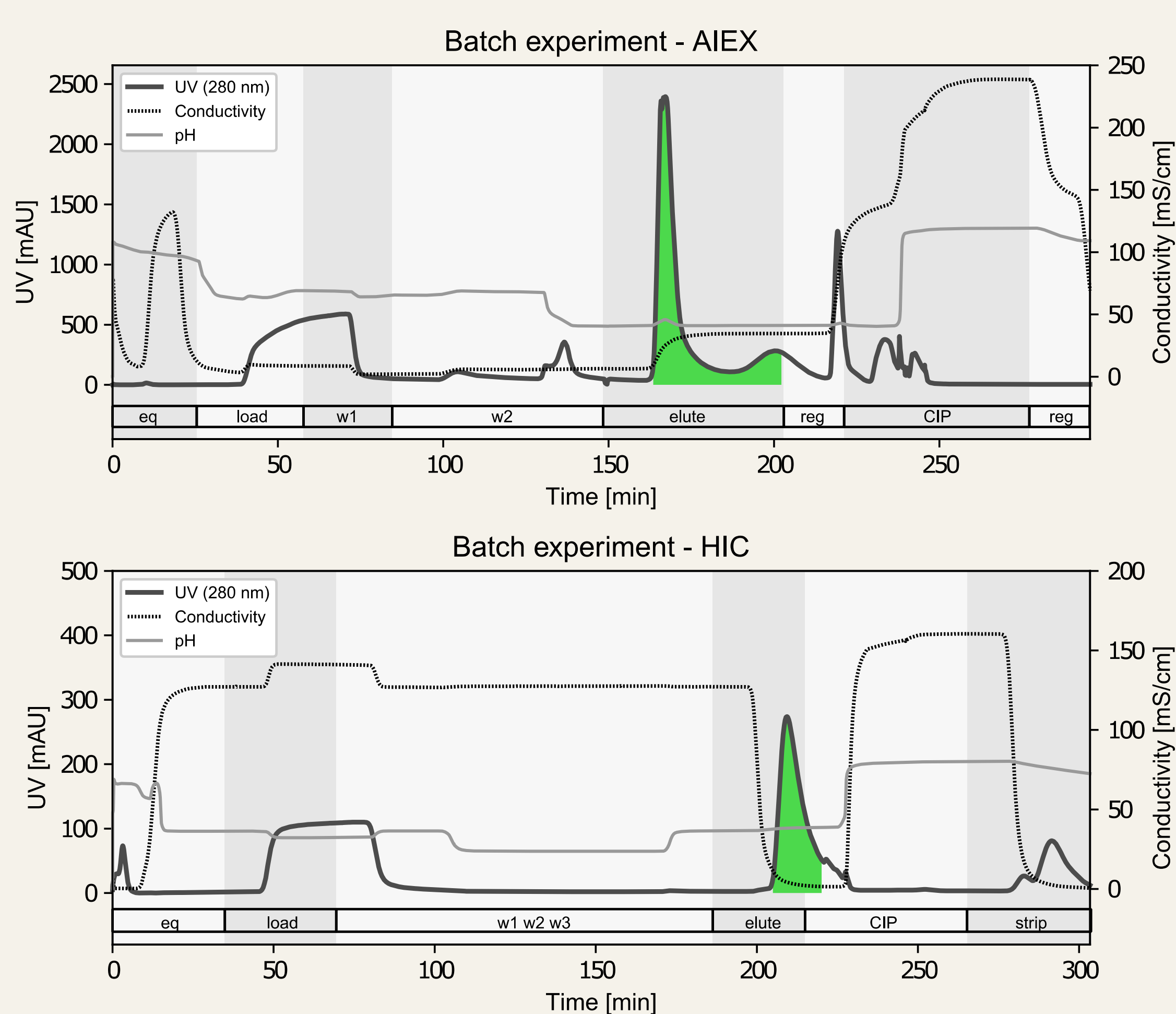
The pool from the AIEX column is directly loaded to the super loop, acting as a virus inactivation vessel. The entire pathway is indicated in green, starting from column 1 and ending in the super loop. When it's emptied it is also directly loaded to the HIC column.

The inline dilution and pH adjustment is performed simultaneously as the pool passes the T-cross.

The entire sequence is automatically generated by orbit after selecting column positions, flowrates and buffers.

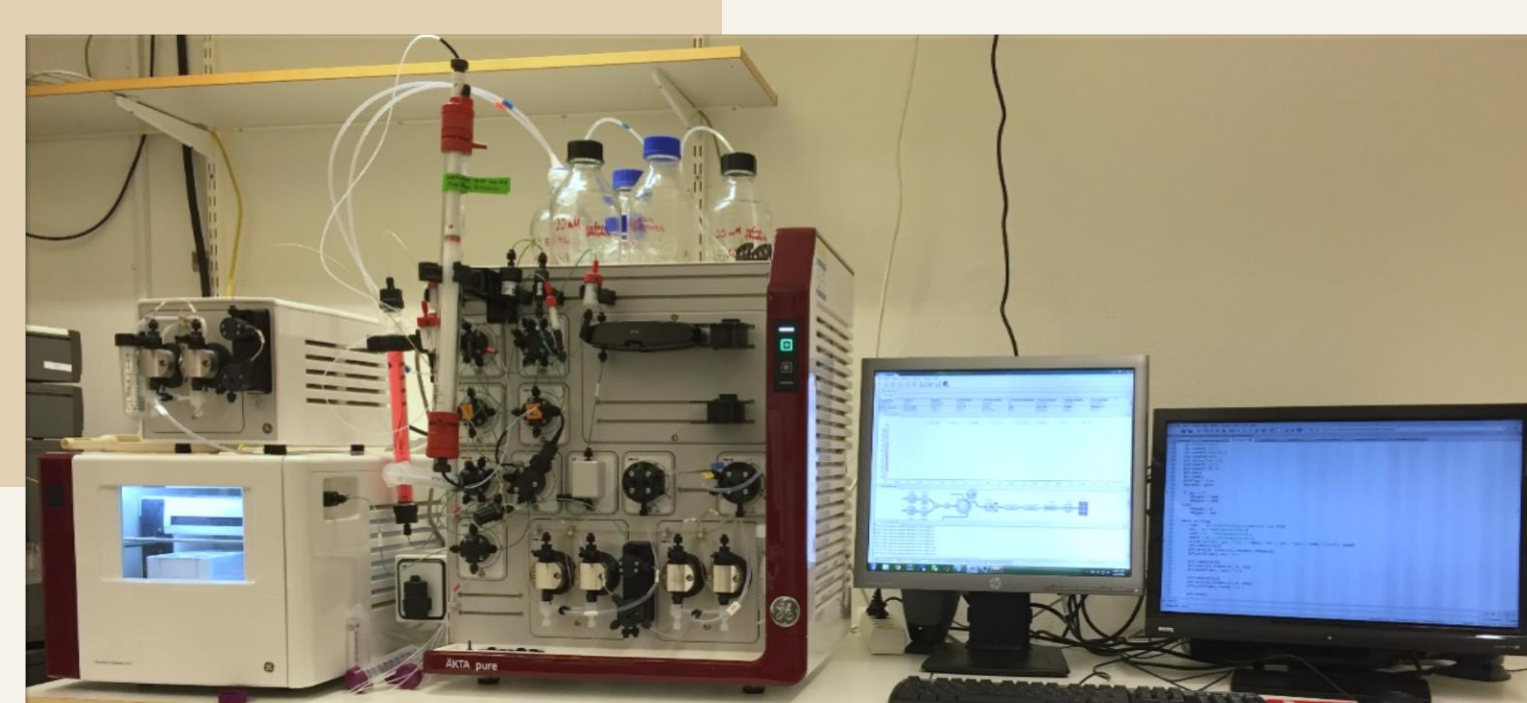
Results

The steps were effectively integrated as seen in the figure below, automating several manual steps. The entire sequence takes 13.6 hours which is syncing well with overnight runs. Multiple sequences in row can also be started automatically with Orbit, simplifying even more manual steps.



The following manual steps were automated:

- Collecting pool from the AIEX column
- pH adjustment
- Add pool to virus inactivation vessel
- Dilution
- Adding sample to the HIC column



Conclusion

The main contribution is to show the methodology for applying an industrial downstream process case study to a single unit integrated column sequence. It was shown to automate several manual steps, allowing overnight runs and therefore better use of personnel. For small scale production, process development or research, this is an interesting option due to the efficient use of equipment and setup.