Miniaturized Sensors for integrated continuous biomanufacturing

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Project term: May 2019 - April 2023
Financed by: CODOBIO (https://www.codobio.eu/)

Project Description

To reduce costs and improve product quality, the transition to a continuous biomanufacturing of monoclonal antibodies (mAbs) is considered as the next step. This will lead to an improvement in productivity, product quality and consistency while drastically reducing the environmental footprint and manufacturing costs.[1]

During the purification scheme, aggregation is a recurrent phenomenon and may lead to an increase in immune response or decrease in efficacy.[2] A major challenge for the analysis of these aggregates is that no single analytical method exists to cover the entire size range or type of aggregates, with measurements performed off-line and not in real time.[3]

Therefore, the creation of an universal method for the evaluation of the formation of aggregates is crucial, producing a critical quality attribute (CQA) measurement for process analytical technology (PAT) use.

The objectives of the project are:

- Development of a miniaturized biosensor to analyze the formation of mAb aggregates during a continuous downstream process, providing an on-line measurement;
- Validation of the prototypes created and an assessment into the critical steps where the biosensors can be successfully implemented, using a continuous chromatographic workstation, controlled by the control software Orbit.

References:

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[3] Philo, J.S., Is any measurement method optimal for all aggregate sizes and types?, *AAPS J*, 2006, 8(3): p. 564-71.

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 812909 CODOBIO, within the Marie Skłodowska-Curie European Training Networks framework.