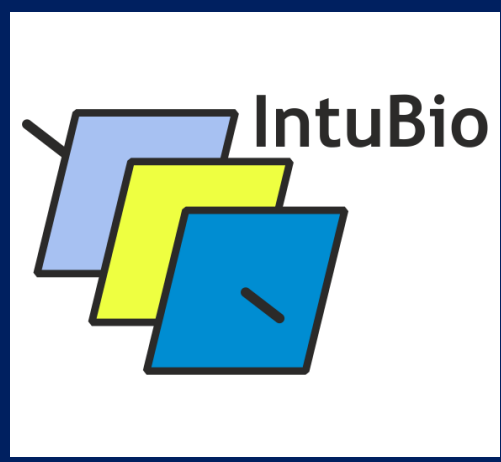
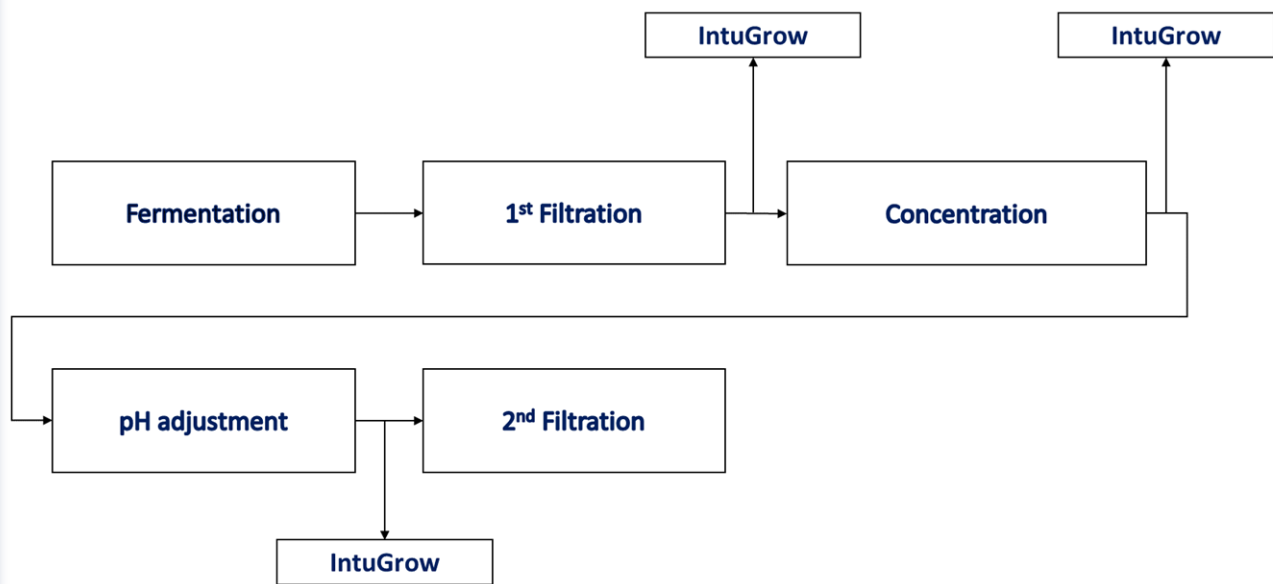


Fast TVC to Avoid Overprocessing

IntuBio ApS
14/12/2020





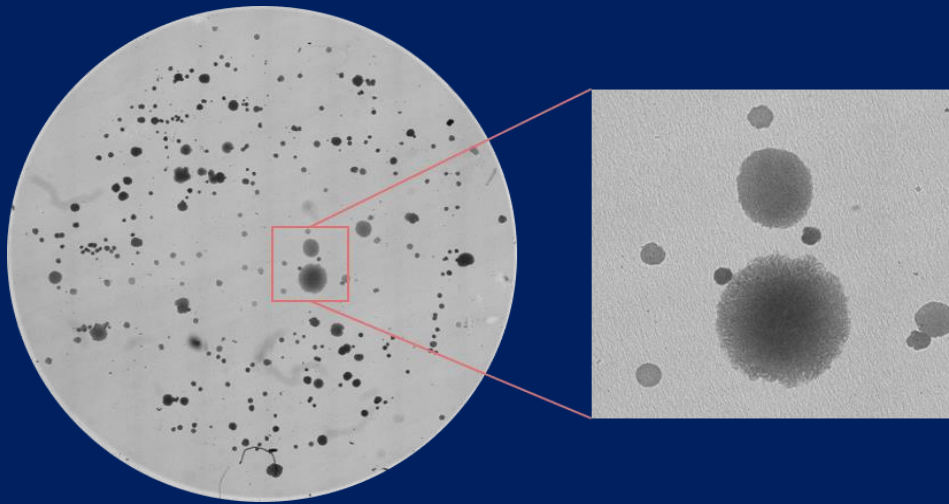
Introduction

When pasteurization is not an option to eliminate the microbiological load of a product, due to temperature sensitivity, filtration steps are routinely employed. Even though filtration through 0,22 µm filters is an effective procedure, significant product loss can be expected.

Prior to this case study, the producer consistently measured a microbiological load below their guideline levels of 10^4 CFU/g before the last filtration rendering it redundant. Due to the redundancy of the filtration product was lost with no real impact on the quality of the formulated product.

The major obstacle for optimizing this process is the long time-to-result (TTR) of the traditional microbiological method (48-72 hours ISO 4833-1).

By implementing IntuGrow this TTR can be reduced to 5-6 hours allowing for adaptive processing of the post-fermentation product with simultaneous analysis of multiple points throughout the line. This enables not only processing decisions resulting in higher yield but also a close monitoring of the production line, with fast response to variations in quality.



Current Problem

With the limitations of the traditional method overprocessing is routinely done leading to significant loss of product.

IntuGrow vs. Traditional Method

As part of the feasibility study extensive comparison studies were performed between the standard method (48-72 hours) and IntuGrow (5-6 hours) to determine the required incubation time required for IntuGrow to reach the same level as the end point measurement of the traditional method. After optimizations to the protocol and analytical software the TTR was determined to be 5-6 hours.

Implementation of IntuGrow

As the IntuGrow analysis is designed to be performed by employees of the producers (chemists and operators), the first part of the implementation was training, customization of the setup to be ideal for the selected site on the production floor. Further optimizations include improving the user-friendliness based on feedback and experience.

Proof of Concept

The concept of eliminating redundant filtration was proved 3 times out of 19 measurements (June-December 2020), with significant yield increase and higher activity of the final product. Most measurements during this period were within the acceptable microbiological level, however other factors impacted the decisions by the producer (e.g., breakdowns and delays). Furthermore, by implementing IntuGrow, close monitoring of the production line was achieved, resulting in a contaminated loop being identified.

Future Implications

The aim is to implement IntuGrow on similar production lines and products, where the long TTR of the traditional method obstructs adaptive processing.

By avoiding overprocessing a substantial reduction in processing cost can be achieved by reducing materials used, and strenuous work can be avoided.

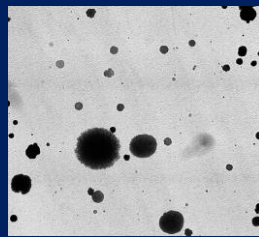
Instruction of operators to assure trained personnel on every shift, who can undertake the analysis is also a priority, to maximize the outcome of implementing IntuGrow.

Future additions to the analysis include using chromogenic media to identify *E. coli*/coliforms with the possibility to broaden the analysis to include other target organisms.



Problem

Product loss due to redundant filtration steps. TTR of traditional methods too long for decision-making.



Solution

By using IntuGrow TVC can be determined within a timeframe allowing for decision-making.



Outcome

Yield increase from every batch not filtered. Reduced material cost and elimination of strenuous work.