Working group: Product Isolation and Purification

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Goal of the Working group on Downstream Processing

The goal of the working group Downstream Processing (Product isolatie en Zuivering) is to keep the members up to date with novel (inter) national activities in the area of separation technologies and exchange information with each other. This can be reached by keeping the website up to date with actual information, symposia, courses, etc. Overall the coordinators of this working group are always open to new suggestions to improve the goals of the working group Downstream Processing. In 2014 two events were organized.

NBC 15 work group session on downstream processing

On May 27th, at NBC-15 the working group has organized a session on Product Isolation / Design for Products and Processes. Besides a company pitch three presentations were given.

Dr. ir. Edwin Zondervan from the Technical University Eindhoven presented a process systems engineering (PSE) approach to process and product design. It was demonstrated how the PSE tools can help in the systematic development of process flow sheets and the generation of new product ideas. Two successful examples of PSE for process and product design were presented: 1) The use of process synthesis tools, such as mathematical programming and super structure optimization for the generation of biorefinery production routes for biofuels from lignocellulosic biomass and 2) the use of the product driven process synthesis method (PDPS) for the generation of process and product ideas for nutraceuticals – polyphenols from tea and proteins from soy.

Dr. Ir. Marcel Ottens from Technical University Delft presented High Throughput Process Development for Biopharmaceuticals. Marcel showed the state-of-the-art of this High Throughput Biopharmaceutical Process Development approach. With the advent of biosimilars, antibody fragment products, antibody drug conjugates (ADC's) and other non-antibody biologicals, process development approaches are sought for that allow process design outside a platform process (1). In order to achieve this, biopharmaceutical industry resorts to high throughput screening (HTS), or High Throughput Process Development (HTPD). Adding mechanistic modeling to HTPD makes this approach more versatile, in line with FDA regulatory guidelines, achieves a better process understanding, and perfectly fits to the Quality by Design (QbD) approach.

Prof. Dr. Ing. Michel Eppink from Wageningen University and Research presented the Biorefinery of Microalgae, mild separation technologies for complex biomolecules. Biorefinery needs to be both mild and efficient to maintain the functionality of the products (e.g. native protein conformation) and thus value. For the development of a sustainable biobased economy and to guarantee economical feasibility it is essential to use all biomass ingredients for high value and bulk product applications. Biorefinery will result in ingredients for a variety of applications (e.g. food, feed, fuel, pharma, chemicals) to cope with the worldwide scarcity of food and fuel in the coming decades. The feasibility of microalgae biorefinery production was presented from biomass concentration, cell wall characterization, cell disruption, extraction towards fractionation technologies.

Mini symposium Vaccines

On November 26th, 2014 a mini symposium was jointly organized with the Working Party on Cell & Fermentation Technology of the Dutch Biotechnological Society (NBV). The Vaccin symposium was hosted by Crucell in Leiden. Three lectures were given.

Zahia Hanas from Merial in Lyon, France presented the development of a next generation vaccine for Foot-and-Mouth Disease. Foot and Mouth Disease (FMD) disease is a, OIE-listed, highly contagious viral disease with severe financial implications for livestock industries. Current vaccines are based on the production of large volumes of wild type FMDV which are chemically inactivated and formulated with an adjuvant. Current vaccines have limited shelf life and require re-vaccination every 4–12 months. Despite, these disadvantages, it will be very difficult to replace conventional killed vaccine in the short term, because of their proven efficacy under laboratory and field conditions and low COGs. Zahia presented a review of the new developments that are expected to bring improved FMD vaccines to the market in the foreseeable future.

Dr. Yvonne Thomassen from Intravacc, in Bilthoven presented a next generation inactivated polio vaccine manufacturing to support Post Polio-Eradication Biosafety Goals. Starting from the current IPV production process based on wild type Salk strains, adaptations, such as lower virus cultivation temperature, were implemented. sIPV was produced at industrial scale followed by formulation of both plain and aluminum adjuvanted sIPV. The final products met the quality criteria, were immunogenic in rats, showed no toxicity in rabbits and were successfully tested in the clinic.

Dr. Beckley Kungah Nfor from Crucell, in Leiden presented a Cost-effective manufacturing method of viral vaccines. Their proprietary PER.C6® cell line and PIN platform technologies have enabled the expression and production of viral vaccines at high titers in cell cultures, thereby shifting opportunities for further CoG reduction to the downstream processing (DSP). Their DSP development strategy to overcome this challenge involves the direct use or adaptation of platform technologies across multiple vaccine candidates, followed by small scale optimization of bottleneck steps and finally process verification at pilot scale.

Activities for 2015

1) A session on the NBV werkgroependag of March 11th will be organized together with NPT. The theme will be Biotech at Work, Integration of the product and value chain.
2) In the autumn we intend to organize a mini symposium.