

EXPERTS MEETING

# Skin Flora:

From discovery to regulations  
& commercialisation of  
microbiome-related products

Organized by BaseClear

**Thursday June 18th, 2020**

# AGENDA

CHAIR: DR. DEREK BUTLER

All times are Central European Time (CET)

## SESSION 1: CURRENT STATUS AND ADVANCEMENT IN SKIN MICROBIOME RESEARCH

- 10:50** Welcome & Opening expert meeting  
Dr. Derek Butler - Commercial Director, BaseClear
- 11:00** Keynote: Skin microbiome - the past, the present and the future  
Dr. Riccardo Sfriso - Scientist in R&D Skin Care, DSM Personal Care
- 11:30** Infant skin microbiome and effects of everyday skin care  
Dr. Georgios Stamatas - Research Associate Director, Johnson & Johnson
- 11:45** State-of-the-art analysis of skin microbiome - status & future  
Dr. Radhika Bongoni - Business Developer, BaseClear
- 12:00** Panel Discussion
- 12:30** End of session 1

## SESSION 2 : APPLICATIONS AND REGULATIONS AROUND SKIN MICROBIOME DATA

- 15:00** A synthetic antimicrobial peptide for the treatment of resistant bacteria in skin wounds  
Dr. Bouke Boekema - Senior Researcher and Biological Safety Officer, Association of Dutch Burn Centres
- 15:15** A novel phage product for acne-prone skin  
Dr. Sailaja Puttagunta - Chief Medical Officer, BiomX
- 15:30** Skin microbiota research and opportunities for prebiotics  
Dr. Heli Anglenius - Senior scientist DuPont Nutrition & Biosciences
- 15:45** Balancing skin microbiota-based cosmetics with the EU legislations  
Patrick Gonry - Business Developer, Gobiotics
- 16:00** Panel Discussion 2
- 16:30** Online social activity
- 17:00** End of Experts Meeting

## BaseClear hosts

### Derek Butler

Derek is the commercial director of BaseClear. Derek completed a bachelor's degree in Biotechnology at Dublin City University in 1995, specialising in Genetics and Immunology. He continued his studies at University College Cork and in 2001 received his PhD degree for work on the genetic regulation of lactic acid bacteria. In the same year he took up a post-doctoral position at the University of Groningen where his work focused on the identification of novel enzymatic activities from thermophilic bacteria. In 2004 Derek joined Lactrys where he worked on vaccine development in probiotic bacteria before joining BaseClear in 2006. He has now more than 15 years' experience working on microbial genomics research projects together with industrial partners.



**DEREK BUTLER, PHD**  
Commercial director

### Radhika Bongoni

Radhika is Business Developer at BaseClear, with focus on markets for application of microbial genomics in food, feed and pharma industries. Radhika received her Ph.D. in Food technology (2014) from Wageningen University & Research (the Netherlands) and an MBA (2015) from Tias School for Business & Society (the Netherlands). With techno-commercial expertise, she is involved in business growth and market penetration by fostering relationships with partners. Prior to BaseClear, Radhika was responsible for establishing dietary supplements market in western Europe, India, South Africa and Russia.



**RADHIKA BONGONI, PHD**  
Business Developer

# Skin Microbiome – the past, the present and the future

**Dr. Riccardo Sfriso**  
Scientist in R&D Skin Care, DSM Personal Care



## ABSTRACT

The skin is a fascinating ecosystem inhabited by trillions of microscopic organisms such as bacteria, fungi, viruses and mites. These are not restricted to the skin surface but extend themselves within the skin appendages and invaginations.

In the late 1600s, microorganisms were discovered for the first time and were defined with the term “animalcules” by the Dutch microbiologist Antonie van Leeuwenhoek. Since then, years of scientific advances in sample collection and cultivation, followed by the advent of genomic technologies based on DNA sequencing together with parallel improvements in data analysis, brought us to get some insights into the structure and composition of the skin microbiome.

To date, despite the enormous progress achieved in this field, the complexity and diversity of the skin microbiome is still far from being fully understood. Nevertheless, the topic has caught the attention of dermatologists and cosmetic industries as the skin microbiota has been proved to be intimately linked to many skin conditions.

What will the future hold for us? We will probably see the implementation of a more polyphasic approach where cultivation and culture-independent analysis such as metagenomic, metatranscriptomic, metaproteomics and metabolomics are combined to get insights into both the structure and the functionality of the skin microbiome. As a consequence, in order to deal with the enormous amount of omics data, artificial intelligence will be more and more deployed.

## BIO

Dr. Riccardo Sfriso studied Pharmaceutical Chemistry and Technology at the University of Padova, Italy with a specialization in Cosmetics. In 2018 he received his PhD in Biomedical Sciences (summa cum laude) from the University of Bern, Switzerland. Dr. Sfriso contributed to high-impact pre-clinical research which has been published in the scientific journal Nature. After a period working as a Postdoc at the Department for BioMedical Research of the University of Bern, in 2019 he returned to the cosmetic field and joined the R&D Skin Care team at DSM as a Scientist. Here, he started his journey on the skin microbiome and stratum corneum research. He is study director and is proficient in cell culture technology, assays development and high-resolution microscopy.



# Infant skin microbiome and effects of everyday skin care

**Dr. Georgios Stamatias**  
Research Associate Director, Johnson & Johnson



## BIO

Dr Georgios Stamatias has over 20 years of industry and academic experience as Biomedical Engineer in upstream research. His areas of interest focus on understanding skin physiology and topical product effects. He also develops in silico, in vitro and clinical methods and models with applications in dermatology. His research on the differences between pediatric and adult skin and has transformed our understanding of newborn and baby skin maturation. Dr. Stamatias holds a PhD in Chemical/ Biomedical Engineering and has more than 80 scientific publications and seven patents to his credit.

## ABSTRACT

In the last couple of decades, the advent of genomic technologies has led to new discoveries relating to skin microbiome. We have shown that infant skin microbiome is different compared to adult and continues to shift during the first years of life in parallel with skin maturation processes. Everyday skin care including cleansing and application of moisturizers can impact the compositional diversity and richness of the infant skin microbiome. We will review recent findings in this area and their impact on infant skin care.

## State-of-the-art analysis of skin microbiome – status & future

**Dr. Radhika Bongoni**  
Business Developer, BaseClear

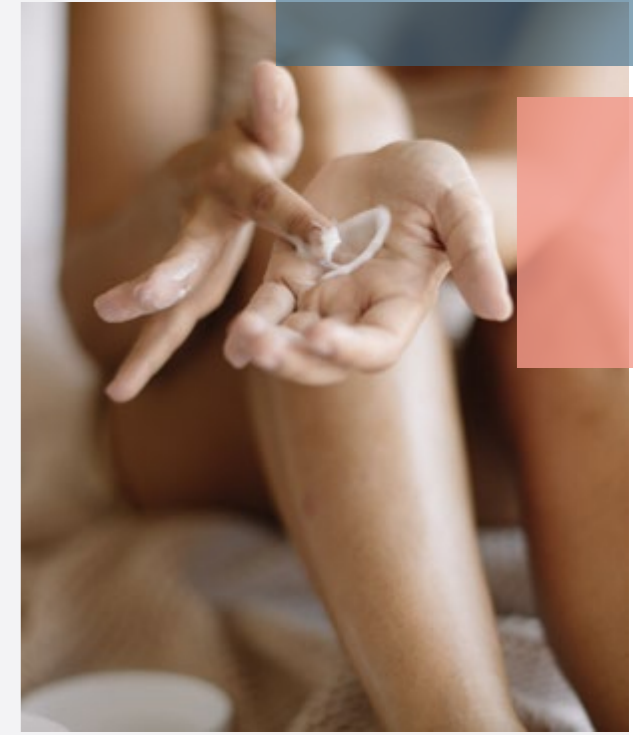


### ABSTRACT

We live with microbes and/or microbes live with us. Skin is just one surface point of this human-microbiome interactions! Nurturing and maintaining a balance in the microbial community on skin is thus pivotal. As an industry, we are broadening and deepening our knowledge in understanding but also modulating skin microbiome. The use of pre, pro and post (and many other versions) of biotics have been shaping the dermatological and cosmetic industry in that sense. We have in parallel also moved from agar plating assays to the use of NGS and advanced bioinformatic tools in assessing skin microbiome. This presentation is a snapshot of pro-cons of various methods of assessing skin microbiome, and the state-of-art genomics technologies & data interpretation that might aid the understanding of role-mechanism of bioactives for skin health. Of course, the challenges still remain, i.e., industry standardisation of analysis methods.

### BIO

Radhika is Business Developer at BaseClear, with focus on markets for application of microbial genomics in food, feed and pharma industries. Radhika received her Ph.D. in Food technology (2014) from Wageningen University & Research (the Netherlands) and an MBA (2015) from Tias School for Business & Society (the Netherlands). With techno-commercial expertise, she is involved in business growth and market penetration by fostering relationships with partners. Prior to BaseClear, Radhika was responsible for establishing dietary supplements market in western Europe, India, South Africa and Russia.





# A synthetic antimicrobial peptide for the treatment of resistant bacteria in skin wounds

**Dr. Bouke Boekema**

Senior Researcher and Biological Safety Officer,  
Association of Dutch Burn Centres



## ABSTRACT

The presence of bacteria in a wound can result in delayed healing and a longer hospital stay. Especially burn patients are more susceptible to opportunistic pathogens, such as *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Because current therapies in burn care still have limited effects in eliminating bacteria and resistance to antibiotics is increasing, additional measures are required. Many different antimicrobials are available to combat burn wound infections but many can have detrimental effects on the healing process. In the past decade, we have explored the use of various alternative treatments to reduce bacterial load and support wound healing. Treatments included medical honey, endolysin from bacteriophage, cold atmospheric plasma devices and antimicrobial peptides (AMPs).

Together with researchers at Leiden University Medical Centre, we investigated a novel synthetic AMP (SAAP-148). SAAP-148 was selected as the most promising AMP from a panel of synthetic AMPs, inspired on the structure of the human cathelicidin, LL-37. SAAP-148 has been shown to be highly effective in vitro against a panel of multidrug resistant pathogens belonging to the ESKAPE panel. The effect of wound dressings, bacterial load and neutralization of residual antimicrobial activity on the antibacterial effect of SAAP-148 on MRSA was tested. In addition, we determined the functional stability and bioactivity of SAAP-148 in biologically relevant environments. The antibacterial efficacy of this AMP was further tested on bacteria in biofilm, in burn wound models of ex vivo human skin, in tape-stripped wounds in mice and in

excisional wounds in rats. Lastly, we estimated the in vitro safety of SAAP-148 at high dosages by using cell cultures and ex vivo human skin. Together, our data demonstrate that SAAP-148 is a promising candidate for the treatment of (antibiotic-resistant) bacteria.

## BIO

Bouke Boekema studied Bioprocess Technology at Landbouw Universiteit Wageningen and obtained a PhD in Infectious Diseases at Veterinary Faculty of Utrecht University in 2003. After a postdoc position at the Microbiology department of Utrecht University, he moved to the preclinical research at the Association of Dutch Burn Centres in 2007. This lab has a strong expertise in research on burn wound healing and full thickness wounds with the aim to improve the quality of healing. Main research lines are tissue engineering, modulation of scar formation, molecular/cellular mechanisms of wound healing and antimicrobial treatments. Various in vitro and in vivo models have been developed to study different processes of wound healing. Boekema started a research line with a focus on

gaining insight into the microbial issues encountered in burns and on testing and developing antimicrobial treatments. Treatments ranged from medical honey to cold atmospheric plasma. Presently he is investigating the pathogen-host interaction of *Staphylococcus aureus* strains in burn wound models using ex vivo human skin. His interest is however not restricted to microbiology, but includes various other aspects of burn care such as dermal substitutes and inflammation. His work has resulted in 5 grants, 37 research articles in peer-reviewed journals and 2 book chapters. He is active as a peer reviewer and received an award for outstanding reviewer in 2019. He is currently board member of the European Tissue Repair Society.



# A novel phage product for acne-prone skin

**Dr. Sailaja Puttagunta**  
Chief Medical Officer, BiomX

## ABSTRACT

BX001 is a topically administered gel comprised of a cocktail of naturally occurring phage targeting *Cutibacterium acnes* (*C. acnes*), a bacterium implicated in the pathophysiology of acne vulgaris. Pre-clinical data includes in-vitro results demonstrating BX001's activity against *C. acnes*, including antibiotic resistant clinical isolates of *C. acnes*, and BX001's ability to penetrate biofilm, a matrix secreted by the bacteria which makes them less accessible to antibiotics.

We recently completed a phase 1 cosmetic clinical study with BX001 in subjects with mild to moderate acne vulgaris. The study was a four-week, randomized, double-blind, dose-finding, placebo-controlled, single center trial which enrolled 75 female subjects with mild-to-moderate acne. Enrolled

individuals were randomized into one of three cohorts: a high dose BX001 cohort, a low dose BX001 cohort, or a placebo cohort (vehicle), and applied study product once daily for 4 weeks. The primary endpoint of the study was safety and tolerability, and key exploratory endpoints included reduction of *C. acnes* bacterial burden and changes in the skin microbiome. In this study, both doses of BX001 were found to be safe and well-tolerated. Following application of the gel once daily for four weeks, measurement of *C. acnes* levels using qPCR showed a statistically significant reduction of *C. acnes* levels in the high dose cohort of BX001 compared to placebo ( $p=0.036$ ) at week five (one week after end of treatment), the final study time point. Additional analyses of the study data revealed that subjects in the high-dose BX001

group with a higher bacterial burden at baseline and also those with characteristics associated with a higher bacterial load at baseline, such as higher sebum levels and/or higher lesion counts, had an earlier and more pronounced reduction of *C. acnes* levels when compared to those in the placebo group. Results from these subgroup analyses inform subject selection criteria to be used in the Phase 2 study to help enrich the study population.



## BIO

A Medical Affairs and Clinical Development physician with experience conducting Phase I to IV clinical trials, contributing to NDA submissions in anti-infective disease areas, product launch preparations, medical affairs and leading teams. Management experience in supervising regional medical directors, study managers and trial leaders, medical writers, and administrative assistants, and matrix leadership experience in diverse cross-functional and cultural environments.

Completed residency in Internal Medicine and Fellowship in Infectious Diseases at Yale University. Board certified in Infectious Diseases and Internal Medicine. Involved part-time in the practice of Infectious Diseases and supervising medical residents at St. Mary's Hospital in Waterbury, CT since 2006.

## Skin microbiota research and opportunities for prebiotics

**Dr. Heli Anglenius**

Senior scientist DuPont Nutrition & Biosciences



### ABSTRACT

The research from skin microbiota and its' potential effect in health and disease has evolved rapidly over the past ten years. Definition of healthy skin microbiota is largely impossible due to ethnic, cultural, geographic and lifestyle reasons. The skin also harbors different microbes depending on whether the site is moist or dry or sebaceous. Nevertheless, distinct microbes have been shown to have interesting beneficial functions in the skin, for instance through production of antimicrobial peptides and skin immune system modulation, and it has been proposed that imbalance in skin microbiota could lead to various skin diseases. A prebiotic has been defined as 'a substrate that is selectively utilized by host microorganisms conferring a health benefit', and classically understood to comprise carbohydrates but can also include other compounds, such as polyphenols. Prebiotics are fermented by the micro-

organisms with production of metabolites, and many of these then can be utilized by the host as energy source or as biosynthetic building blocks. In our recent study the effect of naturally occurring xylitol (Xivia®) controlling skin microbes was studied. Xylitol has dental health benefits, as it reduces the risk for dental caries due to its inhibitory function against *Streptococcus mutans*. When ingested, it is fermented by colonic microbiota to short chain fatty acids, especially butyrate, that is utilized by the intestinal epithelium as energy source, and thus confers health benefits to the host, and function as a prebiotic. It has been shown also to modulate the composition of the gut microbiota. Xylitol can also affect the growth of skin microbes, and the preliminary study shows specific effects on certain skin microbes. The prebiotic potential of xylitol especially in relation to skin microbiota modulation is also discussed.

### BIO

Dr. Heli Anglenius (former Putaala) has worked as a senior scientist at DuPont Nutrition & Biosciences for 15 years, and has a PhD in Karolinska Institutet, Sweden. Prior joining DuPont, she was a postdoctoral fellow in the Academy of Finland and Turku Center for Biotechnology in a project aiming to characterize factors affecting the development of allergies. In DuPont Nutrition and Biosciences her research interests have driven her from the health benefits of bacterially produced metabolites on epithelial cells and tight junctions towards the microbiome research not only in the gastrointestinal tract but also in the skin. Her specific interests involve the role of prebiotics in the gut and skin microbiota modulation, as well as the function of metabolites produced during the fermentation process, and how these metabolites can be translated into a health benefit in the host. During her career she has published 18 peer reviewed scientific articles, written book chapters as well as participated in several patent applications.





# Balancing skin microbiota-based cosmetics with the EU legislations

**Patrick Gonry**  
Business Developer, Gobiotics



## ABSTRACT

Microorganisms have not only invaded our skin, but also the strategy of innovative brands. We are just at the beginning to discover the importance and the endless possibilities of the skin microbiota. New words like probiotic and prebiotic are multiplying rapidly in marketing communication. More and more scientific evidence is supporting this evolution. But what about the legal status of these promising cosmetics? This presentation takes you through a concrete interpretation of the EU legislations to secure the future of skin microbiota related cosmetics.

- The delicate balance between microbiota related claims and the cosmetic legislation
- Concrete obligations of cosmetic products to comply with the EU legislation
- A microscopic research of the legislation reveals interesting opportunities and unexpected restrictions

## BIO

He graduated as a chemical engineer at the university of Ghent, Belgium in '91. Afterwards, he finished an intensive specialisation in cosmetic manufacturing and obtained a degree in dermato-cosmetic science at the medical university of Brussels. In 2001 he started the consultancy company S&C, supporting cosmetic producers and raw material suppliers in product development, global legislation and toxicology. He trained many cosmetic chemists and technical sales representatives. Since 2002 his research and passion are dedicated towards the skin microbiota, which resulted into the launch of the first prebiotic ingredient dedicated to baby care and intimate hygiene. He is the driving force behind many skin microbiota cosmetics in Europe. Through his latest company Gobiotics he offers the industry scientific solutions to support skin microbiota claims.

# How does your product work on the skin microbiome?

**The human skin is home to millions of bacteria, fungi and viruses, which compose the skin microbiota. The skin microbiota is extremely important to the skin health and it plays an essential role in skin protection against external infectious or toxic substances.**

It is important to maintain the balance of the skin microbiota in order to preserve the best physiology of the skin. Skin microbial communities are largely stable over time, despite the exposure of the skin to different external environments. However the skin microbiome can be affected by for instance personal care products, antibiotics, cosmetics, soaps and nutrition.

## **The clinical proof of your product efficacy**

BaseClear offers a complete solution to demonstrate the real efficacy of your product

on the microbiome. Our specialists can give you consultancy and support for your project design, and deliver complete reports including optional in-depth bioinformatics analysis and interpretation of the results.

## **We translate microbiome data to clear results**

The BaseClear team includes a number of experienced PhD-level molecular biologists, microbiome specialists and bioinformatics experts. Get in touch with one of our experts to discuss your project or to learn more about our microbiome analysis solutions.



## **BaseClear**

Your partner in microbiome analysis for skin health and cosmetics research

**MORE INFORMATION?  
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