



12 SEPTEMBER

**2018**

GRANGE CITY HOTEL  
LONDON, UK

# WHERE INNOVATION MEETS REGULATION



# OUR FIRST OTC.*NewDirections* EXECUTIVE CONFERENCE



Nicholas Hall.

**Nicholas Hall**

Executive Chairman & Creative Solutions Director  
Nicholas Hall Group of Companies



With the regulatory goalposts constantly moving, consumer healthcare players need to expand their innovation pipelines in order to keep ahead of the competition. That's why our *OTC.NewDirections* team felt this was the optimum time to establish our Executive Conference series, bringing together the experience of the Nicholas Hall Group with a new strategic focus on opportunities in key topics such as Medical Devices, Digital Health and Switch plus emerging CHC categories such as Cannabis, ultimately identifying Where Innovation Meets Regulation.



My *OTC.NewDirections* team and I will be joined in London on 12 September by eminent speakers to review and debate these issues and navigate the path to identifying, creating and sustaining innovation within our industry.

## INNOVATION FAIR!



Review latest innovations and licensing opportunities which will be available to view and discuss alongside the Conference. Organised by **The CHC Innovation Connection** in association with Nicholas Hall Group of Companies

THE <sup>CHC</sup> INNOVATION CONNECTION  
 • needy consumers • aspirational marketers  
 • ambitious entrepreneurs • *and us joining the dots*

Open from 08:30 – 18:00

# GET INVOLVED

Issue: 17 April 2018



## Content:

- New Ingredients
- Innovation
- New Products
- Medical Research
- Product Safety
- Switch
- Agency News

[10210] PROBI TO ENTER BONE HEALTH MARKET  
SWEDEN: Probi has released new clinical findings that suggest its probiotic strains may significantly reduce bone loss. The trial involved 250 post-menopausal women who were given a probiotic supplement containing a unique combination of three patent-protected Probi strains or placebo daily for one year. The findings of dual-energy x-ray absorptiometry showed significant bone loss in placebo participants, while the probiotic participants in the study the strains were tested in a mouse model of bone loss; the results from the clinical study are to confirm earlier findings. Probi claims this formulation is one of the first probiotic products to enter the bone health segment and plans to launch the supplement later this year targeting both consumer healthcare and functional food markets.

Comment from Consulting Editor, Nina Stimson: This is a tantalising story from Probi, and one which may send shivers down the spines of calcium supplement marketers. As yet, details are limited – trial results have not been published, and the mechanism of action of the probiotics used has yet to be disclosed. Overall, probi is certainly in a sufficient evidence to take this concept to market – alongside the clinical and mouse model results, the probiotics specialist also notes that the literature confirms there is a link between osteoporosis and the gut microbiota, while Biogate recently announced the completion of a smaller (90-subject) study in an older population of 75-80 year-old women. We will watch developments with interest!

Probiotics are one of the many categories examined in Nicholas Hall's VMS Report. This key publication profiles the Top 15 VMS markets globally, features a global VMS outlook with forecasts, and takes a look at brand case studies. For full details, or to order your copy, contact Owen.hartnett@nicholashall.com.

[10211] DEINOVE AND GREENTECH LAUNCH ANTI-AGEING INGREDIENT

FRANCE: Deinove and GreenTech have launched Helybys, the first cosmetic anti-ageing ingredient resulting from their collaboration that began in March 2017. The trademarked active is obtained by fermentation of Sphingomonas

## OTC.NewDirections E-Bulletin

*OTC.NewDirections* e-bulletin is sent direct to your inbox every Tuesday covering many important topics from Digital Health, Switch and Regulations to New Ingredients and innovative New Products, Medical Research and Product Safety.

Sign up to receive a free trial by contacting melissa.lee@nicholashall.com

W: [www.otcnewdirections.nicholashall.com](http://www.otcnewdirections.nicholashall.com)

### KEY CONTACTS:

For all events enquiries:  
Lianne Hill, Events Director  
[lianne.hill@nicholashall.com](mailto:lianne.hill@nicholashall.com)

For more information about innovations & licensing opportunities:  
Ammar Basit, The CHC Innovation Connection  
[amar.basit@nicholashall.com](mailto:amar.basit@nicholashall.com)



## OPENING ADDRESS / KEY REGULATORY AFFAIRS

- 8.30 Registration & Welcome Coffee
- 8.55 Welcome  
**Nina Stimson, VP, Nicholas Hall Group of Companies**
- 9.00 Opening Address  
**Nicholas Hall, Executive Chairman & Creative Solutions Director, Nicholas Hall Group of Companies**
- 10.00 Brexit – How to Prepare for Regulatory Repercussions for MA Holders of Medicinal Products  
With the UK's notice of withdrawal from the EU, unless the withdrawal agreement establishes another date or the period is extended by the European Council, it will become a 'third country' on 30 March 2019. This means that Marketing Authorisation holders may be required to adapt processes and consider changes in advance to avoid any impact on the continuous supply of

medicines within the EU. In this session, Agnieszka will review the potential regulatory obstacles and approach how to handle the Brexit challenges as a Marketing Authorisation Holder. She will also present insights from the President of URPL, giving an agency perspective on this issue.

**Agnieszka Buksowicz, Director of Regulatory Affairs & Board Member, APC Instytut Sp z o.o.**

- 10.30 Reclassification – An insight to the Art of Switching  
The session will explore the strategy of approach and the unwritten landscape of what to consider. There are many considerations and steps. The presentation will explore these and reflect on the approach which companies and healthcare agencies take and in some instances, do not take.

**James Hall, Director, Jenson R+**

## 11.00 Coffee



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## MEDICAL DEVICES

- 11.30 New Medical Device Regulations: Is There a Future for Self-Care Medical Devices in Europe or a BIG Shake Out?  
Many Self-Care Medical Devices were identified as borderline under the current Medical Device Directive. With the new Medical Device Regulations due to come into effect the industry will have a 'clear' legal framework within which we can ensure our products are fully compliant, yet many marketers and regulators are unaware of all these imminent changes, and the significant implications for existing and new consumer-oriented devices and apps. Based on his extensive experience of the medical devices market as well his contribution to the regulatory process, Maikel Hendriks will share valuable recommendations, key watch-outs and pointers for succeeding in what is the fastest growing and most innovative consumer healthcare category.

**Maikel Hendriks, President, Medical Brands**



## DIGITAL HEALTH

- 12.00 Connecting the Dots in Digital Health & Wellness  
The digital health revolution has arrived, marking the convergence of digital and genomic technologies with health, healthcare, living and society to enhance the efficiency of healthcare delivery and make products, solutions and services more personalised and precise. But is this transformation of Health & Wellness actually "revolution" or evolution? Alexis will review the impact of new disruptive players, identify the golden rules for sustainable success in CHC wellness and connected health innovation and present exciting new examples that are truly leading the way in connecting the dots in health & wellness for consumers.

**Dr Alexis Roberts-McIntosh, Independent R&D Healthcare Leader**

- 12.30 Panel Discussion  
**Maikel Hendriks, President, Medical Brands**  
**Dr Alexis Roberts-McIntosh, Independent R&D Healthcare Leader**

- 13.00 Lunch





## THE NEED FOR TRUE INNOVATION

## 14.00 Will a Genuine Consumer-Centric Focus Drive True Innovation?

In order to identify, create and sustain “true” innovation within the CHC industry, are we “missing the boat” – virtually stuck in our old ways while the competitive environment has morphed into the consumer calling the shots on what true innovation means. Ralph will challenge some of the industry knowledge that typically promises innovation and growth. With slowing CHC growth in the past 2 years, volume declines are offset by price increases and line extensions. True innovation is still elusive – lacking product differentiation, with brand over-elasticity and incremental-only launches. Will a “genuine” consumer-centric approach change that? And what does that mean to our innovation lens?

**Ralph Ahrbeck, Founder & CEO, Arqus Advisory**



## HEALTH CLAIMS &amp; HERBALS &amp; NATURALS

## 14.30 Herbals &amp; Naturals: The Unique Position and Importance of Food Supplements in the Consumer Healthcare Market

With food grade substances having a key role to play in the development of non-pharmaceutical products within the consumer healthcare market, Marco Fiorani takes a detailed look at the major stakeholders, expanding consumer health needs and innovations that are critical to our understanding and leveraging of this crucial opportunity, and ensure that as an industry we favour real innovation over “guile” marketing.

**Marco Fiorani, Pharma HQ Business Development  
Nutraceuticals, Angelini**

## 15.00 Emerging Science in “Smart Probiotics”: Functional and Novel Health Applications

Microbiome Revolution: Jennifer’s presentation will focus on how new research has the potential to radically change our views on medicine and nutrition. This thought provoking session will also look at where innovation will evolve next.

**Jennifer Cooper, LPS Health Science Discovery**

## 15.30 Panel Discussion

**Marco Fiorani, Pharma HQ Business Development**

**Nutraceuticals, Angelini**

**Jennifer Cooper, LPS Health Science Discovery**

**Ralph Ahrbeck, Founder & CEO, Arqus Advisory**

## 16.00 Coffee



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## CANNABIS

## 16.30 Medical Cannabis Regulations in Canada – OTC implications

With medical cannabis having been available in Canada for several years under the Access to Cannabis for Medical Purposes Regulation, David will take a brief look at the legislative history leading to the very latest changes enabled through the new Cannabis Act of 2018. He will explore the implications of this legalisation for the industry and consumers, taking a look at the impact on regulatory policies for cannabis-derived compounds. Knowing that the regulations will evolve over the next 12-24 months for all classes of products from foods with health claims, prescription drugs, OTC and NHP medicines, devices and cosmetics, David will summarise each classification and conclude by evaluating the import and export opportunities this could bring.

**David Skinner, Principal, Heuristix Consulting**

## 17.00 Medical Cannabis Landscape and its Current Trends

With the Cannabis market becoming the fastest growing industry in modern times, promising solutions for pain relief, Cancer, ADD, fibromyalgia and various other medical ailments, in this session Avihu will highlight the key growth trends impacting the medical cannabis market, exploring the unique challenges of this industry and the shifting regulatory landscape and how this can affect the commercial positioning of Medical Cannabis.

**Avihu Tamir, Founder & CEO, Kanabo Research**

## 17.30 Summary of Opportunities and Strategies

**Nicholas Hall, Executive Chairman & Creative Solutions Director, Nicholas Hall Group of Companies**

## 17.45 Meeting Close

Networking Drinks Reception



**Ralph Ahrbeck**  
Founder & CEO  
Arqus Advisory

Ralph is the founder and CEO of Arqus Advisory – an International Global Marketing and Strategy Consultancy focused on bridging Asian and Western management philosophies for successful go-to-market business models. A true global citizen, he has lived in 3 continents working in start-ups and turnarounds with Kraft Foods, Roche Consumer Health, Alliance Boots and Shiseido extending from consumer goods through to healthcare and beauty. He is passionate about building consumer-centric global brands and profitable, innovative businesses. Working with a broad range of organisations from Fortune 100 companies to entrepreneurs, he helps clients build cutting-edge global brands, new business models and market leadership by challenging business practices with “out-of-the-box” strategies and best practices.



**Agnieszka Bukowicz**  
Director of Regulatory Affairs & Board Member  
APC Instytut Sp z o.o.

Agnieszka has 25 years of experience working in the life science industry, first as product manager at Bayer AG, later as co-owner of APC Instytut in the role of Business Development Manager and Market Access Director. She is experienced in the entire scope of the registration process of medicinal products, food supplements and medical devices, from creation of registration strategy to pricing and reimbursement scenarios. Her recent activities focus on switches from Rx to OTC as well as from medicinal products to non-pharmaceuticals in the Polish market. She also set up the pharmacovigilance department at APC Instytut and acts as deputy QPPV for medicinal products or local PV contact for the Polish Health Authority URPL. Since 2013 she has been a Board Member of the biggest Industry Pharmaceutical Association in Poland - Izba Gospodarcza Farmacja Polska.



**Jennifer Cooper**  
Chief Scientific Officer  
LPS Health Science Discovery

Jennifer Cooper has spent over 25 years in consumer healthcare and is currently the Chief Scientific Officer at LPS Health Science Discovery. She has held senior R&D and Quality positions in OTC and supplement companies in the US and EU. Jennifer has directed the development of supplements, over-the-counter drugs, homeopathic medicines, functional foods, traditional herbal medicines, medical devices and dermo-cosmetics. She has developed and brought to market over 300 new products in more than 20 different countries.



**Marco Fiorani**  
Pharma HQ Business Development Manager, Nutraceuticals, Angelini

Responsible for Business Development Nutraceuticals at Angelini Pharma HQ in Rome. In the company has held several positions as Marketing Manager, Strategic Marketing, Innovation & Project Manager, Business Planning, Business Unit Head, running the company's Nutraceuticals business and gaining a sound expertise in launch and development of brand new products through different sales channels in Italy and other European countries.  
Board Member, Vice President and President, until 2016, of FederSalus, the main Italian Health Products Manufacturers Association.  
Co-author with Vittorio Silano, Chairman of the EFSA Scientific Committee of a book published in Italy in 2016: "Food Supplements in the European Union. Community legislation and national rules, scientific aspects of safety and efficacy evaluation and EU markets structure".



**James Hall**  
Director  
Jenson R+

In excess of 25 years' regulatory experience, primarily within the OTC sector of the industry. He has worked for major pharmaceutical companies and for the last 12 years as a consultant to a wide variety of clients from small entrepreneurial companies to the large pharma organisations.

James is a Board member within JensonR+ Limited.  
He holds a degree in Applied Biology and is a Fellow of TOPRA.





Nicholas is the founder of the Nicholas Hall Group of Companies, an elite consulting, business intelligence and executive recruitment company primarily serving the OTC healthcare industry since 1978. After a career in marketing and general management with Procter & Gamble, Vicks and GD Searle, Nicholas has managed the company's consultancy practice, which has among its clients many blue chip OTC companies, as well as some of the leading local laboratories in Asia, Middle East and Latin America. He has more than four decades of experience in the healthcare industry and has chaired and moderated over 300 OTC conferences and seminars in 58 countries.

**Nicholas Hall**  
Executive Chairman & Creative Solutions  
Director, Nicholas Hall Group of Companies



Maikel Hendriks is a serial entrepreneur and R&D / regulatory expert in self-care medical devices. In 1996, Maikel started a consulting firm to provide regulatory consulting for medical manufacturers to comply with the recently-introduced medical device directive. Today Medical Brands distributes over 40 products in 68 countries worldwide and has a strong pipeline of new concepts. Maikel's vision is to change the self-care market by providing new innovative treatments without pharmacologic effects. He is actively involved in the establishment of new regulations and codes of conducts, and the promotion of the newly developed Self-Care Medical Device category.

**Maikel Hendriks**  
President  
Medical Brands



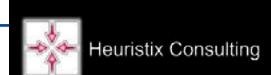

A Senior Entrepreneurial Research & Development Executive with over 25 years' experience in leading and transforming large global R&D teams in the Pharma / Medical Devices, OTC & Wellness Sectors. In these senior leadership roles for a number of Fortune 100 Healthcare Companies she has led significant business growth from insights, disruptive innovation, claims and acquisition of new businesses, organisational end-to-end transformation and re-design, new category development, medical marketing/communication, technical break-through IP generation, digital health transformation and novel innovation processes for such global leading brands as Advil, Sensodyne, Scholl, Durex, Neutrogena, Tylenol, Motrin, Tylenol and Digestive Advantage.

Alexis has extensive global consumer-centric innovation & business leadership experience across multiple regions: EMEA, Asia Pacific (including India, China, Japan), Latin America, Middle East and Africa.

**Alexis Roberts-McIntosh**  
Independent R&D  
Healthcare Leader



Heuristix Consulting is led by David Skinner. Mr. Skinner has over 38 years' experience working in science and policy development. His primary focus has been in the health care field, food and nutrition and the consumer packaged goods industry. Having held positions in research and as the CEO of a national trade association, Mr. Skinner is a trained facilitator and holds the designation of a Certified Association Executive in both Canada and the United States.



**David Skinner**  
Principal  
Heuristix Consulting



Avihu Tamir is a cannabis entrepreneur with over five years of hands-on experience in multiple Israeli medical cannabis ventures. He is the Co-Founder and CEO of Kanabo Research, a medical cannabis R&D company based in Tel Aviv that focuses on building IP for inhaling medical cannabis, through vaporiser technology platforms and applications of patented cannabis formulations.



**Avihu Tamir**  
Founder & CEO  
Kanabo Research

Before starting Kanabo Research, Avihu was the founder of Teva Nature, the leading vaporizer company in Israel, and worked as a senior strategy consultant at Accenture. As a management consultant for many years, Avihu has vast experience in business strategy for major corporations, which he has used in many consulting projects for international cannabis ventures that touch on biotechnology, emerging agriculture and agtech, and other breakthrough technologies in the field of medical cannabis.



## Venue:

Grange City Hotel, London  
Address: 8-14 Cooper's Row, London EC3N 2BQ  
Phone: 020 7863 3700

*We look forward to welcoming you in London!*



## WHERE INNOVATION MEETS REGULATION

12 September 2018 - Grange City Hotel, London

I would like to book \_\_\_\_\_ place/s.

Ticket Price:	Bookings before 31 July £650 GBP	Full Rate from 1 August £850 GBP
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I accept the terms and conditions below and understand that Nicholas Hall Group of Companies reserves the right to amend the agenda.

Signature \_\_\_\_\_

Date DD / MM / YYYY

This conference is being held by Nicholas Hall International Ltd, but for bookings, information and other details please contact our managing agents:  
Nicholas Hall Europe Ltd, 35 Alexandra Street, Southend on Sea, SS1 1BW

N.B: Nicholas Hall Group of Companies is not liable for any incident or injury, which may occur during the course of the meeting or any of the functions, including the networking drinks reception.

The appropriate fee covers attendance at the workshop, event documentation, lunch and coffee breaks during the meetings on 12 September 2018. It does NOT include hotel accommodation or items charged to your room account, or transport to and from the conference.

Pictures and / or videos taken during the event including during speaker presentations, networking breaks, drinks reception and evening events may be used for publicity or marketing purposes.

Bookings may be transferred to a colleague, at no extra charge. Notice of cancellations or transfers of bookings must be given in writing. For cancellations received by 12 June 2018, fees will be refunded in full, less an administration charge of £100. There will be no refund for cancellations received after 12 June 2018, or cancellations where no written notice of cancellation is received.

If you have any questions about this event, please contact lianne.hill@NicholasHall.com or +44(0)1702 220 200