AUGUST 6 – 8, 2024
BOSTON, MA

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Bioactive Infant Formula & Nutrition Summit

Bringing the Nutritional Value of Formula Towards the Holy Grail of Human Breast Milk

Advance the Functionality, Translation & Regulatory Pathway for HMOs, MFGMs, & Novel Bioactive Ingredients for Formula Industry Application

Expert Speakers Include:

Paul Hanlon
Director of Regulatory Affairs
Abbott Nutrition

Stina Jensen
Head of Applied HMOs
Novonesis

Ari Brown
Chief Medical Advisor
Kabrita USA

Andre Groeneveld
Senior Discovery Manager
FrieslandCampina

Tania Porsgaard Bayer
Director of Global Regulatory Affairs
Arla Foods Ingredients

Douglas Burrin
Senior Research Scientist, Children's Nutrition Research Center, Baylor College of Medicine
USDA-ARS

Partner:

COSMOSID®

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www.bioactive-infant-nutrition.com

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Welcome to the Bioactive Infant Formula & Nutrition Summit

Recent years have highlighted the acute need to overhaul the infant formula market, providing **data-backed**, **nutritionally advanced formulas** to safeguard supply chains and provide better alternatives for those who need it. Long-awaited approvals such as IFF's 2'-FL and DSM's LNnT have opened the floor to new horizons for bioactives.

As the race to create infant formula closer in composition to human breast milk gathers pace, join the inaugural **Bioactive Infant Formula & Nutrition Summit** alongside, fellow **formula manufacturers**, **food biotechs** and **ingredient providers** from the likes of **Abbott, FrieslandCampina** and **Reckitt** to create a roadmap for the future of this $60 billion market.

Learn to combine technical and commercial expertise to formulate with **HMOs**, **MFGMs**, and other human milk-like constituents; delve into regulatory approaches from proof of concept in adult nutrition to translation into infant; and pinpoint your product development investments to the most promising targets.

Unite with 60+ **regulatory specialists**, **medical affairs professionals**, **HMO leads** and **nutrition experts** to:

- **Optimize bioefficacy** and **safety demonstrations** to combat regulatory ambiguity and safeguard FDA approaches
- **Bridge the gap towards human milk** by exploring non-standard HMOs and MFGMs as the driver behind novel nutritional potential
- **Streamline preclinical** and **clinical translation** and consumer communication to deliver on nutrition and efficacy promises
- **Advance product functionality** for novel bioactives to enhance humanization

Steering towards robust humanization and nutritional excellence, join us in kick-starting this industry journey striving towards a positive future for infant formula **functionality**, **translation** and **regulatory success**.

Join Your Industry Peers To:

Tap into the Chinese market opportunity through case-study success stories from the likes of **Arla Foods Ingredients** to inspire your regulatory and commercial journey

Join us for a food biotech-special: a panel discussion uniting **TurtleTree**, **Helaina** and **BIOMILQ** to discover innovative formula technologies with translational promise

Attend our **industry regulator-led workshop** to familiarize and unravel GRAS status and pre-submission requirements to mitigate regulatory risk

Collaborate with the likes of **Abbott**, **Reckitt, Bobbie**, **FrieslandCampina**, **Novonesis**, **Kabrita, ByHeart**, and **Helaina** to demonstrate, enhance and translate the nutritional value of infant formula

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Industry-Leading Speakers

Paul Hanlon
Director of Regulatory Affairs
Abbott Nutrition

Vassilis Triantis
Senior Scientist Immunology & Gut Physiology
FrieslandCampina

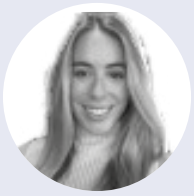
Ari Brown
Chief Medical Advisor
Kabrita USA

Douglas Burrin
Senior Research Scientist, Children's Nutrition Research Center, Baylor College of Medicine
USDA-ARS

Diana Orenstein
Senior Director, Nutrition Science & Research
ByHeart

Stina Jensen
Head of Applied HMOs
Novonesis

Manki Ho
Principal Regulatory Affairs Specialist
Novonesis



Morgan Audino
Director, New Product Strategy
Bobbie

Pedro Antonio Prieto
Chief Scientific Advisor
Bobbie

Leila Strickland
Co-Founder & Chief Executive Officer
BIOMILQ

Zohar Barbash
Chief Technology Officer
Wilk

Tania Porsgaard Bayer
Director of Global Regulatory Affairs
Arla Foods Ingredients

Sebastian Finch
Senior Regulatory Affairs Specialist
Arla Foods Ingredients

Carrie Malinczak
Head of Nutritional Biology & Safety
Helaina

Vanessa Castagna
Director of Clinical & Scientific Affairs
TurtleTree

Sharon Donovan
Director of Personalized Nutrition Initiative
University of Illinois at Urbana-Champaign

Daniel Raiten
Senior Nutrition Scientist, Office of Nutrition Research
National Institutes of Health

Robert DiGregorio
Head of Regulatory Affairs
Harmony Baby Nutrition

"This conference went far beyond my expectations. Not only did we get to hear the latest research, but we also had some amazing open discussions about the challenges with the science."

Founder, Board Certified Functional Nutritionist, **Healthy Mamas for Happy Families,** *Microbiome Series Attendee*

Pre-Conference Workshop Day

Tuesday, August 6

Workshop A

9.00 - 12.00

Achieving the Regulatory GRAS Status with Optimal Review of Safety & Data Generation

The journey to regulatory approval can sometimes seem like a never-ending and complex labyrinth. **Cross-departmental collaboration with regulatory decision makers** will help you bridge this gap and help exercise the skills that are in your control.

Join this workshop to unite with industry-leading regulatory experts to understand the ins and outs of **pre-submission meetings** and **regulatory frameworks** to streamline approval.

This workshop will gather experts to discuss:

- Outlining and assessing GRAS notices to help inform review of safety and identify early market opportunities for specific bioactives
- Pinpointing nuances in data quality to best prepare for pre-submission meetings and effectively demonstrate growth and intake outcomes
- Implementing risk-benefit models for regulatory strategies to compare alternatives and hone in on best directions forward

Workshop Leaders

Tania Porsgaard Bayer
Director of Global Regulatory Affairs
Arla Foods Ingredients

Paul Hanlon
Director of Regulatory Affairs
Abbott Nutrition

Manki Ho
Principal Regulatory Affairs Specialist
Novonesis

Workshop B

1.00 - 4.00

Perfecting Your Experimental Design to Inform Early Decision Making & Future-Proof Business Strategy

As the journey towards regulatory acceptance and commercialization stems from experimental data, it's imperative to set up **fit-for-purpose experimental designs** to secure your forward strategies.

Join this workshop alongside research wizards who have all the experimental know-how to help you adapt experimentation and **inform preclinical and clinical decision making**.

This workshop will gather experts to discuss:

- Assessing public perception surrounding preclinical models to learn how to justify model of choice
- Broadening the scope of your preclinical trials in light of clinical limitations to best predict efficacy effects on infants
- Delving into demonstrations of bioefficacy to effectively translate to internal and external teams

Workshop Leaders

Stina Jensen
Head of Applied HMOs
Novonesis

Douglas Burrin
Senior Research Scientist, Children's Nutrition Research Center, Baylor College of Medicine
USDA-ARS

Sharon Donovan
Director of Personalized Nutrition Initiative
University of Illinois at Urbana-Champaign

Conference Day One
Wednesday, August 7

8.00		**Registration & Morning Refreshments**
8.50	 **Robert DiGregorio** Head of Regulatory Affairs **Harmony Baby Nutrition**	**Chair's Opening Remarks**

Securing Bioefficacy & Safety Data to Streamline Preclinical Translation & Safeguard Regulatory Approval

9.00	 **Stina Jensen** Head of Applied HMOs **Novonesis**	**Demonstrating Proof of Bioefficacy to Streamline Preclinical to Clinical** • Discussing the rationale behind using preclinical models and alternative design of experiment routes to optimally demonstrate bioefficacy • Decoding the translation from preclinical to clinical growth studies to understand how to portray growth within experimental design limitations • Adopting a multifactorial approach to support the business of proving bioefficacy
9.30	 **Sebastian Finch** Senior Regulatory Affairs Specialist **Arla Foods Ingredients**	**Case Study: Tapping into the Chinese Market to Inspire Formula Commercialization & Regulatory Strategy** • Shedding light on the current demographic situation to understand market status and commercial positioning • Navigating the complex infant formula registration journey from trial production to commercialization to pinpoint successes for business strategies within the Chinese market • Eradicating regulatory bottlenecks – from obstacles to approval

Specializing Functionality to Enhance Quality Profiles & Translate to End-Users

10.00	 **Vassilis Triantis** Senior Scientist Immunology & Gut Physiology **FrieslandCampina**	**Assessing the Scope & Progress of Novel Bioactives to Move Closer Towards Human Milk & Direct Future Focuses** • Discussing latest scientific updates on MFGM's in infant formula to understand current and future opportunities • Delving into human milk oligosaccharides and galacto-oligosaccharides to navigate complexities • Providing an in-depth analysis of Bovine IgG to understand its usage in infant formula
10.30		**Speed Networking & Morning Coffee Break** Join your peers in a session of speed networking to foster new relationships
11.30	 **Vanessa Castagna** Director of Clinical & Scientific Affairs **TurtleTree**	**Evolving Functionality to Meet Infant Formula Requirements Regarding Nutritional Profile & Structures Bridging the Gap to Human Milk** • Front-loading ingredient-to-formula compatibility to ensure function is retained for desired physiological and cognitive effects • Analyzing and assessing functional parameters in alignment with human milk functionality to hone in on desired characteristics • Bridging closely towards milk-based flavours and functions to support humanization
12.00	 **Ari Brown** Chief Medical Advisor **Kabrita USA**	**Delving into Translational Science & to Effectively Communicate the Value of Your Formula & Secure Engagement** • Demonstrating beneficial effects and value added from formula to consumers to bridge the gap between scientific approach and understanding • Streamlining from the clinic to the end-user in order to effectively understand requirements and communicate efficacy • Understanding how to prioritize which beneficial effects to communicate in order to support nutritional value added

Conference Day One
Wednesday, August 7

12.30 **Session Reserved for** COSMOSID

12.40 **Networking Lunch**

Leveraging Commercial Factors to Inform Formula Personalization & Influence Perception

1.40 
Pedro Antonio Prieto
Chief Scientific Advisor
Bobbie

Advocating Nutrition Education to Resonate Closely with Your Market in Light of Commercialization

- Depicting language nuances and marketing strategy to closely speak to your scientifically driven market for trust-building
- Leveraging nutrition education and market resonance to identify launch location within timeframes
- Assessing efficacy claim allowance globally to inform launch location and business gameplan

2.10 
Morgan Audino
Director, New Product Strategy
Bobbie

Roundtable Discussion: Addressing the Future Roadmap for Bioactive Ingredient Applications to Drive Technical & Commercial Expansion

- Pinpointing commercial successes and failures beyond standard bioactives to engage consumers and external partners
- Discussing commercial entry approaches for formula products to secure consumer attraction
- Identifying future targets for formula ingredients to shine light on next steps for industry

Optimizing Translation & Communication to Streamline from Science to External Teams

3.00 **Afternoon Break**

3.45 
Diana Orenstein
Senior Director, Nutrition Science & Research
ByHeart

Translating Key Clinical Trial Findings to Support Nutritional & Safety Claims

- Discussing considerations for design and analysis of a clinical trial for translation of outcomes into impactful claims
- Utilizing clinical biomarkers and parent-reported symptoms to explore the safety, efficacy, and health impact of an infant formula
- Understanding the value creation of infant formula trials beyond individual ingredient innovations

4.15 
Daniel Raiten
Senior Nutrition Scientist, Office of Nutrition Research
National Institutes of Health

Understanding Human Milk as a Biological System to Discuss Implications for Infant Feeding & Breastmilk Ecology: Genesis of Infant Nutrition: "BEGIN"

- Addressing unanswered questions regarding chronobiology of human milk to understand infant implications
- Understanding translational implications regarding infant feeding and human milk biology
- Discussing donor milk claims and effects in relation to pre-term infants to address where current requirements lie

4.45 
Robert DiGregorio
Head of Regulatory Affairs
Harmony Baby Nutrition

Chair's Closing Remarks & End of Conference Day One

Conference Day Two
Thursday, August 8

8.00 — **Registration & Morning Refreshments**

8.50 — 
Pedro Antonio Prieto
Chief Scientific Advisor
Bobbie

Chair's Opening Remarks

Tapping into Ingredient Availability & Regulatory Approval to Promote Effective Application for Infant Formula Products

9.00 — 
Manki Ho
Principal Regulatory Affairs Specialist
Novonesis

Case Study: Building the Safety Package for Bioactive Ingredients, Taking into Consideration the Current Regulatory Framework & Product Timeline Horizons

- Discussing the current regulatory challenges surrounding bioactive ingredients that are intended for use in infant formula
- Using case example(s) to highlight the robust safety packages (preclinical & clinical data) that have been gathered to successfully gain regulatory approvals
- Exploring considerations for ingredient providers when setting up regulatory strategies for the approval of bioactive ingredients

9.30 — 
Zohar Barbash
Chief Technology Officer
Wilk


Paul Hanlon
Director of Regulatory Affairs
Abbott Nutrition

Panel Discussion: Discussing the Regulatory Framework & Market Access Approach for Ingredient Providers & Formula Manufacturer Dynamic to Streamline Approval

- Unpicking market access strategy including data packages and ingredient characterization to pinpoint potential challenges and solutions
- Enhancing robustness of market access strategies ahead of regulatory and partner collaboration to promote stakeholder engagement
- Exploring experiment optimization strategies to present evidentiary data to help influence partnership decisions

10.15 — **Morning Break & Refreshments**

Propelling Forth Novel & Innovative Bioactives to Discover Unexplored Opportunity & Direct Products of the Future

11.00 — 
Zohar Barbash
Chief Technology Officer
Wilk

Discussing the Evolution of Technology for Cellular and Precision Fermentation-Derived Ingredients as a Gateway to Sustainability & Economic Feasibility

- Tapping into the changing world of infant formula HMOs vs traditional production to fill in market gaps
- Outlining differences between cell-based and fermentation approaches to pinpoint areas of opportunity
- Developing on proof of concept for cell-based and exosome technologies to pinpoint and exploit major successes for application

11.30 — 
Vanessa Castagna
Director of Clinical & Scientific Affairs
TurtleTree


Leila Strickland
Co-Founder & Chief Executive Officer
BIOMILQ


Carrie Malinczak
Head of Nutritional Biology & Safety
Helaina

Panel Discussion: Keeping Up With the Latest & Greatest in Discussing Opinions & Future Movements on Novel Technologies

- Pinpointing novel bioactive sources and technologies with the most translational promise and consumer benefit
- Understanding best prioritize bioactives within the portfolio according to current demand
- Discussing the extent of potential for cutting-edge cell-based and novel fermentation technologies reach new horizons for infant formula

Conference Day Two
Thursday, August 8

12.15 **Networking Lunch**

Streamlining from Proof of Concept to Technical Implementation for Novel Formulae

1.15

Leila Strickland
Co-Founder & Chief Executive Officer
BIOMILQ

Case Study: Building a Mammary Biomanufacturing Platform to Explore Novel Avenues For Ingredient Production

- Looking into BIOMILQ's biomanufacturing platform that utilizes the unique potential of human mammary cells to produce human milk ingredients for the betterment of human health
- Communicating the rationale behind using bioactive approaches to encourage innovation and shape the future of early life nutrition
- Demonstrating proof of concept for cell-based technologies to support collaboration and streamline investments

1.45

Carrie Malinczak
Head of Nutritional Biology & Safety
Helaina

CCase Study: Discussing a Randomized, Double-Blind, Controlled Trial to Assess the Effects of Lactoferrin at Two Doses vs. Active Control on Markers of Immune Safety

- Displaying novel approaches and innovative technologies to showcase future horizons for formula applications
- Communicating the rationale behind using non-standard and non-approved bioactive approaches to encourage innovation
- Demonstrating proof of concept for humanization of formula ingredients to engage support for experimental trials and regulatory plans

2.15 **Afternoon Break & Refreshments**

Leveraging Research Insights to Inform Efficacy Demonstrations Fit for Proof of Product Claims

2.45

Douglas Burrin
Senior Research Scientist, Children's Nutrition Research Center, Baylor College of Medicine
USDA-ARS

Securing Industry & Academic Collaboration to Effectively Transition From Concept to Proof of Viability

- Learning how to promote your technologies to academia and speak to desired interests to promote engagement
- Examining what's desired regarding IP discussions and publications to uncover what good looks like from an academic perspective
- Tackling translational science from preclinical trials to infant physiology to exploit key benefits through data displays and market delivery

3.15

Sharon Donovan
Director of Personalized Nutrition Initiative
University of Illinois at Urbana-Champaign

Enhancing Preclinical Efficacy for Bioactive Data Demonstration & Displaying Rationale Behind Decisions

- Addressing critical growth parameters and models to support translational science and efficacy
- Discussing the concept of human milk as a biological system (BEGIN project): assessing bioactive ingredients in conjunction vs singular analysis
- Exploring examples of outcomes with single vs. combined ingredients (probiotics/HMO or HMO/HMO) to observe combinatorial effects in preclinical trials

3.45

Pedro Antonio Prieto
Chief Scientific Advisor
Bobbie

Chair's Closing Remarks & End of Summit

Partner With Us at the First Infant Formula Industry Meeting

Your Unique Forum to Explore New Strategic Partnerships & Solidify Existing Relationships

Re-thinking priorities off the back of the 2022 US infant formula crisis, we have since seen companies such as **Yali Bio** transform the face of humanization, in addition to **Nestlé**'s recent investment towards HMO trials to excel forth the opportunity for formula applications.

In collaboration with the likes of **FrieslandCampina**, **Kabrita**, and **Abbott**, who are all contributing towards the $60 billion formula market, alongside innovative advancements into novel cell-based and fermentation techniques for production, this is the time to maximize collaborative opportunities in a market with guaranteed demand.

Established formula manufacturers, food biotechs and ingredient providers need your help with:

Food safety and quality analytics to safeguard product testing and contaminant prevention

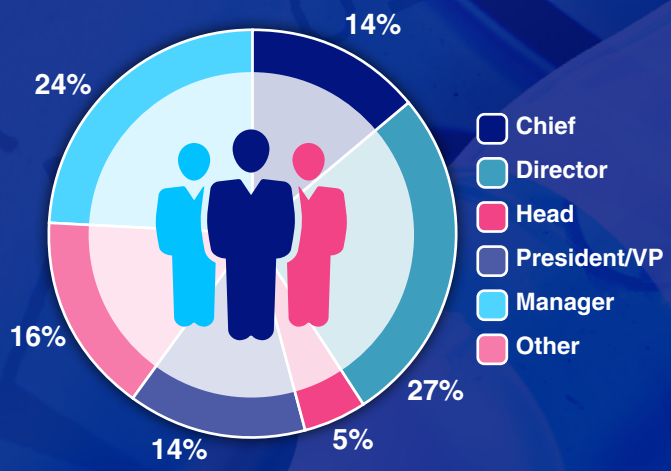
Manufacturing technologies including large-scale processing and formulation capabilities to provide production flexibility

Food regulatory consulting to develop risk-averse regulatory pathways and strategic measures for approval

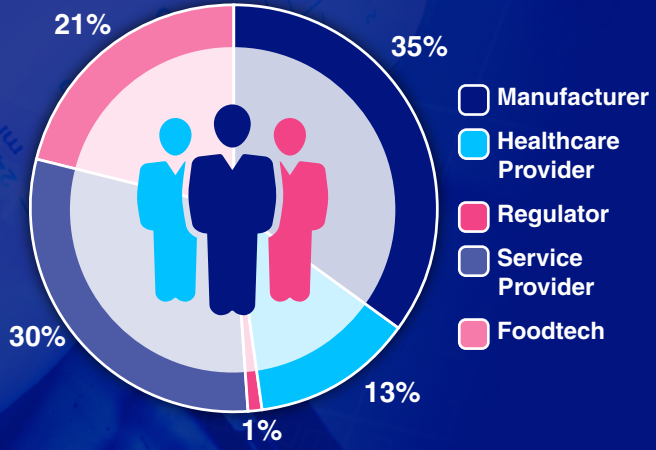
Public affairs and market research expertise to empower product development and innovation

This is the **first and only time** where industry pioneers will be joining forces and willing to invest in partners to help paint a perfect picture for technical expertise and commercial brilliance; join us to **network with professionals** and **establish your solutions** in the infant formula industry.

ATTENDEE BY SENIORITY*



ATTENDEE BY COMPANY TYPE*



*statistics taken from Microbiome Movement - Maternal & Infant Health Summit 2023

Get in Touch

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2024 Partners

CosmosID

We offer end-to-end microbiome science solutions from discovery through clinical validation: short- and long-read DNA sequencing, metabolomics, RNA sequencing, multi-omics analysis and systems biology expertise. Pipelines are supported by CLIA-certified & ICH-GCP compliant NGS, metabolomic, and bioinformatics solutions. Access results via the CosmosID-HUB – a user-friendly cloud software for metagenomic and comparative analysis – or through customized reports. Bioinformatic pipelines enable clonal-level resolution, engraftment analysis correlated to phenotypes, and in-silico strain screens that de-risk selection and reduce development time.

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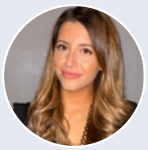
Get in Touch



Marinela Tice
Partnerships Director
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Ready to Register?

3 Easy Ways to Book

https://bioactive-infant-nutrition.com/take-part/register

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Team Discounts

- 3 Delegates: 10% Discount
- 4 Delegates: 15% Discount
- 5+ Delegates: 20% Discount

3 Key Benefits of Attending

1. **UNRAVEL** the complex technical, regulatory and commercial journeys for novel bioactives to optimize humanization and formula nutrition
2. **DEVELOP** your current know-how to support advanced formula and ingredient functionality
2. **TRANSLATE** your internal approaches to external teams to support claims and demonstrate bioefficacy alongside 60+ industry experts

Formula Manufacturer & Ingredient Provider Pricing*	Register & Pay By Friday, July 12	On The Door
Conference + 2 Workshops	$3,847 **(Save $350)**	$4,197
Conference + 1 Workshop	$3,298 **(Save $300)**	$3,598
Conference Only	$2,749 **(Save $250)**	$2,999

Food Biotech & Academic Pricing**	Register & Pay By Friday, July 12	On The Door
Conference + 2 Workshops	$3,247 **(Save $350)**	$3,597
Conference + 1 Workshop	$2,798 **(Save $300)**	$3,098
Conference Only	£2,349 **(Save $250)**	$2,599

Solution Provider Pricing***	Register & Pay By Friday, July 12	On The Door
Conference + 2 Workshops	$4,747 **(Save $350)**	$5,097
Conference + 1 Workshop	$4,098 (**Save $300)**	$4,398
Conference Only	£3,449 **(Save $250)**	$3,699

*To qualify for the industry rate, your company must be a formula manufacturer or ingredient provider. Those who provide services to these companies do not qualify for this rate. Please visit the website for full pricing options or email info@hansonwade.com.

**To qualify for the Food Biotech & Academic Pricing rate, you must be a formula manufacturer, food biotech or ingredient provider with 50 or fewer employees. Service and solution providers do not qualify for this rate. Please visit the website for full pricing options or email info@hansonwade.com.

***Service & Solution Provider Pricing - For those who provide services and solutions to formula manufacturers, food biotechs, or ingredient providers, such as food testing and analytics, regulatory consulting, or equipment providers. Please visit the website for full pricing options or email info@hansonwade.com.

Venue

Hilton Boston Back Bay

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TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organisation can be made at any time.

Changes to Conference & Agenda: Every reasonable effort will be made to adhere to the event programme as advertised. However, it may be necessary to alter the advertised content, speakers, date, timing, format and/or location of the event. We reserve the right to amend or cancel any event at any time. Hanson Wade is not responsible for any loss or damage or costs incurred as a result of substitution, alteration, postponement or cancellation of an event for any reason and including causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities.

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