

4TH
EDITION

AGENDA

RISK & LIFECYCLE MANAGEMENT SUMMIT
ON PHARMA AND BIOPHARMA OPERATIONS

23RD - 24TH FEBRUARY 2021

QRM SUMMIT **2021**
RISK & LIFECYCLE MANAGEMENT



04 Scientific Organizing Committee



Ajaz Hussain, PhD
Independent Consultant
Former Deputy Director, OPS/CDER FDA



António Moreira, PhD
Vice Provost for Academic Affairs
University of Maryland UMBC, USA



Joerg M. Gampfer, PhD
VP Development & Technology Services,
Aenova Holding GmbH



José C. Menezes, PhD
Chairman and Founder
4Tune Engineering

02 Halfdays

04 Scientific Tracks

18 Talks

AGENDA

Presentations and townhall discussions will take place throughout the 2-halfdays, led by experts in the area as speakers, sharing best-practices and hearing senior regulators discuss emerging regulatory trends – concluding what companies need to be doing to stay ahead.

DAY 1

CHOOSE YOUR
SESSION
BEFORE ENTERING

ONLINE EVENT

- 2| Halldays (12:30 - 17:30 UTC)
- 1| Keynote & Q&A to kick-off the day (45min + 10min respectively)
- 2| Sc. Tracks in parallel, with 4 talks & Q&A (15min + 10min respectively)
- 1| Townhall wrap-up session at end of each day

ROOM 1	» 12:30 – 12:45	● WELCOME & OPENING ADDRESS Scientific Organizing Committee Dr. António Moreira – Vice-Provost University of Maryland UMBC, USA Dr. Ajaz Hussain – Independent Consultant, Former Deputy Director, OPS/CDER FDA Dr. Joerg M. Gampfer – VP Development & Technology Services, Aenova Holding GmbH Dr. José C. Menezes – Chairman & Founder, 4Tune Engineering
ROOM 1	» 12:45 – 13:45	● KEYNOTE 1ST DAY A Regulator's Perspective on Quality Risk Management After 15 years of ICH Q9, and Reflections on the Role of Knowledge Management Dr. Kevin O'Donnell - Market Compliance Manager, Health Products Regulatory Authority, Ireland
Sc. TRACK #1		Risk & Knowledge Management in Pharma and BioPharma Operations (I)
ROOM 1	» 13:45 – 14:15	● Acceleration, Compliance, Uncertainties, Excellence: Lifecycle turns 4.0 too. Dr. José C. Menezes - Chairman & Founder, 4Tune Engineering
ROOM 1	» 14:15 – 14:45	● The Path to Knowledge Management in Building Process Understanding: Uncertainties over Lifecycle Dr. Joey Studts - Bioprocess Development Biologicals, Boehringer Ingelheim Pharma GmbH & Co. KG
	14:45 – 15:00	● BIO BREAK
ROOM 1	» 15:00 – 15:30	● Risk Management and Advanced Data Analytics to Support Continuous Improvement Dr. Ulrike Strauss - Principal Scientist Material Science, Roche Diagnostics GmbH
ROOM 1	» 15:30 – 16:00	● FDA's New Guidance on CSA: Risk-Based Critical Thinking and its Implications Ricardo J. Leandro - Head of QRM, 4Tune Engineering
Sc. TRACK #2		Compliance in the Age of Lockdowns & Disruptions
ROOM 2	» 13:45 – 14:15	● The Art of Anticipation - Why using Knowledge is a Competitive Advantage Dr. Joerg Gampfer - VP Development & Technology Services, Aenova Holding GmbH
ROOM 2	» 14:15 – 14:45	● Integrating QRM in the Pursuit of PQS Excellence Dr. Pierre-Marie Eberst - Head of Quality Management Systems – Biopharma, Merck Group KGaA
	14:45 – 15:00	● BIO BREAK
ROOM 2	» 15:00 – 15:30	● Enabling Risk and Lifecycle Knowledge Management: Knowledge-aided Assessment and Structured Application (KASA) Dr. Geoffrey Wu - Deputy Director (acting), OLDP, OPQ, CDER, FDA
ROOM 2	» 15:30 – 16:00	● Lifecycle Management of Human Gene Therapy Products: A CBER Perspective Dr. Y Nguyen - CMC Reviewer for Gene Therapy Products, FDA
ROOM 1	» 16:00 – 17:30	● TOWNHALL DISCUSSION 1ST DAY

DAY 2

CHOOSE YOUR
SESSION
BEFORE ENTERING

ONLINE EVENT

- 2| Halldays (12:30 - 17:30 UTC)
- 1| Keynote & Q&A to kick-off the day (45min + 10min respectively)
- 2| Sc. Tracks in parallel, with 4 talks & Q&A (15min + 10min respectively)
- 1| Townhall wrap-up session at end of each day

ROOM 1 >> 12:25 – 12:30 ● CHECK IN 2ND DAY

ROOM 1 >> 12:30 – 13:30 ● KEYNOTE 2ND DAY

Compliance in the Age of Lockdowns & Disruptions: Different Perspectives on Future Business Continuity, Regulatory Agility & Oversight
Dr. Ajaz Hussain – Independent Consultant, Former Deputy Director, OPS/CDER FDA

Sc. TRACK #3

Risk & Knowledge Management in Pharma and BioPharma Operations (II)

ROOM 1 >> 13:30 – 14:00 ● A Practical Approach of ICH Q9 and GAMP for the Upcoming Computer Software Assurance Model
Flavio Kawakami - Founder and Consultant, Doctorbit Consulting

ROOM 1 >> 14:00 – 14:30 ● Implementation of iRISK™ in GSK R&D Vaccines
Hervé Gressard - Head Global Project Statistics CMC Technical R&D, GSK

14:30 – 14:45 ● BIO BREAK

ROOM 1 >> 14:45 – 15:15 ● Digital Transformation in Biomanufacturing: a Risk and Compliance Perspective
Dr. Francisca Gouveia - Senior Process Expert, MS&T, Novartis BioProduction Operations Huningue.

ROOM 1 >> 15:15 – 15:45 ● Risk Management of Suppliers and Materials for Biologics and Small Molecule Products
Dr. Lucy Cabral – Global Head of Supplier Quality and Product Validity, Roche-Genentech Group

Sc. TRACK #4

Beyond Compliance: Developing A-Class Behaviors

ROOM 2 >> 13:30 – 14:00 ● Quality, Safety and Efficacy in the Age of Accelerated Timelines. Perspectives on the Development of Biologics and Vaccines
Dr. António Moreira - Vice-Provost, University of Maryland UMBC

ROOM 2 >> 14:00 – 14:30 ● A Case Study of QRM in R&D - a Systematic Approach
Dr. Iris Ziegler - Director Development, Business Development & Production, Corden Pharma

14:30 – 14:45 ● BIO BREAK

ROOM 2 >> 14:45 – 15:15 ● Case-Study: How to Implement QRM in a Global Organization to Enable Quality Oversight
Dr. Audrey Schwebel - Risk & Consumer voice Global QA manager, P&G Health International

ROOM 2 >> 15:15 – 15:45 ● Advancing the Roche Raw Material Understanding and Variability Control Strategy
Dr. Stefan Yohe - Principal Materials Science Engineer, Genentech, A Member of the Roche Group

ROOM 1 >> 15:45 – 17:15 ● TOWNHALL DISCUSSION 2ST DAY

ROOM 1 >> 17:15 – 17:30 ● CLOSING WITH WRAP UP BY SCIENTIFIC COMMITTEE

VIRTUAL ENVIRONMENT CONFERENCE

The official conference language will be in english.

FULL CONFERENCE PASS

99€ (VAT included)

WHAT'S INCLUDED IN THE REGISTRATION?

- | 2 halfdays full conference Pass
- | Access to our Virtual Event Platform
- | All Event Materials

JOIN US FIGHTING THE PANDEMIC

By purchasing a ticket, you are joining us in the fight against the SARS-CoV-2 Pandemic.

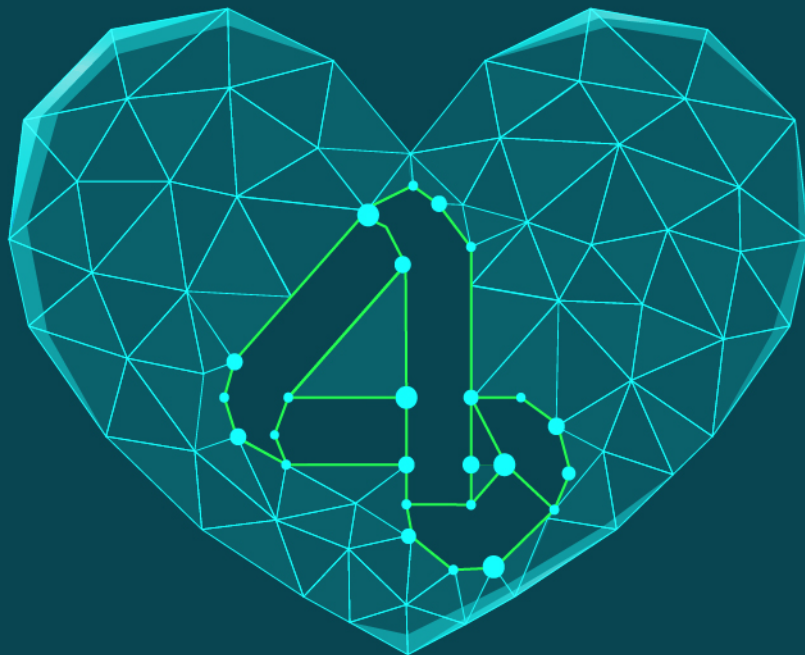
All the revenue of the Conference **will be donated** to COmVIDas, an association that provides support to the elderly who were affected by the pandemic.



COMVIDAS

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WWW.PORTUGALCOMVIDAS.COM



More info and registration
www.qrmsummit.com

Thank You

QRM SUMMIT  **2021**
RISK & LIFECYCLE MANAGEMENT

CONTACT:

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More info and registration
www.qrmsummit.com

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