# Junichi Koga

IABS Board Member

Provost, SCARDA, AMED, Japan

Dr. Junichi Koga currently serves as the Provost, Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) in Japan Agency for Medical Research and Development (AMED) since March 2022.

Junichi Koga was Global Head of Research & Development at Daiichi Sankyo Co., Ltd., and also held the position of President, Daiichi Sankyo Pharma Development, Daiichi Sankyo, Inc. As Head of Global R&D, Dr. Koga co-chaired the Global Executive Meeting of R&D (GEMRAD), the top decision-making body in R&D, and oversaw the R&D organization in the Americas, Europe, Japan and Asia. In his role as President of Daiichi Sankyo Pharma Development, Dr. Koga oversaw the R&D organization at Daiichi Sankyo, Inc.

Dr. Koga joined Daiichi Sankyo, Co., Ltd. in 2009 to lead the Pharmaceutical Technology Unit on Biotechnology, and he quickly established internal biologics capabilities. He has held several leadership positions in the R&D unit in charge of biologics functions over the years, and most recently held the position of Senior Executive Officer and Head of the R&D Division from 2019 to 2022. Before joining Daiichi Sankyo, Dr. Koga was Head of the R&D Division at Amgen Japan. Prior to Amgen, he held the position of Research Unit Head and Director of the Board for JCR Pharmaceuticals, Co., Ltd.

Dr. Koga has served as Biopharmaceutical Committee Chair of the Japan Pharmaceutical Manufacturers Association (JPMA) from 2016 to 2019, Board member of the Japan Bioindustry Association (JBA) from 2017 to 2021, Honorable member of the board, Japan Biologics Forum, and Program Supervisor / Program Officer of the AMED Projects from 2018 to 2021.

Dr. Koga was an Expert Working Group member of International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which is cosponsored by interested parties including government agencies of United State, European Union and Japan.

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Head of Global Analytical Strategy and Regulatory compliance, Sanofi

Since ICH 2 in 1992 representing JPMA, he was a very active participant in the ICH process and a key contributor to the development of the core ICH documents that are the basis of most of what interested parties do within Biotech CMC, namely Q5A (Viral Safety), Q5B (Genetic Stability), Q5C (Product Stability), Q5D (Cell Substrate), Q5E (Comparability) and Q6B (Characterization and Specifications), and also Common Technical Document and Q9, Q10. Q11 series.

Dr. Koga received his Ph.D. in Medical Science from the Kyoto Prefectural University of Medicine, Faculty of Microbiology, and his Bachelor's degree in Agriculture from the Kyoto University, Faculty of Agriculture. He, being as a research fellow, engaged in clinical virology at University of Alabama at Birmingham from 1984 to 1986.