



Dr. Junko Sato is the Director for Office of International Cooperation, Pharmaceuticals and Medical Devices Agency (PMDA).

She started her job at Jikei University, School of Medicine as an instructor. She was involved in the education and the research. In 1997, she gained her doctoral degree from Jikei University. Next year, she joined Office of New Drug, Pharmaceutical and Medical Devices Evaluation Center (PMDEC), and started to work in regulatory agency. She became a review director in Office of New Drug I in 2004 and moved to Office of Safety as a Director for Risk Management in Office of Safety in 2009 to establish a new risk management system through life cycle of drugs. During the period, she worked at US.FDA as a guest reviewer from September 2002 to March 2003. From May 2012 to April 2014, she was dispatched to EMA as the MHLW/PMDA Liaison. She enhanced collaboration between EMA and MHLW/PMDA and got huge success as the liaison. She is a Group Leader of Paediatric Working Group in PMDA and also a member of Regulatory Affairs Committee of Japanese Society of Paediatrics.

She contributes some global harmonization, for example, ICH-E2C(R2) as the co-rapporteur, E2E, E2F, M5, and also CIOMS VII and IX. In 2007 and 2008, she contributed APEC workshops held in Thailand to share current regulation and our consideration of US, Canada and Japan with Asian-Pacific Countries. She made some lectures and facilitated small group discussion. She gained grate success at the workshop. She also contributes many DIA activities. She received DIA Outstanding Service Award 2010.