NEW YORK PHARMA FORUM

FRIDAY, JUNE 22, 2007

(Lunch Program)

TOPIC: **Updates on Clinical Trials, NDA Review and Post Market Activities in Japan: MHLW's Efforts to Deliver Safe and Effective Drugs**

SPEAKER: **Dr. Tatsuo Kurokawa**, Councilor for Pharmaceuticals and Food Safety, Minister's Secretariat, Ministry of Health, Labour and Welfare, Japan

Dr. Tatsuo Kurokawa, who is in charge of drug approvals and oversees Pharmaceuticals and Medical Devices Agency (PMDA), will be making a trip to NY to address NYPF members with updates on clinical trials, NDA review and post market activities in Japan. He will talk about the recent changes in policies such as a five-year strategy for innovative pharmaceutical and medical devices and the Ministry's efforts in speeding drug approvals and their impacts on the industry.

Throughout his career, Dr. Kurokawa has been involved in drug safety. Before he was appointed to the current position in 2004, he worked at the Organization for Pharmaceutical Safety and Research (currently Pharmaceuticals and Medical Devices Agency) as Councilor, following his position as Director of the Safety Division of MHLW for 2000 - 2003. He was head of Office for Promotion and Appropriate Use of Drugs for 1994-1996, where he was responsible for pharmacovigilance. He also participated in ICH activities as Japan's ICH coordinator, then as the Japanese representative to the ICH Steering Committee. His service continued from the very first preparation meeting for ICH in 1990 to ICH-3, in Yokohama in 1996. Dr. Kurokawa also worked for the WHO at their headquarters in Geneva, and at their Western Pacific Regional Office in Manila. On several occasions, he served as a member of the Japanese Delegation to the World Health Assembly.