Reminder !

NEW YORK PHARMA FORUM PROGRAM
MONDAY, JUNE 7, 1999

SPEAKERS and TOPICS:

Dr. Koichi Shudo, Director General
Pharmaceutical and Medical Devices Evaluation Center
National Institute of Health Sciences
"New Directions of Japan's Pharmaceutical and Medical Devices Evaluation Center (PMDEC)"

Dr. Shunsuke Ono, Chief Reviewer
Pharmaceutical and Medical Devices Evaluation Center
National Institute of Health Sciences
"MHW Strategies for the Implementation of J-GCPs: Success and Challenges"

Dr. Hajime Inoue, GCP Inspector
Pharmaceutical and Medical Devices Evaluation Center
National Institute of Health Sciences
"MHW GCP Inspections outside Japan"

For this special program, three key officials who play the major roles in Japan's new drug evaluation system will give an update on what's happening with drug evaluation and approval policies in Japan. This is a rare opportunity to hear from MHW insiders on these important issues.

Dr. Shudo will address MHW's organizational structure, the pathways for review and approval of a submission, and MHW's opinion on the use of foreign data to support registrations in Japan.

Dr. Ono will provide an update on issues regarding J-GCPs, such as how hospitals and investigator sites involved in clinical trials are adapting to J-GCPs, the role of the Study Coordinator and J-GCP training. He will also explain MHW's expectations of the sponsor companies' quality assurance group and their audits and source data verification process.

Dr. Inoue will give an overview on how MHW's inspectors conduct inspections at sponsor companies and investigator sites inside and outside of Japan. He will also explain what sponsors should do to prepare for an inspection.