

## Outline of 17<sup>th</sup> SAM & GMP Meeting

On August 8, the Japan Affiliate Regulatory Committee's 17<sup>th</sup> SAM & GMP Meeting was held at Taiho Pharmaceutical Co., Ltd.'s Tokushima Plant, under the theme of "Pharmaceuticals' Quality and Risk Management."

The program included a plant tour as well as lecture. The nearly 100 attending the event offered ample evidence of the high level of interest in the chosen theme of the Meeting.

The program called for invited speakers Yutaka Ueno, Plant Manager, Taiho Pharmaceutical Co., Ltd., Taiichi Mizuta, formerly of Shionogi & Co., Ltd. and Denka Seiken Co., Ltd., and Tadatsugu Tanino, General Manager, Industrial Technology Laboratories, Shionogi & Co., Ltd., as well as others, to speak on GMP philosophy, risk management, and quality systems.

Explanations were given on ICH Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality System), and practical as well as interesting case studies of pharmaceutical development were introduced.

Participants gained a good understanding of the topics, with the goals of the Meeting being satisfactorily achieved.

During the plant tour, the recently completed solid dosage facility was introduced. This included its aseismic features, latest manufacturing technologies adopted, and other matters of interest for the tour members.

A very active Q&A session followed before the Meeting was formally closed.