Japan Affiliate’s GAMP® 5 Seminar

ISPE Japan Affiliate’s GAMP® 5 Seminar, titled “GAMP® 5: Updated Guidance on Computer System Validation (CSV)”, was held on 13th May in Tokyo, Japan. Sion Wyn, Director, Conformity Ltd. and editor of “GAMP Guide for Validation of Automated Systems”, was invited to be the lecturer. With over 250 participants, attendance at the event exceeded expectations, clearly indicating the heightened interest in this topic area. The seminar was also attended by representatives from Japan’s Ministry of Health, Labour and Welfare (Pharmaceutical and Food Safety Bureau), and various pharmaceutical related organizations such as The Federation of Pharmaceutical Manufacturers’ Association of Japan (FPMAJ) and the Japan Pharmaceutical Manufacturers Association (JPMA). The participants contributed actively during the Question & Answer session, demonstrating a good understanding of the background and main concepts of GAMP® 5.