

## Welcome Greeting

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Since the release of first US FDA guidance on bioanalytical method validation (BMV) in 2001, EMA/MHLW guidelines were issued in 2011 and 2013/2014 and pharmaceutical industry BMV has been implemented in accordance with these guidance/guidelines in each respective region and country. With the release of the draft ICH M10 guideline in 2019, we are now getting into a new age of international harmonization of BMV and, in fact, the 11th JBF symposium will be held under the theme of “The beginning of a new era”.

With the recent changes in drug development environment and modalities, the technology and knowledge required for bioanalysts to understand are drastically changing. In this symposium, the invited domestic and overseas speakers will initiate a wide range of discussions on various bioanalytical topics such as BMV guidelines and metabolite analyses, as well as sharing the latest information on the new modalities and the artificial intelligence. We also plan to provide a new type of closed session for exchanging information and opinions with researchers from other companies. Our sessions have been gaining in popularity every year by covering topics such as the achievements/recommendations of JBF discussion groups, the poster sessions and the basic courses. We are looking forward to fruitful discussions among all attendees in the symposium.