

Closing Remarks



8th JBF Symposium
9 February 2017

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1. Brief introduction

2. Recent activities

JBF Scope and Mission



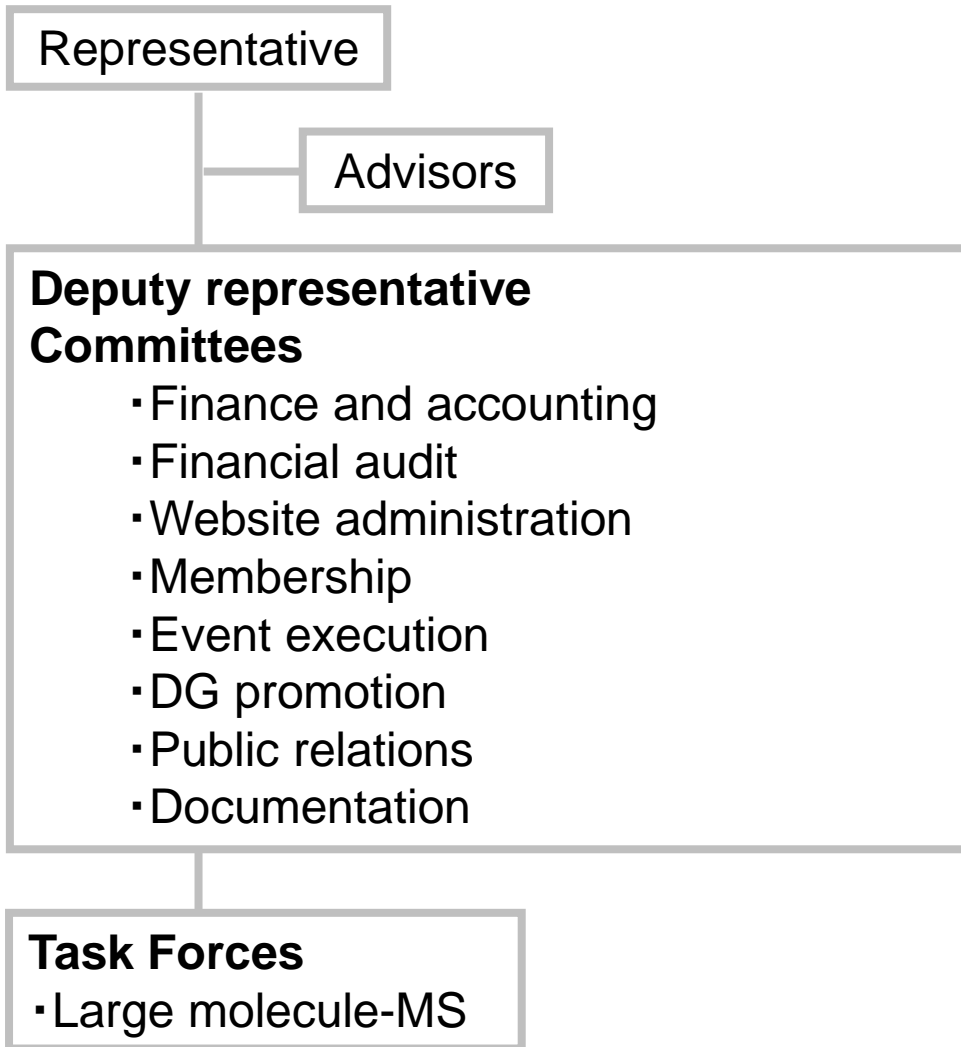
■ Scope: Regulated Bioanalysis

- Small molecule drugs (e.g. LC-MS/MS)
- Large molecule drugs (e.g. LBA)
- Biomarkers (endogenous substances)

■ Mission

- Facilitate a discussion on regulated bioanalysis in Japan
- Interact with Japanese regulators in the field of bioanalysis
- Represent Japan in worldwide bioanalysis community

Organogram



- JBF partner
- DG member
- DG supporter



Corporate Members



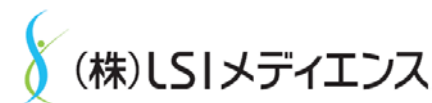
- グラクソスミスクライン (株)
- 日本ジェネリック (株)
- 武田薬品工業 (株)
- あすか製薬 (株)
- エーザイ (株)
- 興和 (株)
- 旭化成ファーマ (株)
- 沢井製薬 (株)
- 小野薬品工業 (株)
- 田辺三菱製薬 (株)
- 大日本住友製薬 (株)
- EAファーマ (株)
- 千寿製薬 (株)
- 第一三共 (株)
- JCRファーマ (株)
- 日本たばこ産業 (株)
- 東和薬品 (株)
- 大塚製薬 (株)
- 味の素 (株)

申し込み順 2017/01/10 現在

Supporting Members 1/2



- 株式会社エービー・サイエックス
- サーモフィッシャーサイエンティフィック(株)
- 株式会社島津製作所
- 株式会社住化分析センター
- 日本ウォーターズ株式会社
- 株式会社新日本科学
- 株式会社LSIメディエンス



Supporting Members 2/2



- バイオタージ・ジャパン株式会社
- シミックファーマサイエンス株式会社
- 株式会社ネモト・サイエンス
- 株式会社日本医学臨床検査研究所
- エルガ・ラボウォーター
- 株式会社島津テクノロジー
- 株式会社東レリサーチセンター
- PPC株式会社
- 株式会社サンプラネット
- 株式会社スクラム

Contents



1. Brief introduction

2. Recent activities

Discussion group



- Started in 2013
- One DG has one selected topic and several (up to 10) experts in JP industry (including pharma and CRO)
- Discussion and cross-industry survey
- Outcome is presented within a year (JBF symposium)
- Several DG per year
- JBF DG members are accountable for their outcome

Recent publication and presentation



- Niwa, Makoto, et al. "Survey on the tiered approach for Japanese bioanalysts operated by Japan bioanalysis forum DG2014-09." *Bioanalysis* 8(2) (2016): 93-98.
- Nakamura, Takahiro. "7th Japan Bioanalysis Forum symposium: regulated bioanalysis, to a new stage." *Bioanalysis* 8 (20) (2016): 2097-2102.
- Nanba, Eitaro, et al. "Survey results on the use of microsampling and the issues involved in its use (Survey conducted by the Discussion Group DG2015-17 of Japan Bioanalysis Forum)" 43rd JSOT Annual Meeting in Nagoya, Japan on 29 Jun-1 Jul 2016
- Nanba, Eitaro. "Application of microsampling in the Japanese pharmaceutical industry and the technical issues involved in its use" 31st JSSX Annual Meeting in Matsumoto, Japan on 13-15 Oct 2016
- Junji Komaba "Regulatory challenges related to bioanalysis in global filings: From a JBF perspectives" AAPS Annual Meeting and Exposition in Denver, CO, USA on 13-17 Nov 2016

Recent publication and presentation



- Yoshiaki Ohtsu “Scientific Validation: Feedback from JBF Discussion Group” 9th EBF Open Symposium in Barcelona, Spain on 16-18 Nov 2016
- Harue Igarashi et al. “Recommendations from JBF discussion group, DG2013-01 on the preparation of calibration standards and QC samples for bioanalysis of small molecular drugs” 9th EBF Open Symposium in Barcelona, Spain on 16-18 Nov 2016
- Akira Wakamatsu et al. “Recommendation for alternative matrix in the quantitative assay method of endogenous substance in biological samples - Selection and evaluation of appropriate matrix - by JBF discussion group (DG2015-15)” 9th EBF Open Symposium in Barcelona, Spain on 16-18 Nov 2016

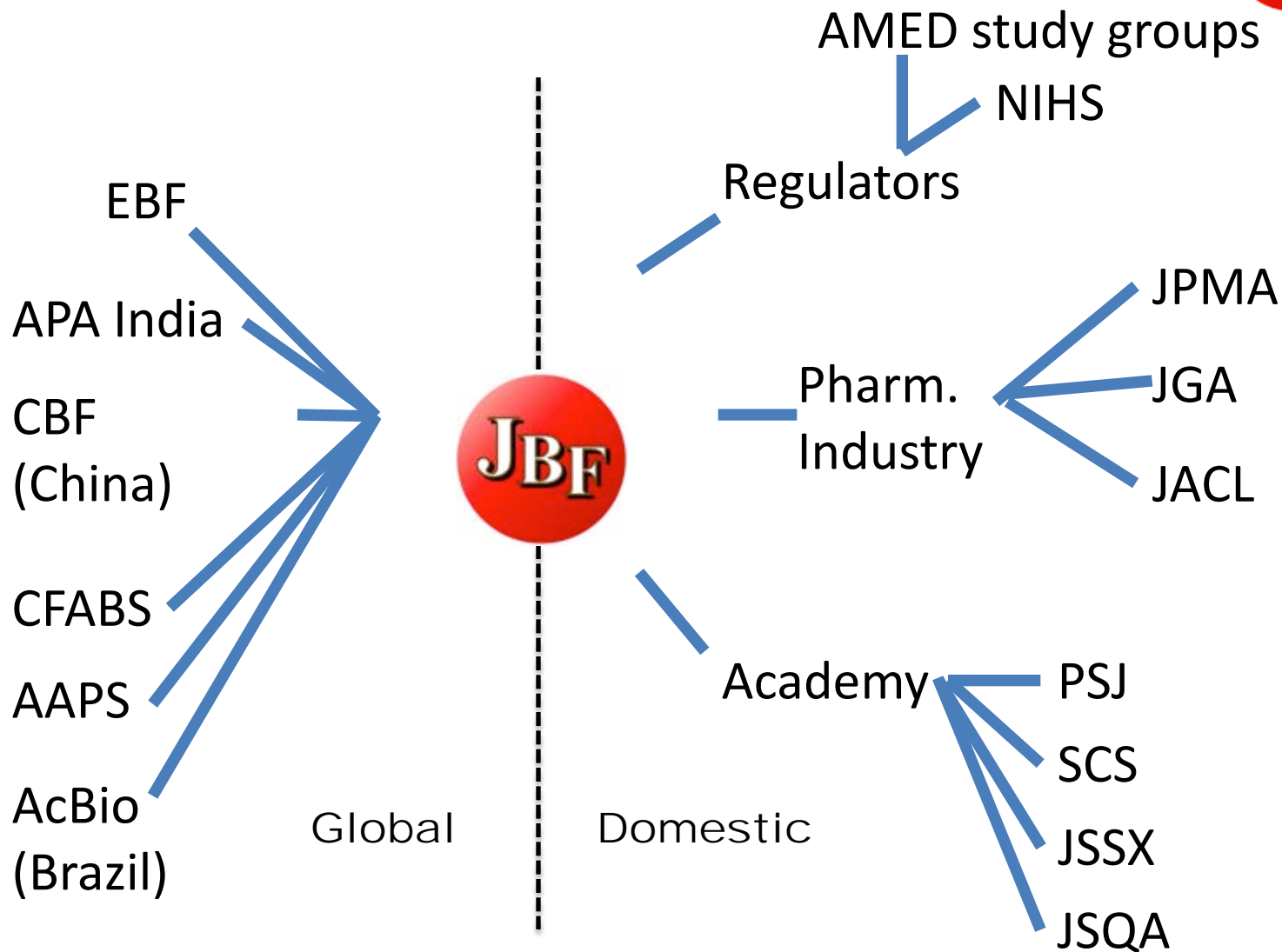
Contribution to JPN regulatory agencies



- BMV Study Group (large molecule-MS, biomarker)
- Study group for ICH S3A Q&A ¹⁾
- Study group for ICH M10 ¹⁾

1) Note that JBF is not one of ICH members.

Relationship with other organizations





Thank you for your participation

See you at next JBF symposium

