



GBC-HT 全般の進捗状況 Overview of GBC Discussion

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HT-Task Force in JBF



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- Japanese GBC-HT members
- HT Supporters in Japan
- How often TCs have been held?
- Information of A10 (New Frontiers) and A11 (Biomarkers)



Japanese GBC-HT members

A01 – A11

Team		HT member from Japan
A01	Scope and regulations	Tomoko Arakawa (Pfizer)
A02	Tiered approaches for method validation	Tomoki Yoneyama (Takeda)
A03	Method Transfer, partial/cross validation	Masanari Mabuchi (Mitsubishi Tanabe)
A04	Reference standards and reagents	Takahiko Osumi (Otsuka)
A05	Sample Management	Harue Igarashi (GSK)
A06	Stability	Yoshiaki Ohtsu (Astellas)
A07	Repeat analysis and ISR	Masahiro Taniguchi (SCAS)
A08	Documentation	Hisanori Hara (Novartis)
A09	Analytical Instrument Qualification	Hidehisa Tachiki (Towa)
A10	New Frontiers	Keiko Nakai (MCM)
A11	Biomarkers	Yuichi Yamamoto (Pfizer)



Japanese GBC-HT members

L01 – L06, S01-S03

Team		HT member from Japan
L01	Large molecule specific run acceptance	Katsuhiko Yamamoto (Kyowa Kirin)
L02	Large molecule specific assay operation	Yoshiyuki Minamide (Shimadzu TR)
L03	Assay formats	Yoshitaka Taniguchi (TRC)
L04	Reagents and their stability - Link with tiered approach -	Mami Imazato (Novartis)
L05	Automation practices in LM bioanalysis	Takahiro Nakamura (SNBL)
L06	Immunogenicity (Effect on PK)	Kazuhiko Sonehara (SCAS)
S01	Small molecule specific run acceptance	Noriko Inoue (JCL)
S02	Small molecule specific assay operation	Kazutaka Togashi (SCAS)
S03	Chromatographic Run Quality Assessment	Junji Komaba (Ono)



HT Supporters in Japan (1)

- Each Japanese HT member has knowledge and experiences regarding to the own HT topic, however the Japanese scientific community for bioanalysis would be very helpful...
 - To confirm whether his/her opinion is common or not among Japanese bioanalysts
 - To get information about unfamiliar topics in HT discussions
- HT TF asked to participate to the HT supporters group after the 1st JBF symposium in August 2011



HT Supporters in Japan (2)

- In total, 38 bioanalysts have joined to the HT Supporters Community
 - 28 people from pharmaceutical companies
 - 10 people from CROs
- The community consists of 58 bioanalysts from 36 companies
- The mailing list has been already established since Jan 2012
- About 200 e-mailings were happened in the first one month



Telecon on HT discussions

Team		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
A01	Scope and regulations	15-Jun	29-Jun	27-Jul	24-Aug	14-Sep	5-Oct	19-Oct	2-Nov	23-Nov	12-Feb							
A02	Tiered approaches for method validation	16-Jun	18-Aug	11-Oct	30-Nov	12-Jan	9-Feb											
A03	Method Transfer, partial/cross validation	9-Jun	28-Jun	12-Jul	19-Jul	9-Aug	20-Sep	18-Oct	8-Nov	6-Dec	13-Dec	10-Jan	7-Feb	14-Feb	21-Feb			
A04	Reference standards and reagents	Stability test for reference standard solutions																
A05	Sample Management	22-Sep	10-Nov	12-Jan	2-Feb	23-Feb												
A06	Stability	27-Jun	14-Jul	29-Jul	8-Sep	6-Oct	3-Nov	3-Dec	15-Dec	22-Dec	26-Jan	9-Feb						
A07	Repeat analysis and ISR	19-Oct	20-Oct	9-Nov	1-Dec	15-Dec	20-Jan	16-Feb	23-Feb									
A08	Documentation	16-Sep	11-Oct	8-Nov	22-Nov	14-Dec	3-Jan	26-Jan	9-Feb	23-Feb								
A09	Analytical Instrument Qualification	6-Jul	3-Aug	7-Sep	5-Oct	2-Nov	1-Dec											
A10	New Frontiers																	
A11	Biomarkers																	
L01	Large molecule specific run acceptance	19-Aug	16-Sep	21-Oct	10-Nov	16-Dec	17-Jan	10-Feb	2-Mar									
L02	Large molecule specific assay operation	19-Aug	16-Sep	21-Oct	10-Nov	16-Dec	6-Jan	10-Feb										
L03	Assay formats	18-Jul	23-Sep	14-Oct	7-Nov	25-Nov	9-Dec	9-Jan	16-Jan	23-Jan	30-Jan							
L04	Reagents and their stability - Link with tiered approach	8-Jul	24-Aug	28-Sep	10-Nov	30-Nov	21-Dec	11-Jan	1-Feb	22-Feb								
L05	Automation practices in LM bioanalysis	-	-	1-Nov	17-Nov	12-Dec	17-Jan											
L06	Immunogenicity (Effect on PK)	-	-	22-Sep	27-Oct	17-Nov	15-Dec	19-Jan	16-Feb									
S01	Small molecule specific run acceptance	30-Aug	27-Sep	11-Oct	25-Oct	8-Nov	22-Nov	6-Dec	20-Dec	3-Jan	10-Jan	17-Jan	31-Jan	7-Feb	14-Feb	21-Feb	28-Feb	6-Mar
S02	Small molecule specific assay operation	4-Aug	16-Aug	31-Aug	29-Sep	3-Nov	21-Nov	16-Dec	11-Jan	18-Jan	25-Jan	1-Feb	15-Feb	22-Feb	29-Feb	7-Mar		
S03	Chromatographic Run Quality Assessment	Re-integration of chromatogram and LIMS																



A10 New Frontiers

- No TC has been held so far
- Sub-groups (3 or 4) will be organized
 - DBS & micro sampling → Nakai-san
 - AMS
 - LM new technologies
 - ICP-MS (Tentative)
- Please contact to JBF HT-TF (jbf.ht.2011@gmail.com) if you are interested in A10 discussion



A11 Biomarkers

- No TC has been held so far
- Wide topics would be expected

- Please contact to JBF HT-TF (jbf.ht.2011@gmail.com) if you are interested in A11 discussion



Thank you !

- JBF HT Taskforce (敬称略)
 - 五十嵐 春江 / グラクソ・スミスクライン株式会社
 - 大住 孝彦 / 大塚製薬株式会社
 - 中井 恵子 / 三菱化学メディエンス株式会社
 - 原 久典 / Novartis Pharma AG
 - 松丸 剛久 / 日本ベーリンガーインゲルハイム株式会社