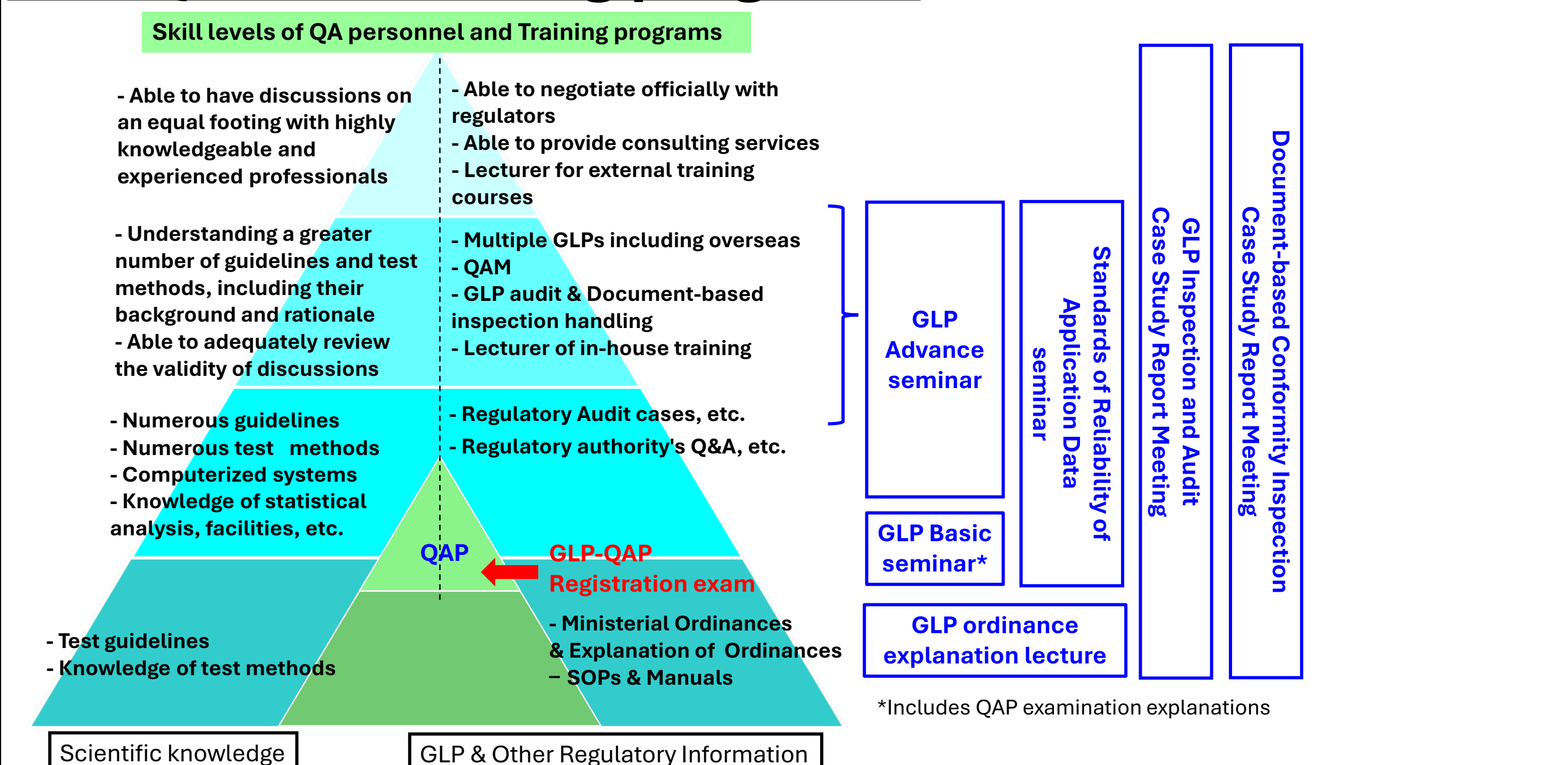


Introduction:

Development of QA personnel is one of 3 important elements for missions and visions of the Japan Society of Quality Assurance (JSQA). The JSQA GLP Division provides two different types of GLP related training programs (Seminar and GLP related Discussion in usual JSQA study group activities) for JSQA members. We share with you the details of our GLP seminar program and results of surveys held after each seminar. In addition, we would like to introduce how we try to improve the QA skills of our members through usual study group activities and how we share knowledge among the members through producing our biennial deliverables which reflect our usual activities.

1. JSQA GLP training programs



The GLP division provides several training courses according to the skills and purpose of its members.

Name of seminar	Target	Style of seminar	Topics	Contents
GLP ordinance explanation lecture	Beginners	OnDemand	Essences of the GLP ordinances	Lecture
GLP Basic seminar	Early career QA personnel (<3 years QA experience)	Onsite/ OnDemand (Alternately every year)	Basic knowledge and technique for GLP QA audit	Lecture Small group short discussions
GLP Advance seminar	Middle and High experienced QA personnel (>3 years QA experience)	Onsite	Topic following current GLP trends (e.g. Risk based approach and DI)	Lecture Group works and discussions

Differences in the style of seminars come from the contents of each seminar and reflect the most suitable way to improve the QA ability of JSQA members.

2. Selection of lecturers

Name of seminar	Lecturer	Candidate of new lecturer	Training for new lecturer	Issues in lecturer recruiting
GLP ordinance explanation lecture	- High experienced QA personnel - Beginners	Beginner members	Highly experienced lecturer acts as mentor for beginners.	No issues
GLP Basic seminar	- High experienced QA personnel	- Lecturer of the ordinance lecture - High motivated attendees	Attendees joining as support members experience all steps of preparation for the seminar and become new lecturers.	Candidates for new lecturer are limited due to being busy with their daily work.
GLP Advance seminar	- High experienced QA personnel	- High motivated attendees		

All lecturers serve for no compensation, but they repeatedly become lecturers because they can learn GLP deeply through lecturer actions.

On the other hand, finding and training new lecturers remains a somewhat difficult problem.

Conclusion:

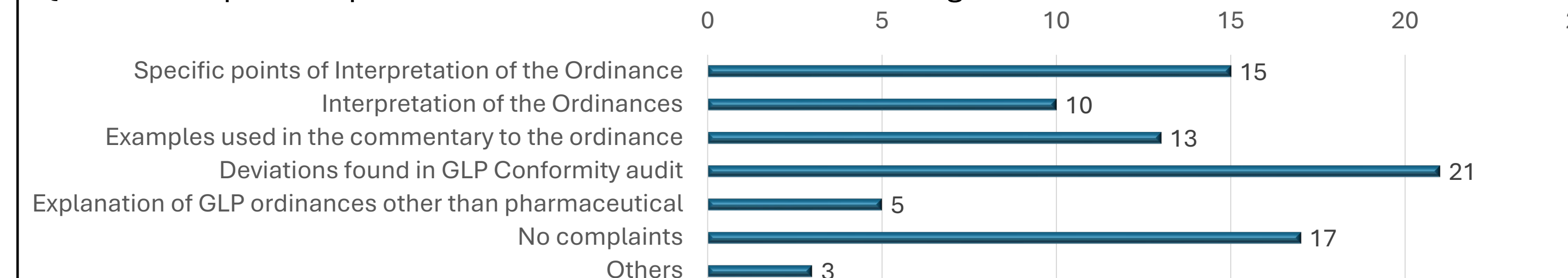
The JSQA GLP division provides several training courses according to the skills and purpose of its members. Attendees of the seminars wish to know cases and points of regulatory inspections and QAU audits. GLP division members share knowledge and information through questions & answers in usual study group activities and try to improve their daily QA activities.

Acknowledgements:

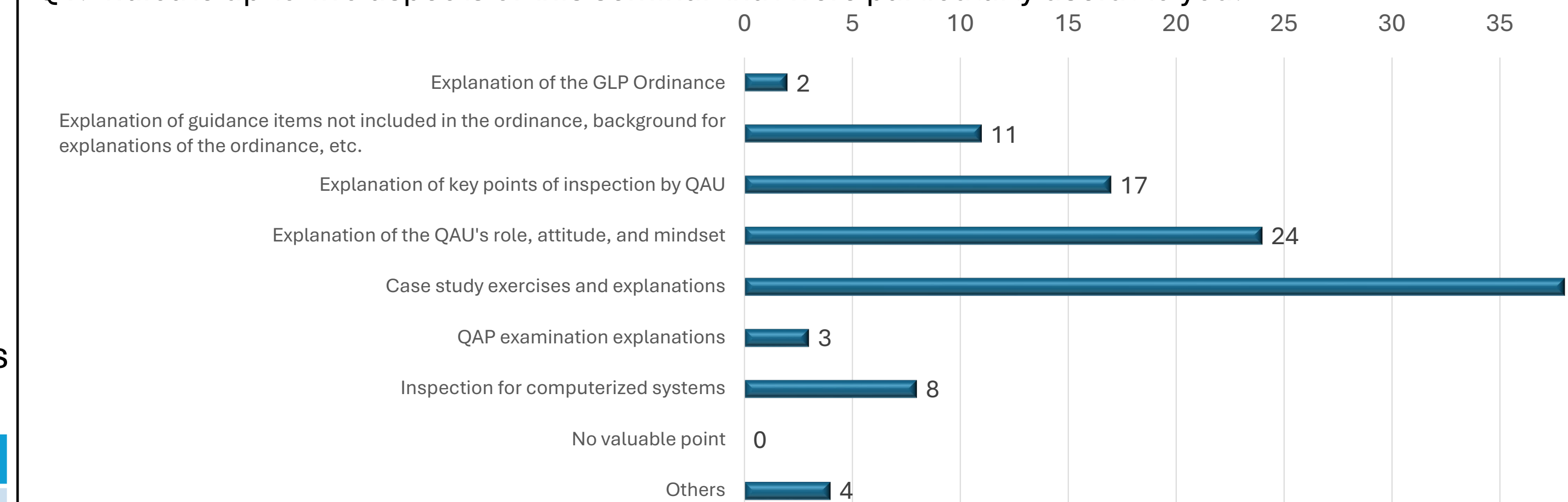
We thank the members of the GLP Training Committee and Ms. Ayami Fukuda very much for their cooperation in preparing this poster presentation.

3. Result of surveys held after seminar

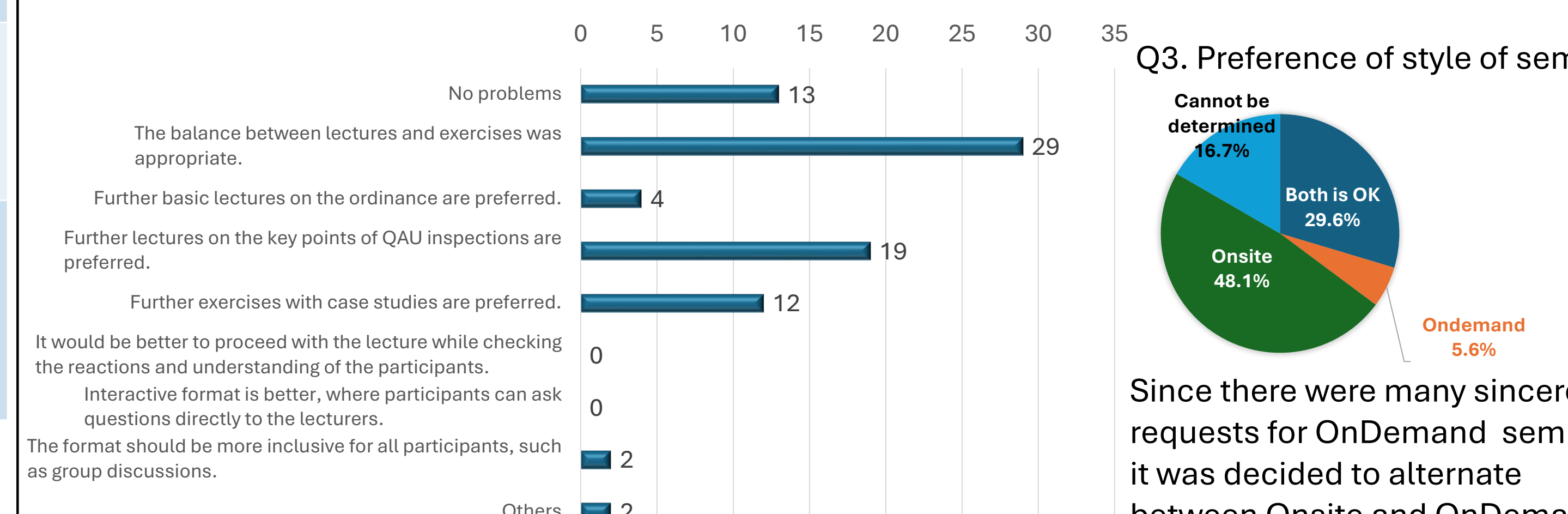
<GLP ordinance explanation lecture (Ondemand)>
Q. Indicate up to two points in this course that were "not enough" or "would have liked to hear more".



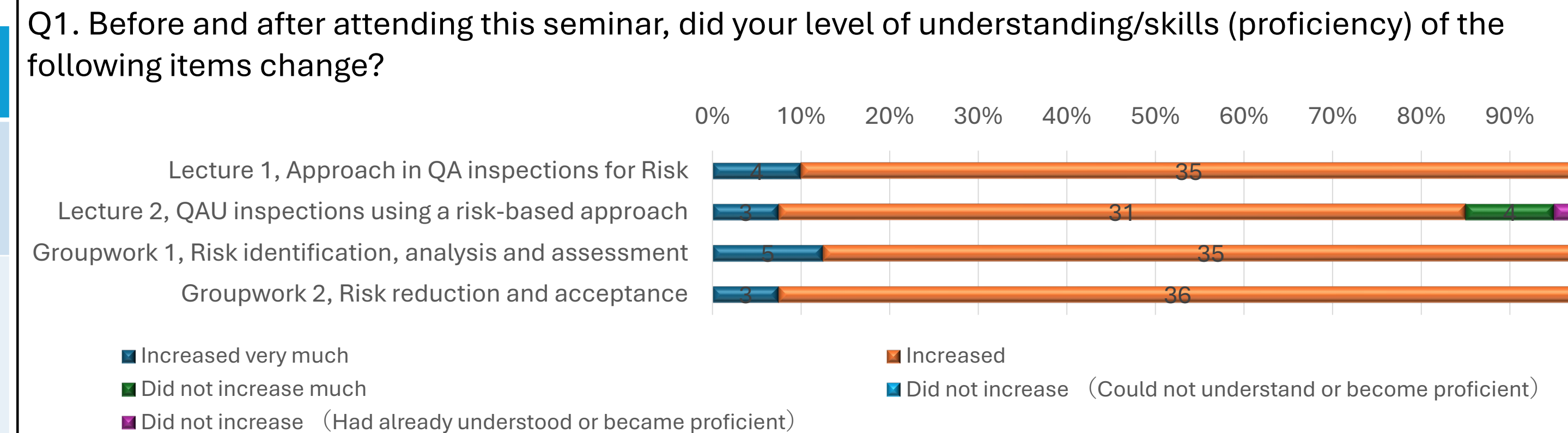
<GLP Basic seminar (Onsite)>
Q1. Indicate up to two aspects of this seminar that were particularly useful to you.



Q2. Select up to two comments regarding the style and content of this seminar.



<GLP Advance seminar (Onsite)>
Q1. Before and after attending this seminar, did your level of understanding/skills (proficiency) of the following items change?



Q2. Comments for Group works

It was interesting to hear various opinions from the participants having different backgrounds, however it was hard to summarize their opinions.

Levels of knowledge and experience are different depending on facilities and participants, therefore it needs to be grouped at similar levels.

Not enough time for group work. The discussion could have been smoother if the prerequisites for discussion were set in advance.

Negative comments regarding another person's opinion would quickly taint the harmonious atmosphere.

4. JSQA GLP division's study themes and members

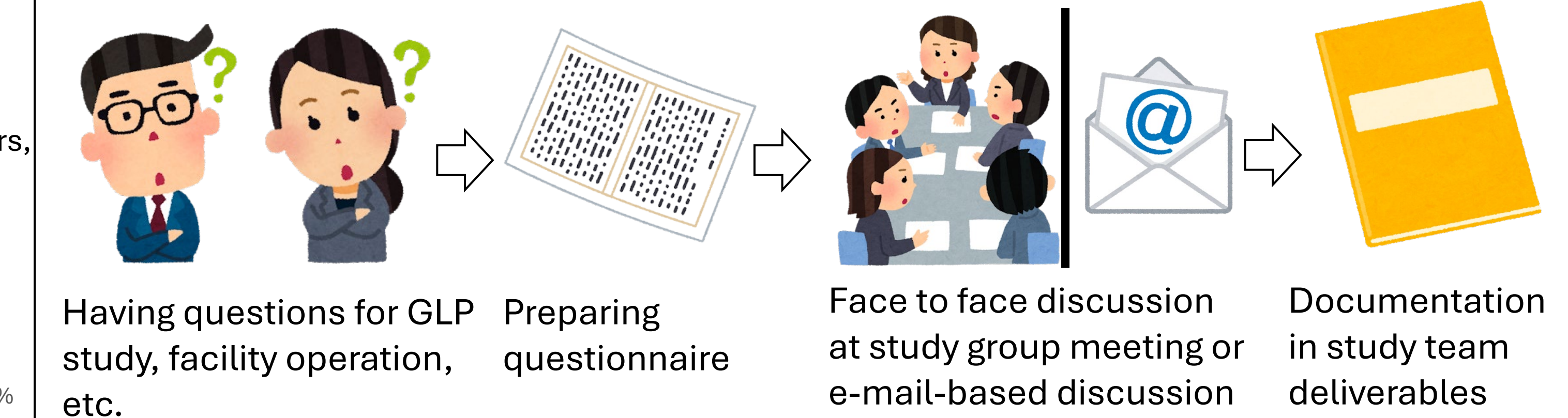
Study Group	Study theme	Member type
Group 1	GLP for Pharmaceutical, Agrochemical, Industrial chemical, Medical equipment and Regeneration medicine	
Group 2	"Standards of Reliability of Application Data" (e.g. Pharmacological study, ADME study, CMC, and etc.)	
Group 3	Computerized system	
Group 4	Cross-function issues on Non-clinical studies	
Group 5	Research integrity, Testing in academic facilities	
Data integrity	Discussion of Data Integrity issue cross-Study Group	
Global	Collaboration with overseas QA associations	

Many of GLP Division members are QA Personnel or Study Personnel of Pharmaceutical, Medical device, Agrochemical, Chemical companies and Contract Laboratories. Members of the GLP division chose the joining study group which reflected the opinions of the organizations they belonged to.

[As of July 1, 2024]

5. Knowledge and information sharing in usual study group activities

In usual study group activities (held every 1~2 months), some study teams share knowledge and information through questions & answers about GLP operations and QA activities to improve their daily QA activities. Some study teams document questionnaire activities on the study team's biennial deliverables.



Example of a Questionnaire

Questions/problems Description sheet (In meeting/E-mail)

In meeting or E-mail	E-mail
Questioner's Facility / Type of GLP	A Corp. / Agrochemical GLP
Questioner's name	XX
Title of Question	
Article of GLP ordinance	
Questions / Problems	
Background / Reference	
Respondent's Facility / Type of GLP	B Lab. / Agrochemical GLP
Respondent's name	
Response	
Other Opinions and/or Supplementary Information	
Questioner's conclusion and impression	

Discussion topics

- Deviation from a protocol in multisite study
- Confirmation of temperature during transportation of test substances
- Management of blank paper forms
- Using Microsoft 365 Excel in a GLP study and its validation
- Using electronic SOP
- Describing of unexpected events on the final report
- CSV inspection in PMDA GLP audit
- etc.