Introduction to the Group Exercise

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Introduction

What sort of a quality management system does the Japanese programme need?

You may like to consider:

- Many (probably most) QA systems are about procedures for controlling data (e.g. traceability) and documents (e.g. production, review & archiving) but
  - How is the 'correctness' of the data, including appropriateness of the errors, checked?
  - Who is responsible for this?
  - Who checks/controls how the data are used?
- As a team leader, how could you be confident in the data, models or other results produced by your group?
- If your organisation is committed to a code of ethics for its staff, could you implement it through a QM system?

Organisation of the exercise

Understanding the viewpoints of different organisations - “Role playing” in groups

- 1 groups is a regulator organisation:
  - Group 1: safety case review team
- 2 groups are implementers:
  - Group 2: safety case production team
  - Group 3: external project management team
- 2 groups are data producers
  - Group 4: research laboratory team
  - Group 4: field characterisation team

- 3 hours for team discussion & preparation
- 20 + 10 mins presentation and discussion

Allocation of participants to groups

Group 1	Group 2	Group 3
S. Masuda	H. Umeki	K. Hioki
H. Makino	S. Suzuki	Y. Ochi
M. Shibata	S. Muraoka	T. Miwa
K. Ono	T. Ebashi	S. Hirusawa
Regulator - SC review team	T. Fukusima	Implementer- project management team
	Implementer - SC production team	

Group 4	Group 5
W. Okazaki	Y. Ichikawa
N. Sugiyama	H. Osawa
O.Tochiyama	T. Semba
K. Kawano	K. Shimizu
Data producer - research lab team	Data producer - field char. team

The exercise

- For each group, consider all aspects of QC in **your organisation** e.g.:
  - What data production or handling (e.g. review) is involved?
  - Is this in-house or involving contractors / partner organisations?
  - How do you decide levels of QA for different actions?
  - How do you use and manage these data production, interpretation & documentation?
  - How do you manage development and use of models, e.g. to ensure limitations and assumptions are understood?
  - If QA is carried out by contractors, how do you audit their methodology?
  - How are safety case arguments developed, supported or reviewed?
  - Does staff training & development ensure sufficient consistency across the programme and over time?

Output

- Identify the major issues particular to your group's function (i.e. regulator, implementer, data producer)
- Identity approaches for dealing with these issues within your organisation:
  - What form will your measures take?
  - How will you implement them?
  - How can you ensure staff 'buy-in' to the process?
- How will these measures impact on your interaction with other organisations?
- How might QA systems or requirements of other organisations impact on your work?

Example: Code of Ethics for Scientists

- Rigour
  - Rigour, honesty and integrity

    Making sure you keep your own skills fresh, and encouraging others to do so, particularly if you are responsible for a team. Encouraging **strict adherence to scientific method** whatever the subject area, understanding how your results have been informed by the work of other scientists and acknowledging those factors which have influenced you. Careful and complete documentation of all work.
- Respect
  - Respect for life, the law and public good

    Ensuring that your work is lawful and justified. Minimising and justifying any adverse effect your work may have on people or the environment
- Responsibility
  - Responsible communication, listening and informing

    Communicating results and intentions honestly and accurately, and understanding that your work or its outputs will have an impact on society in its broadest sense.