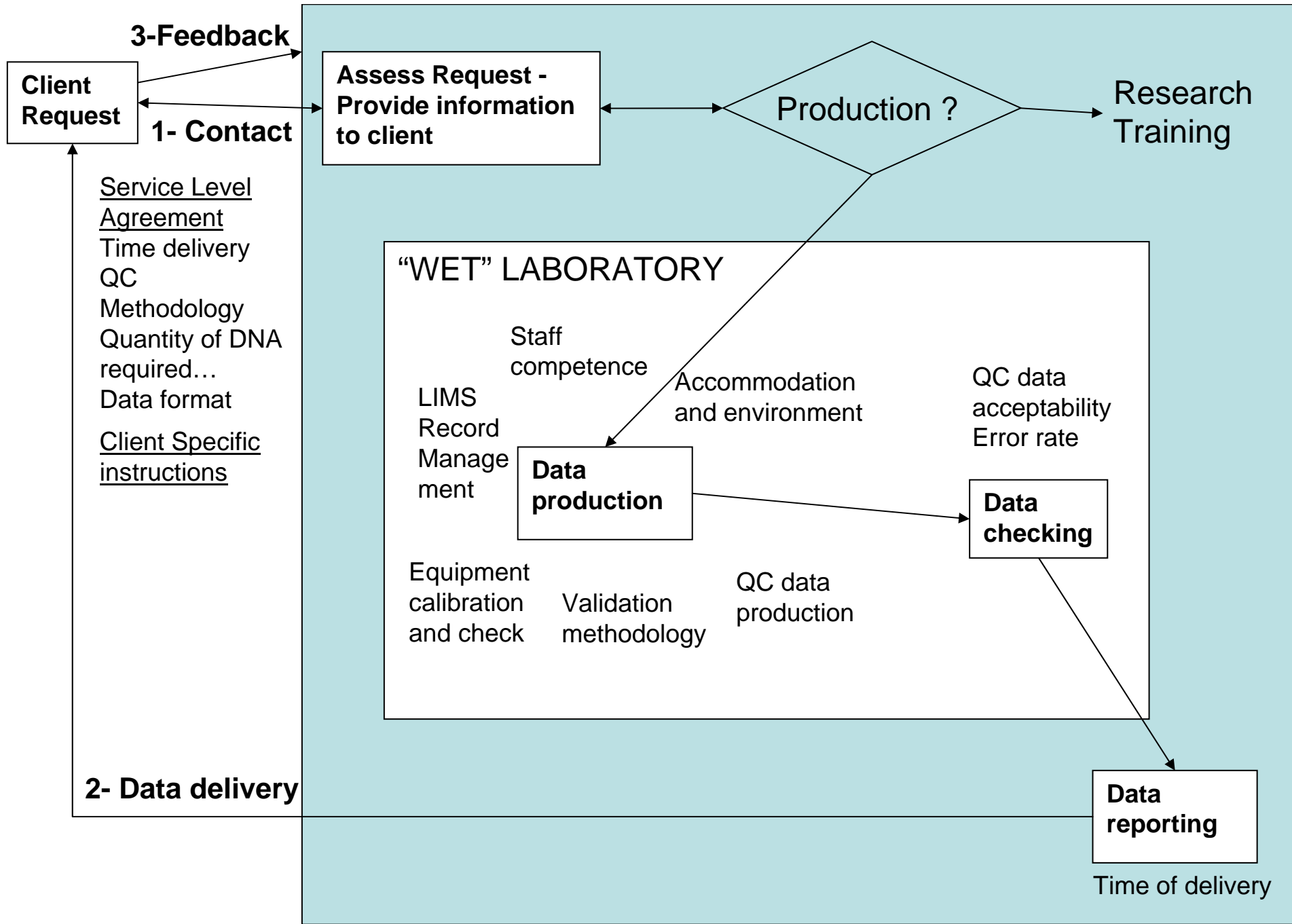


# GCP's Labs

- Defining the target of our analysis
  - Research
  - Service (sl)
  - Training
- The expectations
- A work flow
- Looking more in details

# A client would expect ...

- accuracy
- reproducibility-repeatability
- efficiency
- fit for the purpose
- completeness
- competence
  - track record
  - Infrastructure
  - trained staff



# More details....

- Following the “UK data quality standards”
  - General requirements for the competence of testing and calibration laboratories, BS EN ISO/IEC 17025:2005
  - <http://www.bsi-global.com/en/Shop/Publication-Detail/?pid=000000000030159674>
  - 118 £

# Section 4: Quality management

- 4.2. Management system, including
  - 4.2.2. 2 important responsibilities
    - Technical management: person or group of people who take the responsibility that the data be generated by the laboratory (high level of responsibility)
    - Quality manager: person responsible for the maintenance of the system, control documentation, audit system
- 4.3. Document control
  - People in the lab should have the more up-to-date documentation, plus a review process.
  - A document should be checked every once a year for example (and a max of 4 years for example)

# Section 4: Quality management

- 4.4. Exchange with the client
  - Contract view process in place
- 4.5. Subcontracting
  - Ex sequences, external quality control, or sharing of the work. Expectations ? relationships with other organisations ?
- 4.6. Purchasing services and supplies
  - Chemicals, reagents, softwares
  - If there are critical reagents, critical things to use. How do you know the quality ?
  - Need to be documented, traces in the procedure.
  - Decision making for critical reagents
- 4.7. + 4.8 Service for the customer
  - Feedback, complains should be written (complains should be official = constructive), try to encourage people to do thinks, even proactively.

# Section 4: Quality management

- 4.9 to 4.11 What to do when things go wrong, how to put a corrective action?
  - Stop the work, investigate what goes wrong, evaluate what goes wrong and inform the client
  - Loop of tests
  - Find through an audit, through a complain, through a lab work. Investigation and implementation of a corrective action.
  - Fundamental to the system: openness.
- 4.13 Control of the records
  - Chain of traceability. Be able to follow completely a sample.
- 4-14+4-15 Internal Audit
  - Monitoring how the system is working (use people within your organisation, which cannot audit their own work, but audit another part), see how you can improve the system. Performance indicators, performance system in place?

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# Section 5: Molecular Lab work

- 5.2. Competence of people
  - Training record:
    - experience, background, activities that person is authorised to carry out.
    - Organisational record of who has done what and specific activities.
    - Different stages of performance (traced back):
      - formation,
      - carry out with someone,
      - carryout alone,
      - being able to run and take responsibility.
  - How to monitor people's performances ?
    - Need to be within the working unit = not organised, nor linked formally with "human resources".

# Section 5: Molecular Lab work

- 5.3. Environmental conditions
  - Formalise the good housekeeping of the organisation in the laboratories
  - Including reviewing
  - How do we prevent resistance to transparency ?
  - Including the controls, problem to health
  - But safety is not in part of the quality system... (= if it not affecting the quality of the data, no issue)

# Section 5: Molecular Lab work

## 5.4. Test and methodology

- Setting the method
- Document, proofs that the methodology is working, production of validation data.
  - Organised as separate blocks, completed with a flow chart of organisation
  - House, manufacture, published papers ?
  - Make thing simple
  - Adjust the level of validation according to the novelty of the method
- Validation of the method: How do we prove that the methodology is fit for purpose?
  - either already published
  - cross controls
  - Accuracy, precision, sensitivity, robustness (times on the slightly different conditions), calibration...
    - Accuracy: are the results fitting your expectations ?
    - Precision: can you reproduce
    - Sensitivity: are you in the range of detection ?
    - Robustness: can it be transferred to another lab ? can it suffer different conditions ?
    - Calibration: are the results linear ? or can you
- Performance of the laboratory itself
  - risk control
  - Crop/Lab/Method
    - **test of consistence of the lab itself**
    - **test btw labs**
    - **test of methods**
- 5.4.7. Control of data
  - Importance of managing the data, validate the data transfer.
  - Is the data coming out the right data ?

# Section 5: Molecular Lab work

- 5.5. Equipment
  - Equipment record (see 5.5.5 of the thinks which need to be in the equipment record), checking the functionality of the equipment.
    - Pipettes, PCR, oven-incubators, etc...
- 5.6. Traceability
  - Should be related to national or international standards.
  - Need to think about the appropriate works
  - But for molecular work, the term of traceability is not always appropriate.
  - Reference standards, reference materials
  - Size standards for example

# Section 5: Molecular Lab work

- 5.7. Sampling
  - Representing of the sample
  - Sampling of the seeds.... General policy of making the material available. Lot.
- 5.8 Handling the tests items
  - Procedure to trace how the sample is received, stored and processed through the system.
  - Unique identity is crucial, bar coding scenario, in the lab
- 5.9. Quality control
  - What is appropriate to your technology?
  - Statistical control to monitor trends within the data.
  - Measure of a quantity for example, with a standard according to time, within 2 sd is ok, but outside of the 3 sd is a concern. Look for trends. Shewhart Chart. Real visual indication of the performance.
  - Keep quality control and qualibration separate.
- 5.10 Report the results
  - Accurate, clear, unambiguous way of reporting the results.

# Wrap-Up / GCP actions.... 1/6

- **LIMS:** Number of activities have already been supported (ICARDA, ICRISAT, open source community with WS) but still lack...
  - Stress the importance of LIMS to the management
  - Revive the importance of the open source community
  - Physical support of development (ICRISAT, CIP...)

# Wrap-Up / GCP actions.... 2/6

- **Raising capacity and staff concern**
  - Data analysis workshops,
    - practical,
    - middle level staff (people with hands on..).
  - With statisticians
  - People are knowing the complete workflow (no black box),
  - Staff costs are budgeted, require that a continuity should be made.... How to do ?

# Wrap-Up / GCP actions.... 3/6

- **GCP's help promoting quality management systems**
  - Raising awareness, aiming of quality at a management level
  - GCP Newsletter: summary of the workshop (T van Hinthum)
  - GCP website: which would indicate a road map of implementing a quality management workflow (D Galsworthy)
    - links with resource person
    - resource sites (CIP, ICRISAT, ILAC...),
    - resources documents (world wide standards for laboratory operations, EU documents, etc...).
  - Quality project workshop (T Metz and R Simon)
    - Held in a place where things are going well (Central Science Laboratory)
    - 30 people, at a decision level (lab management or above)
    - august 2008
  - Auditing/assessment/consultancy of D Galsworthy (and/or R Weekes), visit of 4 places (one week each) after the workshop.

# Wrap-Up / GCP actions.... 4/6

- **GCP requirements for the projects**  
(DMarshall, SKresovitch, JF Rami...)
  - Quality standards for running and following GCP work
  - Statistical set-up (involved at the beginning), 10% of the material reproduced on a separate, method used proven to be useful...
  - Need of the establishment of standards such as Miami standards (check if already exist)

# Wrap-Up / GCP actions.... 5/6

- **Quality indicators** (DMarshall, JFRami, Fvan Eijk in contact with THazelkamp) (March 2008)
  - Focus on SSR data for now
  - Each dataset in the GCP repository should have a status on quality
    - Test not possible
    - Possible and generated
  - R script (missing data, frequencies, etc...) available in the depository
  - Check for duplications/complementarity with existing projects (GenDiversity - M.Ruiz and JF. Rami)

# Wrap-Up / GCP actions.... 6/6

- **Reproducibility of data analysis/ Research** (R Simon, R Varshney, JC Glaszmann) (SP4, march 2008)
  - Standard analysis protocols
  - R script (opfweaf and sweaf) which exists to export different analyses (to openoffice)
  - Provided for Training material, comparison of analyses...
  - Microarray data + SSR analysis comparison