

Self-assessment tool of quality management for livestock gene banks

There are 37 questions ordered in 10 fields with a scoring system. The maximum score is 64 when you have addressed all issues needed for the full implementation of a QMS. Your total score shows where you stand. The field score tells you in which area you should prioritise your efforts.

FIELD	No	Work in Progress	Done
A- General gene bank management	Score 0	Score 1	Score 2
1. Does the gene bank have a formally documented organizational and management structure?			
2. Has the gene bank prepared formal cryoconservation goals?			
3. Has the gene bank undertaken a stakeholder analysis?			
4. Does the gene bank have a communication strategy and/or plan?			
5. Have the major risks to the effective long-term sustainability of the gene bank's operations been identified?			
6. Has a mitigation plan been prepared for all major risks?			
Score for FIELD A			
B- General quality management	No	Work in Progress	Done
7. Has the gene bank established a Quality Management System?			
8. Does the quality assurance involve a) formal certification or b) internal guidelines?			
9. Has the gene bank established a formal quality policy?			
10. Has the gene bank identified a specific employee to serve as the Quality Manager?			
11. Have the key processes for the gene bank's operations been identified?			
12. Are standard operating procedures documented for all key processes?			
13. Does the gene bank maintain a collection of relevant regulatory texts or references?			
14. Does the gene bank have an up-to-date system for management of its quality system documentation?			
Score for FIELD B			

C- Gene bank equipment	No	Work in Progress	Done
15. Have the critical equipments for operations of the gene bank been identified?			
16. Has the gene bank established standard operating procedures for regular maintenance of the critical equipments?			
17. Does the gene bank have a system to record when critical equipment undergoes controls, routine maintenance and/or calibration?			
Score for FIELD C			
D- Gene bank personnel	No	Work in Progress	Done
18. Have the key personnel of the gene bank been identified?			
19. Does the bank have a gene bank manager (i.e. a person who is responsible for overseeing all aspects of the gene bank)?			
20. Do all key personnel have a formal job description?			
21. Does the gene bank have an employee training programme?			
Score for FIELD D			
E- Genetic material database	No	Work in Progress	Done
22. Does the gene bank have a database system to record and trace the stored material?			
23. Is access to the database restricted for writing?			
24. Is the database backed up according to a regular schedule?			
Score for FIELD E			
F- Genetic material acquisition	No	Work in Progress	Done
25. Are formal contracts (such as Material Acquisition/Transfer Agreements) used when exchanging material from/to the gene bank?			
Score for FIELD F			

G-Material collection (for those gene banks that collect germplasm)	No	Work in Progress	Done
26. Does the gene bank follow standard operating procedures for processing of and freezing of materials?			
27. Does the gene bank have a quality control system for each collected sample of material?			
28. Does the gene bank use a labelling procedure that uniquely identifies each unit of material in the gene bank?			
Score for FIELD G			
H- Introduction of previously processed material (if relevant)	No	Work in Progress	Done
29. Is there a specific policy for receiving genetic material for the bank?			
30. Does the bank have a specific area dedicated to receiving incoming genetic material from outside sources?			
31. Is there a system to ensure quality of material collected by other providers?			
32. Is there a set of required quality control tests to be performed on all material from outside sources prior to being stored?			
Score for FIELD H			
I- Material storage	No	Work in Progress	Done
33. Is access to the storage area restricted?			
34. Does the gene bank have a system to record the entry of persons into the storage area?			
35. Does the gene bank have a system to store separately different types of material?			
Score for FIELD I			
J- Material distribution	No	Work in Progress	Done
36. Does the gene bank have a formal policy and procedure for providing access to stored samples for use by other persons or organizations?			
37. Does the gene bank have a standard operating procedure of preparing and shipping samples for distribution to users?			
Score for Field J			
TOTAL SCORE			