

Summary of external evaluation

ASSISTANCE PUBLIQUE - HÔPITAUX DE PARIS (AP-HP) - HÔPITAL EUROPÉEN GEORGES POMPIDOU
Platform Biological Resource Centre and Tumour Library (PRB HEGP)

Nature : Recertification audit according to the NF S 96 900 standard

Audit Date : 10/12/2020

Organization: Afnor Certification

1-Summary of the inspection

The NFS 96 900 management system demonstrates its maturity and pragmatic organisation, which has made it possible to secure practices and deal with the health crisis while continuing its activity in the service of research. The continuous improvement of the management system and its performance was noted during the audit.

The integration of the CRBEPiGENETEC platform and collaborative work with the DMU's BRC network are elements to be followed up next year.

2- Assessment of the findings:

- 5 strong points
- 14 areas for improvement
- 0 sensitive points
- 0 minor non-conformity
- 0 major non-conformity

Type	Wording of the finding	Process	Site concerned
Strong point	Work is underway with the federation of the Institute CRBs (Cochin, Necker, HEGP) to find points of synergy between the three platforms and thus offer an improved service to patients (validity and withdrawal of consent) or clients (one-stop shop) in order to meet a need for simplification and transparency. This work should lead to process changes to be seen in the coming years	Steering and strategy	HEGP
Strong point	Management is present at the Management Review, showing its leadership	Steering and strategy	HEGP
Strong point	The evaluation of stakeholder satisfaction is carried out via surveys and interviews. The areas for improvement are then the subject of effective system improvement actions	Continuous improvement	HEGP
Strong point	A risk analysis for the manipulators and for the samples was carried out when handling studies with samples potentially contaminated with the corona virus. The operating mode was modified, dedicated areas were identified, personnel were trained, methods were adapted and the associated documentation was updated	operational processes	HEGP

Strong point	Un mode opératoire spécifique est créé pour chaque protocole pris en charge par la PRB. Ce mode opératoire est le résultat des discussions avant que l'étude ne démarre entre la PRB et le promoteur de l'étude. Il suit le circuit de validation formalisé dans la gestion documentaire	operational processes	HEGP
Path to progress	The scope of the QMS does not take into account the activity concerning the paraffin blocks in the Tumour Library. This activity is performed by the Tumour Library (with some outsourced activities) but is not included in the certificate. This is not a SP as work is being done to clarify responsibilities and should be completed in 2021	Steering and strategy	HEGP
Path to progress	The platform carries out a SWOT presented at the Management Review, however this SWOT does not generate any action to control the risks or take advantage of the opportunities identified	Steering and strategy	HEGP
Path to progress	The platform's quality policy does not reflect the strategic guidelines set by the strategic committee. These are cited in the management report. For example, two major elements on which the platform is working, namely the merger with EPIGENETEC and the rapprochement with the DMU's CRBs, may have an impact on the QMS and do not appear in the policy. On the other hand, these two elements are found in the quality objectives in the management report. We therefore have a bypass of the quality policy, which is immutable, with strategic axes and quality objectives that are adapted to reality and are found in the management report and then in the action plan.	Steering and strategy	HEGP
Path to progress	The interactions between processes are identified by arrows in the mapping. However, there is no real analysis of what these arrows symbolise (documents, contracts, traceability elements, expression of needs or constraints, etc.)	Steering and strategy	HEGP
Path to progress	As the PRB always uses external auditors for internal audits, the audit reports are disparate and do not systematically meet the needs of the PRB. for example, the objective of the audit is not systematically present, nor is the chapter of the standard concerned by the finding	Continuous improvement	HEGP
Path to progress	Internal audits are planned. However, the processes or objectives chosen do not systematically correspond to an identified risk and the planning is not re-evaluated during the management review	Continuous improvement	HEGP
Path to progress	The effectiveness of the improvement actions implemented is analysed. However, the criteria for assessing effectiveness are not systematically evident	Continuous improvement	HEGP
Path to progress	The QMS is now stable, however the frequency of document review has not been adapted to the risk of having an obsolete document in relation to practices. The resource used for the revision of the documents is therefore poorly adapted to the needs	Document management	HEGP

Path to progress	Biobank has identified critical equipment and created a list. However, there is no correlation between this list and the way the equipment is monitored	equipment management	HEGP
Path to progress	Agreements have been signed between the biobank and the various hospital entities providing services to the platform. A document review frequency has been established and has not been reviewed in relation to the maturity of the system. This results in operations that are not linked to a risk (cumbersome system) with the risk of not carrying out these actions and therefore generating a NC.	Purchasing management	HEGP
Path to progress	Some of the premises are shared with other teams (sample storage area, for example). However, there are no agreements with non-biobank users concerning the rules for using these premises	facilities management	HEGP
Path to progress	The personnel are qualified and in case of absence rehabilitated for a certain number of key tasks. This frequency is not adjusted in relation to risks (newcomer, change of post, change of methods, etc.) which would ensure that the resources for re-evaluation are used effectively.	operational processes	HEGP
Path to progress	Work is carried out before taking on an academic study in order to understand the sponsor's needs and express the biobank's operational constraints. There is no formalization of these exchanges, so it is difficult to validate the content of the operating procedures describing the handling of samples in relation to the client's requirements	operational processes	HEGP
Path to progress	The compliance of the biological resource is checked at the time of release (existence of consent). The existence of consent at the time of collection creation is not checked earlier (e.g. at the reception phase). As a result, all the work of reception, processing and storage is carried out without ensuring the presence of consent (problem of efficiency and ethics).	operational processes	HEGP