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Summary of external evaluation

ASSISTANCE PUBLIQUE - HÔPITAUX DE PARIS (APHP) HEGP
PRODUCTION AND CONTROL UNIT OF THE PHARMACY
Referential : ISO 9001 2015
Phase: Audit Surveillance 1
Audit date : 28/09/2020

Organization: AFNOR Certification

1. Summary of the management system

n ISO 9001:2015 system that is still young but deployed on a robust structure:
- QMS based on the risk approach, applied to each of the processes, to the evaluation of the criticality of non-conformities, to internal projects.
- The evaluation data on the functioning and performance of the processes are analysed in a relevant manner in the process reviews and taken up in the management review. The summaries make it possible to define and validate the priority areas for improvement, to update the roadmap and to structure a strategic quality action plan.
The audited QMS presents a pragmatic organisation that makes it possible to secure and make reliable practices at all levels of service provision.
The evaluation of service providers and suppliers impacting the quality of services remains to be perfected.

2- Assessment of the findings:

- 2 sensitive points
- 2 areas for improvement
- 2 strong points

Processes / Principles / Organization	Type	N°	Wording of the finding	Referential	Closed	Concerned site
INFRASTRUCTURES	Sensitive point	2019-09/01	2019 : No supplier evaluation. But collaboration contract being drawn up with the hospital's administrative divisions, with with whom evaluations will be carried out. The same applies to critical service providers Preventive and curative maintenance contract	ISO 9001 2015 8.4.1 General	No	Paris HEGP

Type" : Non-conformité majeure (NC Maj), Non-conformité mineure (NC Min), Point sensible (PS), Piste de progrès (PP), Point fort (PF), Constat de conformité (Note)

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			for the control laboratory, and chain HPLC (analytical control), local isolators... Drafting of collaboration contracts in the the QAP and will be extended to critical suppliers. 2020 : Services are monitored (orders and quality at reception). However, the assessments have not been finalised in 2020.			
PURCHASES	Sensitive point	2019-09/02	2019 : Critical suppliers identified. Model collaboration contract being drafted. drafting. Observation noted in PS and not in NC because the action is action is included in the QAP and followed up. 2020 : Contracts are drafted (Isolators in particular). The collaboration contracts with the functional units functional units are underway. The ISD and the The ISD and the biomedical department are very involved in the and participate in the management review. The documentation for biocleaning is covalidated with the team.	ISO 9001 2015 8.4.1 General	Yes	Paris HEGP
RESEARCH AND DEVELOPMENT	Areas for improvement	2020-09/01	Research and development activities of new techniques for the analysis and control of chemotherapy products are carried out carried out in the context of the management of university projects (publications on changes in practice, evolution of analytical analytical techniques). The projects are structured in a project sheet. The process could be integrated into the the QMS in the long term so as to enhance the excellence which is developed internally.	SO 9001 2015 4.4 Management system management management system and its processes		Paris HEGP
ASSESSING PERFORMANCE	Areas for improvement	2020-09/02	Commitments to deliver products on time are of products are followed (claim, PIP listening)	ISO 9001 2015 9.1.3 Analysis and evaluation		Paris HEGP

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			(complaints, PIP listening): 2 hours if request not 2 hours if the request is not anticipated, 1 hour if the request is anticipated before 13:00 D-1. However, no quantified indicators are available (2 software programs with no data). available (2 software programs with data that cannot be consolidable data). The evaluation of this commitment could be factualised in the long term.			
All the processes of realization	strong points		. Taking into of risks and impacts on ongoing activities has been activities has been well understood and anticipated in order to guarantee continuity of service during the work in compliance with GMP (project phasing, management of environmental environmental health risks, organisation of work spaces work spaces, flow management, etc.). The outsourcing of activities was planned in in "degraded mode" in the event of an incident (collaboration with Hôpital Cochin, thanks to the availability of mobile isolators). The environment is subject to reinforced monitoring. At the time of the audit, the organisation of the teams allows services to be provided in good conditions.	ISO 9001 2015 6.1 Actions to be taken in response to risks and opportunities		Paris HEGP
All of the processes	strong points	2020- 09/02	Robust risk analysis methodology (FMEA type with rating). Deployment on processes in a cartography. The method is applied to the analysis of of non-conformities. SWOT overall and for each process. The work site for the change of insulators also underwent a relevant risk approach. approach.	ISO 9001 2015 6.1 Actions to be taken in response to risks and opportunities		Paris HEGP

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