

REGULATION AND PREQUALIFICATION DEPARTMENT

VACCINES ASSESSMENT TEAM

TEMPLATE					
EXEMPLAR TIMETABLE					
Doc No: IMD/TP/14b	Version No: 2		Revise before: 1 Apr 2028		
Effective date: 1 Apr 2025	Replaces: Annex 2		Page 1 of 2		
Approved by:	For TL-VAX, date: 2	7 Mar 2025	ADG-MHP, date: 28 Mar 2025		
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First Day			
	Duration	Suggested persons present	Notes
Introduction	½ hour	Senior management including Quality Manager (QM) plus other lab staff.	
Vertical audit	2 hours	Senior lab staff (1), Technician.	Pre-arranged project report and test demonstration
Lunch	1 hour		
Horizontal audit	S		
Calibration	1 hour	QM, calibration engineer.	
Training	1 hour	QM	
Uncertainties	1 hour	QM, appropriate engineer.	
Second Day			
Vertical audit	2 hours	Senior lab staff (1), Technician.	If the lab wishes to cover more than one E00 category.
Quality manual	1 hour	QM	
Lunch	1 hour		
Evaluation	1 hour	Auditor	Time to draft summary
Evaluation meeting	1 hour	All of the above	
Any other business	1 hour	As appropriate	

The above timings are flexible according the auditor's needs and staff availability. Note that the days are not over-full to allow time to move between departments and observe other areas in the laboratory.



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Note: the auditor is at liberty to observe almost anything and talk to anyone. Only exceptions are confidential project which would already be signed off before the audit visit. If other areas are prohibited, then the auditor should record this in the report.