

GLP requirements for using visual bee monitoring technology in ecotoxicological studies



Frederic Tausch, Katharina Schmidt, Julian Eberhardt, Aline Mack
apic.ai GmbH | Haid-und-Neu-Straße 7, 76131 Karlsruhe | Contact: katharina.schmidt@apic.ai

apic.ai

PROBLEM

Automatic bee monitoring systems can enhance the risk assessment of plant protection products prior to market approval. They allow the integration of continuous, reliable, precise data on sublethal effects such as activity and pollen foraging. In order to allow the use of such new technologies in trials under the OECD Guidelines on Good Laboratory Practice (GLP) there is a number of challenges to solve.

MATERIAL AND METHODS

Upon integrating the apic.ai monitoring technology into a GLP study, we identified a number of key challenges, and developed solutions to ensure compliance for the apic.ai monitoring technology. For the following areas in the cooperation with a test facility, a necessity to include considerations of GLP requirements was identified:

1. Assessment of apic.ai technology to be suitable for the task
2. Agreement on terms of cooperation when concluding contract
3. Preparation for the monitoring phase
4. Handover and on site installation of the camera systems
5. Supervision of data collection during the monitoring phase
6. Pick-up of data storage devices from camera systems
7. Data analysis and derivation of insights into effects
8. Decommissioning of camera systems and data archiving

The following documents were developed for validation and to assign clear responsibilities of the test facility and apic.ai.

Technology Qualification		Service Level Agreement	
Responsibility: apic.ai		Responsibility: apic.ai & test facility	
<p>This document describes the technology and all processes that are undertaken to qualify it for the purpose of use. It consists of:</p> <p>Installation Qualification</p> <ul style="list-style-type: none"> • End points • Hardware description • Software description • Algorithm performance • Limitations & requirements • Data aggregation, storage & layout • Decommissioning • Risk management <p>Operational Qualification (OQ) Description of requirements and conduct of tests prior to the start of the monitoring phase.</p>		<p>The Service Level Agreement lays down study-specific arrangements between apic.ai and the test facility in line with GLP requirements. It defines the responsibilities of the respective parties, regarding:</p> <ul style="list-style-type: none"> • Operational Qualification (OQ) and study site conditions check • Installation and Performance Qualification (PQ) • Operations monitoring and incident handling • Incident and intervention documentation • Permissions and restrictions regarding data access, use and ownership • Risk reduction possibilities (switching the systems off at night, access to raw data...) • Consultation obligations for standard and special incidents (list of responses apic.ai can do remotely without individual approval). 	
		Performance Qualification (PQ) Description of requirements and conduct of tests at the on-site set-up before monitoring.	Operations Monitoring (OM) Description of monitoring procedures, requirements and recommendations.
Additional documents OQ		Additional documents PQ	
<p>OQ report This is a signed validation report, for tests undertaken by apic.ai to ensure the camera systems are operational prior to hand-over to the test facility. It comprises:</p> <ul style="list-style-type: none"> • Component verification • Camera calibration validation • Consideration of on-site conditions based on information provided by test facility e.g. hive type and setup, internet reception quality • Documentation of the software version and its characteristics <p>Responsibility: apic.ai</p>		<p>PQ test report Signed report documenting the correct installation, check of the correct camera calibration and functionality of the bee detection. The validation is conducted at the study site and confirmed by the test facility.</p> <p>Responsibility: Test facility</p>	
		<p>Operations monitoring reports Report on the functionality of the camera systems during the monitoring phase and special actions taken by apic.ai. This includes:</p> <ul style="list-style-type: none"> • Documentation of remote and on-site interventions. • Documentation of necessity for special interventions, reaction chosen with consent of test facility as well as outcome. <p>Responsibility: apic.ai & test facility</p>	
		<p>Decommissioning report Documentation on handling of camera systems after the monitoring phase until they are taken out of service.</p> <p>Responsibility: apic.ai</p>	

INSIGHTS AND RESULTS

The test facility must be able to validate the functionality of the camera systems

- ✓ Before delivering the camera systems, apic.ai conducts an Operational Qualification of each device. The test facility can assess the correct installation as well as critical system functions during a Performance Qualification on site.

The monitoring setup must be adapted to the on-site conditions

- ✓ To minimize the requirement for on-site customizations, information about the hive type, internet availability and solar powering possibilities should be available two weeks before the start of the monitoring phase.

The operating conditions for data collection must be secured

- ✓ To ensure that the data can be trusted, regular checks are recommended for (1) no additional entrances or exits beside the camera system, (2) a clean and sharp field of view of the camera and (3) systems operability. A close cooperation for incident assessment, handling and documentation is required during the monitoring phase.

Permission for remote incident handling reduces downtimes

- ✓ Software restarts fix most problems related to the camera systems. By permitting apic.ai to initiate restarts to pre-defined incident without prior consultation of the test facility, downtimes can be avoided. Every intervention is document either by the test facility or apic.ai.

The test facility must have direct, exclusive access to the raw data

- ✓ The test facility can collect the data directly from the systems on a USB stick. The frequency of data collection can be agreed in the SLA.

The test facility must be enabled to analyze the data

- ✓ The raw data is aggregated into a .csv file of the end point data in minutely and daily intervals with apic.ai software running on the camera systems. This file can be used for further analysis. The data from the different hives must be combined for this. Upon request, apic.ai provides reference analysis to the test facility for comparison, to ensure that the data was analysed correctly.

Raw data and analysis results must be documented by the test facility and be reproducible for years

- ✓ On-device analysis of video footage in volatile memory. Raw data is algorithm output, not video. Raw data is a .csv file of all bee movements.

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