BINDER

GOOD LABORATORY PRACTICE

YOUR CHECKLIST FOR GLP-COMPLIANT RESEARCH AND DEVELOPMENT

Why GLP?

FDA Regulation 21 CFR Part 58 describes “Good Laboratory Practices” for non-clinical studies, e.g., in the case of food additives and colorants, feed additives, active ingredients in human and veterinary medicine, medical products, biological products, and electronic products. Examples of non-clinical studies include in vitro and in vivo biocompatibility tests, e.g., with bacteria. **Microbiological incubators** and **cooling incubators** play a crucial role in this regard. **Safety drying chambers** and **vacuum drying chambers** are ideal for safe, gentle drying processes in the chemical, pharmaceutical, food, and cosmetics industries. Alongside qualification documentation and calibration certificates, Data Loggers are also important in ensuring independent temperature and humidity measurements.

The solutions in the checklist can easily be integrated into your own standard operating procedures (SOP).

1. Quality assurance measures

How often is recalibration carried out on site? ☐ Yes ☐ No

Solution:
Talk to BINDER Service. BINDER recommends carrying out recalibration once a year.

Has installation been carried out properly? ☐ Yes ☐ No

Solution:
Installation by BINDER. Unpack and set up unit, connect to existing connections.

Have the installation conditions been met? ☐ Yes ☐ No

Solution:
BINDER operating manual. Available 24/7 in the Download Center.

Have Installation Qualification and Operational Qualification been carried out? ☐ Yes ☐ No

Solution:
Supporting documents for validation performed by customer, including:
IQ/OQ checklists, unit schematics, and QM certificate in accordance with ISO 9001.

Have the authorized users received instruction? ☐ Yes ☐ No

Solution:
Instruction by BINDER. Unit functions, operation and programming of the controller.

Is the operating manual immediately accessible? ☐ Yes ☐ No

Solution:
Available 24/7 in the BINDER Download Center.

Is the operating manual helpful, meaningful, and clearly structured? ☐ Yes ☐ No

Solution:
Available 24/7 in the BINDER Download Center.

Has the unit designation been entered correctly in the inventory? ☐ Yes ☐ No

Solution:
BINDER type plates are located on the left-hand side on the bottom or on the front of the housing.

Any further questions about quality assurance measures and our solutions? We would be happy to advise you!

› SEND AN INQUIRY NOW!

2. Documentation

Is communication software which meets the requirements of FDA 21 CFR Part 11 required? ☐ Yes ☐ No

Solution:
APT-COM™ 3 GLP Edition for GLP-compliant control, programming, and documentation of up to 30 networked units or controllers.

Is communication software without FDA CFR Part 11 required? ☐ Yes ☐ No

Solutions:
- APT-COM™ 3 Basic Edition for simple requirements regarding control and documentation with only one unit connected.
- APT-COM™ 3 STANDARD Edition fornetworking 30 connected units with automated documentation options.

Are the parameters recorded continuously and independently? ☐ Yes ☐ No

Solutions:
Data Logger Kits for various areas.

**Any further questions about documentation and our solutions?
We would be happy to advise you!**

› SEND AN INQUIRY NOW!

3. Security

Have the audible and visual alarm systems been set and connected correctly? ☐ Yes ☐ No

Solution:
Instruction by BINDER. Unit functions, operation and programming of the controller or BINDER operating manual.

**Any further questions about security and our solutions?
We would be happy to advise you!**

› SEND AN INQUIRY NOW!

4. Organization and precautions

Has a cleaning plan been drawn up? ☐ Yes ☐ No

Solution:
Manufacturer recommendations can be found in the BINDER operating manual. CO_2 incubators should be decontaminated on a regular basis with a 180°C hot air sterilization.

Has a maintenance plan been drawn up? ☐ Yes ☐ No

Solution:
Manufacturer recommendations can be found in the BINDER operating manual.

Has preventive maintenance been scheduled and carried out according to the manufacturer's instructions? ☐ Yes ☐ No

Solutions:
BINDER preventive maintenance according to maintenance plan.

Have you arranged a warranty extension? ☐ Yes ☐ No

Solutions:
Ask the BINDER Service team about our current offers for warranty extensions.

Do you have a form for a clearance certificate?
This form must be filled out for every product that is returned to the manufacturer.

☐ Yes ☐ No

Solution:
BINDER operating manuals in the Download Center.

Any further questions about organization and precautions and our solutions? We would be happy to advise you!

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5. Back-up systems

Is a continuous CO_2 supply ensured? ☐ Yes ☐ No

Solution:
BINDER CO2 gas tank changer for connecting two gas tanks with audible and visual alarms as well as zero-voltage alarm output. For BINDER CO_2 incubators only.

Are there back-up chambers available for emergencies? ☐ Yes ☐ No

Solution:
BINDER would be happy to advise you.

**Any further questions about back-up systems and our solutions?
We would be happy to advise you!**

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We wish you every success with your GLP-compliant work in the future.

BINDER